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PREVENTION AND REHABILITATION: RANDOMIZED CLINICAL TRIAL

Comparison of manipulation and stabilization exercises in patients with sacroiliac joint dysfunction patients: A randomized clinical trial

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ABSTRACT

Background: Manual therapy and exercise therapy are two common treatments for low back pain. Although their effects have been discussed in several studies, the superiority of one over the other for patients with sacroiliac joint dysfunction is still unclear.
Objectives: The aim of this study was to compare the effects of manipulation (M) and stabilization exercises (S) in patients with subacute or chronic sacroiliac joint dysfunction.
Methods: The participants in this randomized controlled trial study were patients with subacute or chronic sacroiliac joint dysfunction for more than 4 weeks and less than 1 year. A total of 40 patients were randomized with a minimization method to the M ($n = 20$) or S ($n = 20$) group; 15 patients in each group received treatment. The treatment program lasted 2 week in group M and 4 weeks in group S. Pain and the Oswestry Disability Index (ODI) were recorded before and immediately after the treatment period.
Results: Both groups showed significant improvement in assessed pain and ODI ($P < 0.05$). There were no statistically significant differences between groups in post-intervention assessed pain or ODI ($P > 0.05$).
Conclusions: Despite the improvements seen after both manipulation and stabilization exercise therapies in patients with sacroiliac joint dysfunction, there was no significant between-group difference in the treatment effects. This result suggests that neither manual therapy nor stabilization exercise therapy is superior for treating subacute or chronic sacroiliac joint dysfunction.

1. Introduction

Low back pain (LBP) is recognized by its most common symptom – pain – and is known as the primary cause of disability in industries (Ferreira et al., 2007; Goldby et al., 2006). It has been reported that 11%–12% of patients with LBP are disabled (Balagué et al., 2012). Considering its high cost to society, providing optimal treatments to reduce pain and disability has become a major challenge for researchers.

One of the most frequent pain-producing factors in patients with LBP is sacroiliac joint dysfunctions (SJD), with a prevalence as high as 75% (Cohen et al., 2013; Hamidi-Ravari et al., 2014). Due to the anatomical and biomechanical complexity of this joint and the variable clinical picture among patients, the best methods of diagnosis and treatment for SJD are unclear (Foley and Buschbacher, 2006; Hamidi-Ravari et al., 2014; Isaacs and Bookhout, 2002). Sacroiliac joint dysfunction (SJD) can cause localized pain in the SIJ or referred pain to the groin, hip and occasionally towards the leg, foot and toes (Hamidi-Ravari et al., 2014; Shearar et al., 2005). Although SIJ provocation tests may be unreliable, clinicians use them to diagnose SJD (Hamidi-Ravari et al., 2014). Different treatments that have been tried for SJD include pharmacotherapy, manual therapy, pelvic stabilization exercises, balancing exercises, orthosis, injection and surgery (Foley and Buschbacher, 2006; Hamidi-Ravari et al., 2014; Zelle et al., 2005). Currently the

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two most common treatments that clinicians advocate for patients with LBP are exercise and spinal manipulation therapy.

A number of different studies have evaluated the effectiveness of stabilization exercises or manual therapy, and compared them with each other or other treatments methods. Current studies have suggested that significant improvement can be achieved by manipulation in most patients with SJD (Hall et al., 2013; Herzog et al., 1991; Kamali and Shokri, 2012; Osterbauer et al., 1993). However, Herzog et al. showed that back school therapy was superior to manipulation (Herzog et al., 1991).

In general, evidence has shown that stabilization exercises can reduce pain and disability in chronic LBP, and is superior to other treatments such as usual care and education, but not to conventional physiotherapy protocols (Byström et al., 2013; Cairns et al., 2006; Ferreira et al., 2006; May and Johnson, 2008). In addition to the strong consensus on the effects of stabilization exercises in patients with chronic LBP, there is also some evidence for its benefits in patients with SJD (Al-subahi et al., 2017; Barbosa et al., 2013; Ferreira et al., 2006; Stuge et al., 2004a, 2004b). Furthermore, Monticone et al. concluded that stabilization exercises were more effective than laser therapy for the treatment of SJD (Monticone et al., 2004). Studies that compared stabilization exercises with manual therapy have yielded conflicting results (Byström et al., 2013; Childs et al., 2004; Neha et al., 2016; Rasmussen-Barr et al., 2003; Stuge et al., 2004a, 2004b).

Despite the need to identify the most effective treatment options, controversy still remains. None of the previous studies used inclusion criteria that targeted patients with SJD. The heterogeneous populations considered in earlier research may mask the true effects of treatments and contribute to the current controversy. Also, since most studies used a combined intervention package with both manual therapy and stabilization exercises, the real effectiveness of each element cannot be inferred.

The present study was designed to compare the effects of manual therapy and stabilization exercises on pain and disability in a subgroup of patients with nonspecific LBP that had SJD.

2. Materials and methods

This single-blind randomized clinical trial was approved by the Shiraz University of Medical Science Institutional Review Board (IRB) and registered in the Iranian Registry of Clinical Trials (IRCT) as IRCT138808232708N1.

2.1. Participants

All patients had subacute or chronic LBP that had lasted at least 4 weeks and up to 11 years, and were referred from the orthopedic clinic of two local hospitals to the physiotherapy clinic at Shiraz School of Rehabilitation. They were recruited from April to August 2009. All patients were enrolled and screened by two physiotherapists in charge of the study, who were experts in examination procedures for patients with LBP. Men and women aged 20–60 years, with pain localized in the SIJ region with or without radiation to the knee, pain intensity between 30 and 80 mm on a visual analogous scale (VAS), and with a diagnosis of SJD were included in the study. The diagnostic criteria for SJD were five clinical tests including compression, distraction, sacral thrust, thigh thrust and Gaenslen tests (provocation tests) (Laslett et al., 2005; Laslett et al., 2003). Any set of three positive tests was indicative of SJD. Although the reliability of each SIJ test is poor, it can be enhanced by selecting a combination of tests (Broadhurst and Bond, 1998; Shearar et al., 2005). None of the participants had any lumbar region dysfunction. Patients with LBP lasting more than 1 year, prior stabilization training or manual therapy in the preceding 6 months, cervical and thoracic pain, spondylosis and spondylolisthesis, fracture, known lumbar disc hernia, neurological signs, spinal surgery, osteoporosis, scoliosis, pregnancy, or malignancy were excluded. All eligible patients provided their written informed consent and were asked not to commence any additional new treatments during the study.

2.2. Randomization

Of the 100 volunteers, 40 patients were included in the study and 20 patients were randomized to each group. A covariate adaptive randomization (minimization) was used to assign patients to the manual therapy or stabilization exercise arm (Taves, 1974). We considered duration of disease (<10 and >10 months), age (<50 and >50 years old), and sex as covariates. The methodologist of the research team assigned each new individual according to the examination of previous participant group assignments (case-by-case decision). Patient assignment was concealed from the investigators at the time consent was provided (allocation concealment). The patients were aware of their treatment, but were blinded to the type of treatment in the other group.

2.3. Interventions

2.3.1. Manual therapy

According to Maitland's recommendation, the repetition of a manipulation in more than five or six sessions produces hypermobility in patients with LBP; therefore in the manual therapy group patients were treated individually three times a week for two weeks by a physiotherapist expert in manual therapy with six years' experience. In each session, the therapist performed a manipulation technique on the side with positive SIJ test results (Kamali and Shokri, 2012) (see appendix 1). If innominate bone rotation was observed in the long sitting test, after determining the direction of innominate rotation the therapist performed a manipulation with the patient in the side-lying position (Castro-Sanchez et al., 2016)(see appendix 1).

2.3.2. Stabilization exercise

In the stabilization exercise group, patients were seen individually by a physiotherapist with expertise in the training of stabilization exercises and seven years' experience. All patients exercised for 20 min three times a week, for four weeks. In this group the maximum number of sessions that could be completed was 12 sessions. However, the actual number of completed sessions was from 8 to 12, depending on when complete improvement was observed. In the first session the patients were told how to find and maintain control of neutral spine alignment both in the lumbopelvic region and in relation to the thorax and hip joint. During the second and third sessions the patients were taught to consciously recruit tonic, low intensity isolated contractions (15%–20% of maximum voluntary contraction) of the local stabilizers of the lumbopelvic region to ensure segmental control in different positions (e.g. supine, crook-lying, side-lying, prone, four-point kneeling, sitting and standing). Exercises in each position were performed in 10 repetitions. The goal was co-contraction of the local muscles [transverse abdominis (TA) and deep fibers of multifidus (MF)] with normal breathing patterns. Contraction of the TA and MF was monitored by palpating just medial and inferior to the anterior superior iliac spines, and lateral to the spinous process of the lumbar spine or sacrum bilaterally, respectively. The exercises were gradually intensified in subsequent sessions by applying low loads to the muscles through the upper and lower limbs and thoracopelvic movement in different positions, and then based on proprioceptive neuromuscular facilitation patterns with an elastic resistance band. In the two final stages the patients were trained in how to move from the neutral spine position to other positions, which is essential for stability during many functional activities (e.g. sitting up, rotating the pelvis or upper trunk). All movements were performed in 10 repetitions. The patients were also taught how to use the contraction of local muscles during daily activities.

Patients in both groups were not allowed any additional home exercises. In the first or second sessions in both treatment groups, medication was used under supervision of their physician if a patient had severe pain. In both groups the physiotherapist monitored mild and moderate musculoskeletal adverse events during each visit, and referred patients promptly to a specialist if needed.

2.4. Outcomes

All outcome measures were recorded before and immediately after the treatment period (within 2 days after the last treatment session) by a research physiotherapist experienced in examination procedures in patients with LBP, and who was blinded to the patients' treatment allocation. The primary outcomes with respect to treatment efficacy were pain and functional disability. A VAS was used to assess pain on a 0–100 mm scale; 0 indicated no pain and 100 the worst pain. The patient indicated the magnitude of pain with a mark on the line. The mean level of pain at the moment, the worst pain in the previous week, and mean pain during the previous week were considered the final outcome measures.

The Oswestry Low Back Pain Disability Questionnaire (Iranian version) was used to evaluate physical dysfunction (Fairbank et al., 1980; Mousavi et al., 2006). Each item was scored on a scale of 0–5, and the maximum score for the Oswestry disability index (ODI) was 50. For each participant, the total score was divided by the highest possible score and then multiplied by 100.

2.5. Statistical analysis and sample size

For an 80% likelihood that a 10-point difference between the two groups in mean pain and functional disability scores would be significant (at the two-sided 5% level), 20 patients in each group (40 in total) were required. A standard deviation of 10 and a loss to follow-up of 20% were assumed. The statistician was blinded to group allocation.

Pain intensity (VAS score) and ODI were analyzed before and after treatment in each group. The percentage change in all endpoints was also compared between groups.

The assumption of normal distribution was checked with the one-sample Kolmogorov–Smirnov test. To compare percentage changes in the outcome measures (VAS and ODI) between the two treatment groups, Student's *t*-test for independent samples was used. Paired *t* tests were used to compare the variables before and after treatment within each group. Statistical tests were done with SPSS software (version 11.5), and the level of statistical significance was set at $P < 0.05$.

3. Results

3.1. Participants

Of the 100 initial volunteers, 40 patients were included in the study and 20 patients were randomized to each group. Ten patients (5 in each group) dropped out of the trial after inclusion because of a preference for other treatment, or other problems (see Fig. 1). Fifteen patients in group S completed the 4-week intervention, and 15 patients in group M completed the 2-week intervention (see Fig. 1). At baseline, there were no significant differences between the two groups in age, gender distribution, and duration of pain or pre-intervention values of all variables (see Table 1). The numbers of visits (mean and standard deviation) were 8.94 ± 2.49 in group S, and 5.4 ± 1.45 in group M.

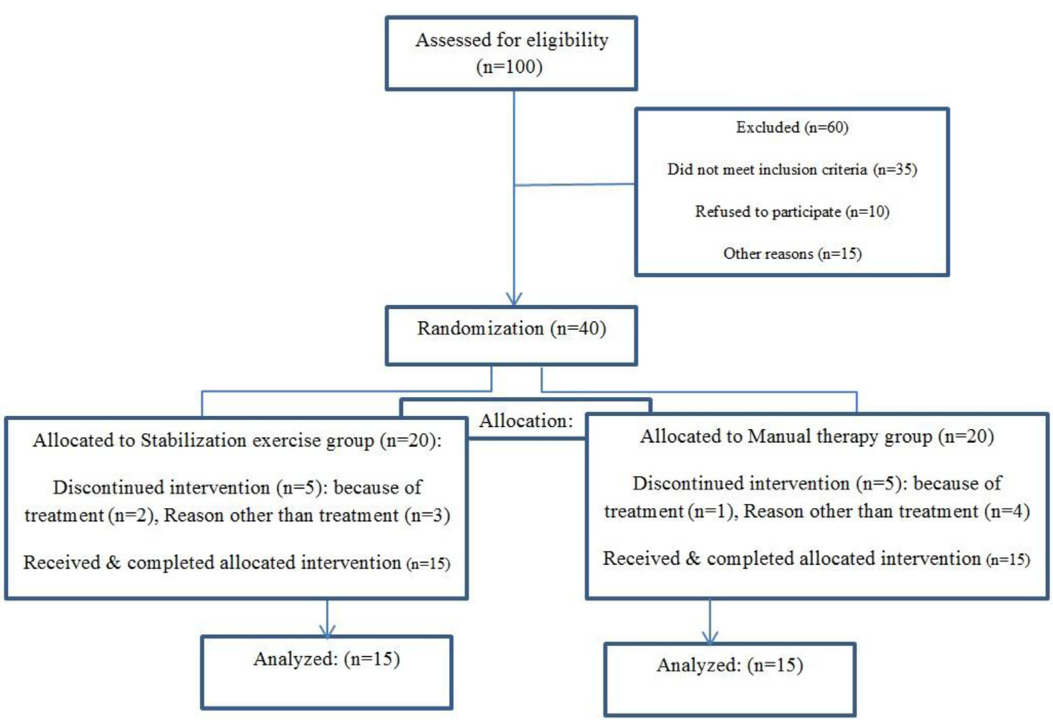

Fig. 1. Flowchart showing eligibility and enrollment, allocation, follow-up and analysis.

Table 1
Basic characteristics of patients in Stabilization exercise (S) and Manual therapy (M) groups.

Parameter	S group (N = 15)	M group (N = 15)	P value
Age (years) (Mean ± SD)	40.2 ± 14.26	42.07 ± 14.03	0.72[c]
Gender (female/male number)	(10/5)	(11/4)	0.5[d]
Duration of pain (years) (Mean ± SD)	4.63 ± 2.21	4.73 ± 3.07	0.92[c]
VAS[a] (Mean ± SD)	47.26 ± 20.24	57.75 ± 14.06	0.11[c]
ODI[b] (Mean ± SD)	25.88 ± 8.2	32.86 ± 16	0.14[c]

[a] Visual Analogue Scale.
[b] Oswestry Disability Index.
[c] Two independent sample *t*-test.
[d] Fisher-exact test.

3.2. Outcomes

As shown in Table 2, significant improvements in assessed pain and ODI were found in both groups ($P < 0.05$). Comparisons of the percent changes in pain and ODI between the manipulation and stabilization exercise groups showed no statistically significant differences ($P > 0.05$) (see Table 3).

There were no adverse or side effects in either group.

Table 2
Comparison of pain and Oswestry Disability Index (ODI) before and after interventions in the stabilization exercise (S) and manual therapy (M) groups.

Parameter	Group	Before	After	P value
VAS (Mean ± SD)	S	47.26 ± 20.24	17.67 ± 14.38	0.0001[a]
	M	57.75 ± 14.06	22.8 ± 19.27	0.0001[a]
ODI (Mean ± SD)	S	25.88 ± 8.2	14.4 ± 7.95	0.0001[a]
	M	32.86 ± 16	19.67 ± 14.35	0.0001[a]

[a] Paired *t*-test.

Table 3
Comparison of percent changes in pain and Oswestry Disability Index (ODI) between the stabilization exercise (S) and manual therapy (M) groups.

Parameter	S (n = 15)%	M (n = 15)%	P value
VAS (Mean ± SD)	65.19 ± 23.26	59.3 ± 32.4	0.6[a]
ODI (Mean ± SD)	47.05 ± 30.89	42.66 ± 33.76	0.73[a]

[a] Two-independent-sample *t*-test.

4. Discussion

The aim of the present study was to compare the effects of manipulation and stabilization exercising in patients with SJD. Although significant improvements in pain and functional disability were found in both groups after the interventions, there was no significant difference between groups.

Like other authors (Al-subahi et al., 2017; Balthazard et al., 2012; Ferreira et al., 2007; Goldby et al., 2006; Shearar et al., 2005; Stuge et al., 2004b), we found a reduction in pain and disability in the manipulation group, although the ODI score changes were smaller than other studies reported (Aure et al., 2003; Flynn et al., 2002). In this connection it should be noted that most previous studies used longer durations of treatment (Aure et al., 2003; Ferreira et al., 2007; Goldby et al., 2006; Stuge et al., 2004a, 2004b) or additional treatments (Flynn et al., 2002). Our results were in favor of short-term manual therapy for patients with SJD, in agreement with the conclusions of Kamali et al. (a single session) and Shearar et al. (2-week intervention period) (Kamali and Shokri, 2012; Shearar et al., 2005). In contrast, Castro-Sanchez et al. found no clinical benefits after three sessions of spinal manual therapy in patients with chronic non-specific LBP (Castro-Sanchez et al., 2016). However, it is likely that a subgroup of patients with nonspecific LBP and SJD, as in the present study, would benefit more from manual therapy.

Biomechanical and neurophysiologic mechanisms at the peripheral, spinal and supraspinal levels (Bialosky et al., 2009; Herzog et al., 1999) may have played different roles in the improvements in pain and disability in patients with SJD in the manual therapy group. The favorable effects of this treatment can be explained by the stimulation of mechanoreceptor afferents (Sung et al., 2005) and the neuroendocrine system (Pickar, 2002), regulation of muscle tone (Herzog et al., 1999; Suter et al., 1999, 2000), presynaptic inhibition of nociceptive afferents (Shearar et al., 2005), and decreased H-reflex and motor neuron excitability (Murphy et al., 1995). Beneficial effects have also been suggested for postural control; however, this hypothesis was not supported by Goertz et al. and Farazdaghi et al. (Farazdaghi et al., 2017; Goertz et al., 2016). An additional factor in the positive effects of spinal manipulation may have been the facilitation of normal joint play, which may release articular or related soft tissue adhesions and trapped synovial folds or plica (Shekelle et al., 1992).

There is evidence that manual therapy may refine SIJ function (Tullberg et al., 1998) by acting on nearby muscles. Muscles create forces, direct movements and increase pelvic girdle stability (Hamidi-Ravari et al., 2014). In this connection, a study by Cibulka et al. suggested that SIJ manipulation can modify innominate bone tilt in patients with SJD (Cibulka et al., 1988). Another study found decreased spinal crepitation after manipulation, which may suggest smoother spinal movements (Cramer et al., 2017). These factors may have contributed to the improvements in this group.

In addition to providing additional evidence for the beneficial effects of stabilization exercises for chronic LBP (Byström et al., 2013; Ferreira et al., 2006, 2007; Goldby et al., 2006; May and Johnson, 2008), the present study confirms that improvements in pain and disability can be seen in the subgroup of patients with chronic and subacute SJD. This finding is consistent with studies that found similar results in women with postpartum pelvic pain (Hall et al., 2013; Stuge et al., 2004a, 2004b) and in patients with LBP and chronic or subacute SJD (Al-subahi et al., 2017; Monticone et al., 2004). Without adequate control of the abdominal and/or back muscles, abnormal spinal movement, shearing forces and clinical instability might occur. Thus the activation of stabilizing muscles may have enhanced neuromuscular control and stability (Hamidi-Ravari et al., 2014; May and Johnson, 2008; Zelle et al., 2005). In addition, Richardson and colleagues showed that TA contraction with MF muscles significantly decreased sacroiliac joint laxity (Richardson et al., 2002). These effects would be expected to improve pain and disability. Another factor that may contribute to effects of stabilization exercises on pain modulation may be activation of the opiate system (Pickar, 2002).

The comparison of manual therapy and stabilization exercises showed no differences between the two treatments in the outcomes used here. Some earlier studies reported similar results (Byström et al., 2013; Cairns et al., 2006; Goldby et al., 2006; Merepeza, 2014; Neha et al., 2016; Peterson et al., 2012); in contrast, others reported that manual therapy (Aure et al., 2003; Childs et al., 2004) or stabilization exercising (Byström et al., 2013; Rasmussen-Barr et al., 2003; Stuge et al., 2004a, 2004b) was superior. However, comparisons between the present study and earlier research are next to impossible, considering the different types of interventions and participants. In contrast to other studies of different intervention packages, the present study compared two single treatments. Although this enabled us to report the specific effect of each treatment, this approach may not be in line with normal practices at physiotherapy clinics. In addition, this may be a reason of the smaller relative changes in Oswestry score in both groups compared to other studies (Aure et al., 2003; Flynn et al., 2002). Also, to the authors' knowledge, this is the only study to date designed to compare the effects of single manipulation and stabilization exercises in a subgroup of patients with LBP and characteristics of SJD. Because of this aspect of the study design, the findings reported here can guide clinicians in matching effective interventions to a particular subgroup of patients with LBP. We note in this regard that the participants in most previous studies were not patients with SJD (Aure et al., 2003; Childs et al., 2004; Rasmussen-Barr et al., 2003) or were women with pregnancy-related back pain (Stuge et al., 2004a, 2004b), who may react differently to same treatments.

Despite the absence of significant differences between the two groups, the results reported here suggest that 2 weeks of manual therapy may be as effective as a 4-week exercise therapy program. This finding raises the possibility that the beneficial effects of manipulation may be achieved in a shorter treatment period. The potential benefits in terms of cost and time savings may be a point for clinicians to consider in deciding which treatment options to offer patients with a diagnosis of SJD. However, additional studies with different designs will be needed to further test this idea.

5. Limitations

Because this study did not have an untreated control group, changes in the outcome measures in patients with SJD who received no intervention were not considered. Thus studies that include an untreated control group to elucidate the true effects of each intervention would be helpful. In addition, long-term follow-up in both groups in combination with back school instruction to prevent inappropriate activities could provide additional evidence to evaluate the consistency of the effects of each intervention. This study did not use SIJ injection to diagnose SJD; however, the reliability of positive SIJ provocation tests is similar to the invasive gold standard diagnostic method (Young et al., 2003). Because there is no single specific and sensitive test to diagnose SJD, we used a group in which the diagnosis was based on the SIJ provocation tests.

In addition, the low statistical power for comparisons in this study (0.2) means that type 2 error was possible despite calculation of the required sample size before recruitment. It was found that the low power for the comparisons was because of the large variability between patients in the two arms, and not from the small sample size. Despite considering a 20% loss to follow-up in the sample size calculation at the beginning of the study an unexpected number of dropouts from this study was another cause of low power. These limitations make it advisable to design future studies that consider low effect sizes and include larger sample sizes.

6. Conclusion

Although this study shows that both manipulation and stabilization exercise therapy can effectively improve pain and disability in patients with sacroiliac joint dysfunction, neither treatment was superior. The outcome measures used in this study did not reveal any differences between the effects of the two treatments. It should be noted that there may be other accurate, objective variables that can be used in future studies to search for differences between the two treatments.

Conflicts of interest

The authors state that there were no conflicts of interest.

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Appendix 1. Procedures for manual therapy techniques

Manual therapy techniques	Procedure
Supine SIJ manipulation	The therapist stood opposite to the side of SIJ dysfunction and moved the patient onto his or her side, leaning toward the side of SIJ dysfunction. Then the therapist rotated the patient toward himself and delivered a quick posterolateral and inferior thrust through the anterior superior iliac spine.
Side-lying SIJ manipulation (correction of anterior innominate bone rotation)	The patient lay on his or her side with the dysfunction side up, and the therapist stood in front. The therapist applied flexion to the top of the lower extremity and rotated the trunk toward the opposite side (the trunk posteriorly and the pelvis anteriorly), until movement was felt at the lumbosacral junction. Then the top foot was placed in the lower popliteal space. While stabilizing the trunk and forearm in the ischial region, the therapist applied thrust to the pelvis.
Side-lying SIJ manipulation (correction of posterior innominate bone rotation)	As in the above technique, but the therapist stood near the patient's forearm posterior to the region of the iliac bone, and applied thrust to the pelvis.

SIJ: Sacroiliac joint.

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