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Original Research Articles

Diagnosis and Treatment of Posterior Sacroiliac Complex Pain: A Systematic Review with Comprehensive Analysis of the Published Data

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Abstract

Objective. To assess the evidence on the validity of sacral lateral branch blocks and the effectiveness of sacral lateral branch thermal radiofrequency neurotomy in managing sacroiliac complex pain.

Design. Systematic review with comprehensive analysis of all published data.

Interventions. Six reviewers searched the literature on sacral lateral branch interventions. Each assessed the methodologies of studies found and the quality of the evidence presented.

Outcome Measures. The outcomes assessed were diagnostic validity and effectiveness of treatment for sacroiliac complex pain. The evidence found was appraised in accordance with the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system of evaluating scientific evidence.

Results. The searches yielded two primary publications on sacral lateral branch blocks and 15 studies of the effectiveness of sacral lateral branch thermal radiofrequency neurotomy. One study showed multisite, multidepth sacral lateral branch blocks can anesthetize the posterior sacroiliac ligaments. Therapeutic studies show sacral lateral branch thermal radiofrequency neurotomy can relieve sacroiliac complex pain to some extent. The evidence of the validity of these blocks and the effectiveness of this treatment were rated as moderate in accordance with the GRADE system.

Conclusions. The literature on sacral lateral branch interventions is sparse. One study demonstrates the face validity of multisite, multidepth sacral lateral branch blocks for diagnosis of posterior sacroiliac complex pain. Some evidence of moderate quality exists on therapeutic procedures, but it is insufficient to determine the indications and effectiveness of sacral lateral branch thermal radiofrequency neurotomy, and more research is required.

Key Words. Posterior Sacroiliac Complex Pain; Lateral Branch Block; Radiofrequency Lateral Branch Neurotomy; Sacroiliac Joint

Introduction

The sacroiliac complex includes articulation between the sacrum and ilium, together with its capsule that forms

the sacroiliac joint proper (SIJ), the ligaments that support this joint anteriorly and posteriorly, parts of some regional muscles that cover the joint, and the nerves that supply these structures.

The nerve supply of the sacroiliac complex has been described variously as posterior (by the lateral branches of the S1–S3 dorsal rami with some fibers of the L4 and L5 dorsal rami), anterior (by branches of the lumbosacral trunk and the obturator and superior gluteal nerves), and both posterior and anterior [1-4].

"Sacroiliac pain" can arise from any of the structures of the sacroiliac complex. It is not a single, discrete entity but an assortment of pains that vary according to the anatomic structures from which they arise. This fundamental point seems not to have been appreciated by many authors who have written on the subject. The literature is confounded by equating, confusing, or combining SIJ pain and pain from other parts of the sacroiliac complex, particularly that from the posterior ligaments. The resultant confusion is illustrated by many papers which, in their titles, describe their topics as "sacroiliac joint pain" but then address pain stemming from the posterior ligaments or some other (extra-articular) structure(s). Accordingly, in this review, pain that arises from the sacroiliac region but has not been demonstrated conclusively to be generated from a specific structure will be designated "sacroiliac complex pain."

The SIJ was first described as a potential pain source in 1905 [5] and was addressed as a possible source of pain in papers published over subsequent decades [1,2,6]. SIJ pain was not defined precisely in the literature until 1994, when Fortin et al. showed that SIJ pain could be generated in asymptomatic volunteers by distending the SIJ with contrast medium and diagnosed by analgesic responses to image-guided intra-articular injections of local anesthetic [7,8]. The following year, Schwarzer et al. measured the prevalence of SIJ pain and demonstrated an association between SIJ pain and disruption of the anterior capsule of the joint made evident by leakage of contrast medium during arthrography of the joint [9]. The concept of sacroiliac complex pain, pain that arises in the sacroiliac region but not necessarily from the SIJ itself, has emerged in the literature over the last 15 years or so.

This review is focused on the diagnosis and treatment of pain arising in the posterior elements of the sacroiliac complex. In particular, it addresses the published evidence on local anesthetic injections around the sacral lateral branch nerves (sacral lateral branch blocks [SLBBs]) for diagnosis and sacral lateral branch thermal radiofrequency neurotomy (SLBTRFN) for treatment.

Methods

Six independent investigators, who are members of a multisociety Appropriate Use Criteria Task Force convened by the International Spine Intervention Society

(ISIS), searched the scientific literature for publications on the validity of SLBBs for the diagnosis of sacroiliac pain and the effectiveness of SLBTRFN for the treatment of sacroiliac complex pain. They conducted digital searches using the search engine Ovid to explore the databases Embase, Medline, and EBM Reviews using the keywords sacroiliac, sacroiliac joint, sacroiliac complex, lateral branch blocks, radiofrequency lateral branch neurotomy, radiofrequency lateral branch denervation, radiofrequency lateral branch ablation, and variants of those terms with "radiofrequency" coming after "lateral branch." The searches encompassed all scientific papers published until January 2014. Foreign language papers were included. The only exclusions were nonhuman studies, conference abstracts, and single case reports unrelated to complications. When suitable papers were retrieved, the references of each were perused for relevant citations that had not been identified by the database searches.

The papers retrieved by the searches on SLBBs were separated from those on SLBTRFN. Each batch of papers was then sorted into two groups: primary publications (reports of studies that produced original data) and secondary publications (those not producing original data, such as literature reviews, editorials, and letters). Only primary publications are included in this review.

The primary papers on SLBBs were appraised by each of the investigators independently to assess their methodologies and the evidence they produced of the diagnostic validity of SLBBs.

The primary studies of SLBTRFN were then further classified into three categories: observational studies, pragmatic studies, and explanatory studies. Observational studies are defined as those that described the outcomes observed after the use of an intervention; note was taken of whether the observational study design was prospective or retrospective. Pragmatic studies are defined as those in which the outcomes of one intervention were compared with those of another intervention expected to have a useful effect. Explanatory studies are defined as those in which the outcomes of the intervention under study were compared with those of an intervention not expected to have a useful effect (a sham treatment). Explanatory studies show whether or not the studied treatment has an attributable effect (i.e., a therapeutic effect greater than the nonspecific effects of a sham treatment).

After being classified, the primary publications on SLBTRFN were appraised by each of the investigators independently. The investigators first considered the methodology of each study; then, they assessed the data produced as evidence of the therapeutic effectiveness of SLBTRFN. Categorical data were sought as the preferred evidence of effectiveness as data reflecting a binary decision such as success or failure of individual patients to achieve a set outcome (expressed as success rates) can be collated to produce a body of evidence of effectiveness based on outcomes for specific patients. In this review, the primary outcome measure sought was success rates for the relief of pain arising in the sacroiliac complex.

The appraisals were done using instruments developed by the ISIS Standards Division based on the principles of the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) system of evaluating evidence. The GRADE approach provides systematic guidance for rating the quality of a body of evidence and grading the strength of recommendations for use of an intervention, based on consideration of factors such as risks of bias in the production of the data that contribute to the body of evidence and estimates of effect size. These instruments were used to maximize the reliability of assessment of studies and facilitate comparison of findings. The investigators then compared the results of their appraisals and discussed them to reach consensus on what the two bodies of evidence (on SLBBs and SLBTRFN) showed. The evidence was then evaluated in accordance with the GRADE system of rating quality of evidence [10].

Results

The relevant scientific literature was found to include two primary publications on SLBBs for the diagnosis of sacroiliac complex pain and 15 primary papers on SLBTRFN for the treatment of sacroiliac complex pain.

SLBBs

The two publications were appraised for evidence of the validity of diagnostic blocks of the sacral lateral branches.

The first paper, published in 2008, reported an experimental, randomized, controlled study to investigate the physiologic effectiveness of single-site, single-depth, sacral lateral branch injections [11]. Initially, 15 asymptomatic volunteers underwent fluoroscopically guided probing of their dorsal sacroiliac ligaments and injection of their SIJs with contrast medium until capsular distension occurred; the presence or absence of pain with each test was noted. The subjects were then allocated randomly to two groups for sacral lateral branch injections with 4% lidocaine (as the active intervention) or saline injections (as the control). The injectates were placed in single sites at single depths for each lateral branch. After 30 minutes, all had repeat ligamentous probing and capsular distension of the SIJ on the same side as the injections. The observations were that four subjects or 40% (95% confidence interval or Cl₉₅ 10-70%) of the active group and one subject or 20% (Cl₉₅ 0-55%) of the control group did not feel pain on repeat testing after the lateral branch injections; the overlapping confidence intervals show these results were not significantly different. Within the same manuscript, the results of a parallel anatomic study were reported. In

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this study, two nonembalmed cadavers were injected with green dye over the S1 and S2 lateral branches, and dissection was undertaken to quantify the degree of staining of the target lateral branch nerves. The authors found variability in the exact anatomic location of the sacral lateral branch nerves, and using single-site, single-depth injections, only four (36%) of the 11 identified lateral branch nerves were stained. These results show that both physiologically and anatomically single-site, single-depth SLBBs more often than not fail to infiltrate adequately the nerves they target, which seriously compromises their face validity as a diagnostic test.

In 2009, the same authors [12] published an experimental, randomized, controlled trial, this time designed to determine the physiologic effectiveness of multisite, multidepth sacral lateral branch injections. Initially, 20 asymptomatic volunteers underwent fluoroscopically guided probing of their interosseous and dorsal sacroiliac ligaments and the entry points for their SIJs, and their SIJs were distended with contrast medium. Again, the presence or absence of pain with each maneuver was noted. The subjects were then allocated randomly to two groups: 10 subjects received 0.75% bupivacaine (active) injections and 10 received saline (control) injections. All injections were performed with fluoroscopic guidance, targeted at the sacral lateral branches, and placed in multiple sites at multiple depths with each target receiving 0.2 mL of the allocated agent. On repeat ligamentous probing and capsular stimulation after 30 minutes, the presence or absence of discomfort with each maneuver was recorded again. The results were that seven patients or 70% (Clas 42-98%) of the active group had insensate interosseous and dorsal sacroiliac ligaments and inferior dorsal SIJ vs none or one (for different ligaments) or 0-10% (Cl₉₅ 0-29%) of the control group. From these findings, the authors concluded that multisite, multidepth SLBBs are physiologically effective for the diagnosis of extra-articular posterior sacroiliac pain at a rate of 70%. It was also of interest that six of seven subjects (86%) who received 0.75% bupivacaine and had insensate posterior ligaments still retained the ability to feel repeat capsular distension. From these results, the authors concluded that multisite, multidepth SLBBs do effectively block the posterior ligaments of the sacroiliac complex but do not effectively block the SIJ. They interpreted this finding as physiological evidence that the SIJ is not exclusively innervated by the sacral lateral branches but must be innervated from both ventral and dorsal sources, as described in anatomical studies [1-3].

The evidence on multisite, multidepth SLBBs was found, in accordance with the GRADE system of rating evidence, to be of moderate quality [10]. That rating was determined because the positive evidence is from a single well-designed, controlled, experimental study. Readers can be moderately confident in the estimate of effect, and the true effect is likely to be close to that estimate, but there is a possibility that further research might show the effect is substantially different.

SLBTRFN

The 15 primary papers on SLBTRFN consisted of 13 observational studies and two explanatory studies. There were no pragmatic studies. Of the 13 observational studies, four were prospective and nine were retrospective reviews.

The literature was very diverse. The 15 papers described widely different criteria for patient selection and a variety of treatment techniques, which differed both in structures targeted and radiofrequency (RF) technologies used.

Criteria for patient selection in the 15 studies included different degrees of pain relief after injections of local anesthetic at various sites, single injections in some studies and dual (comparative) injections in others, and with the injection of a corticosteroid as well as the local anesthetic in many cases. Patients who had at least 75% relief on two occasions, following single-site, single-depth lateral branch blocks and local anesthetic blocks of the L5 dorsal rami, were selected for treatment for one of the explanatory studies [13]. Other patient selection criteria were relief after each of two comparative injections into the deep interosseous ligaments in one study [14], relief after comparative intraarticular or ligament injections for another study [15], and relief after intra-articular injections in the other 12 studies. The percentage relief required for a response to be considered positive also varied: 80% [16,17], 75% [18,19], 70% [14], and 50% in the remaining studies, except for one in which the percentage relief was not specified [20]. Patients were selected for treatment following double blocks in most studies and following a single block in four [18,20-22]. Steroid was injected with local anesthetic in the majority of the intra-articular injections and was also included in the injections into the deep interosseous ligaments [14].

Treatment targets described in the 15 studies included the SIJ itself, the sacral lateral branches, and the L4 and L5 dorsal rami. Radiofrequency lesions were placed over the posterior aspect of the SIJ in one study and did not directly target the sacral nerves [20]. In another, treatment targeted the lateral branches of the sacral dorsal rami in half of the patients, and the sacral lateral branches and the L4 and L5 dorsal rami in the other patients [21]. Lesions targeted the lateral branches of the sacral dorsal rami and the L5 dorsal rami in the other 13 studies, and the L4 dorsal ramus was also targeted in four of those studies [16,18,23,24].

Different RF technologies used included bipolar RF neurotomy in two studies [20,25], unipolar RF neurotomy in five studies [14–17,21], cooled RF neurotomy in six studies [13,18,19,22,26,27], and both unipolar and cooled RF neurotomy in two studies [23,24]. Unipolar RF neurotomy was used to treat the L4 and L5 dorsal rami in three of the studies in which cooled RF neurotomy or bipolar RF neurotomy was used to treat the sacral lateral branches [18,19,25].

Observational Studies

Three of the 13 observational studies of SLBTRFN reported only continuous data with results expressed as changes in group data recorded before and after treatment or no outcome data at all. Their results were not suitable for collation with those of studies producing categorical data which yielded success rates. The first was a pilot study of nine patients treated with bipolar RF neurotomy; the group's median pain score was 8/10 before treatment, and it was reduced to 3.5/10 at 1 month and 3 months after treatment and to 4.5/10 at 6 months and 12 months [25]. A study designed to determine whether pain distribution patterns predict outcome after SLBTRFN using unipolar electrodes reported favorable outcomes (defined as >50% reduction in pain intensity at a time not specified after treatment) for the majorities of patients in four groups with different pain maps, but group results were illustrated in a bar chart, and no numerical outcome data were provided [15]. In another study the results of 100 consecutive patients who had undergone SLBTRFN using either unipolar or cooled RF electrodes were expressed as rates of difficulty of the two techniques; no outcome data were reported as the paper was essentially a technical report on the methods used [27].

Ten of the 13 observational studies of SLBTRFN provided categorical data expressed as successful outcomes for specific patients, from which success rates could be calculated. These data were suitable for inclusion in a body of evidence of the effectiveness of SLBTRFN in practice. As outlined above, the methods of these 10 studies varied in criteria for patient selection, treatment targets, and RF technologies used. The general standard for successful outcome was defined as at least 50% reduction of the index pain for periods of between 2 months and 9 months after SLBTRFN. Some also reported results for complete relief of the index pain.

Bipolar RF was applied in one retrospective study, the earliest study of SLBTRFN [20]. Patients were selected on the basis of relief (extent not specified) following a single intraarticular SIJ injection. Strip-like lesions were placed over the posterior aspect of the joint using bipolar electrodes. Of 33 patients treated, 12 reported at least 50% pain relief for 6 months; thus, the success rate was 36% (Cl₉₅ 20–52%).

Unipolar RF electrodes were used in four of the 10 studies. Three studies of patients treated with unipolar RF were published in 2003 and 2004. Patients were variously selected on the basis of intra-articular blocks of the SIJ and subsequent blocks of the L4 and L5 dorsal rami, and the S1, S2, and S3 lateral branches [16], fluoroscopically guided deep interosseous ligament injections of local anesthetic and steroid [14], and a single intra-articular block [21]. The first was a pilot study reporting treatment retrospectively of nine nonconsecutive patients [16]. At review 9 months after treatment, eight of the nine patients or 89% (Cl₉₅ 69–100%) reported >50% relief of pain, and two of the nine or 22% (Cl₉₅ 0–49%) reported total pain relief. The second of these studies was also retrospective; it reported that

Table 1 Success rates of observational studies of SLBTRFN for achieving \geq 50% relief of the index pain for 6 months (or the period nearest to that for which data were reported)

Study	Selection	RF Treatment	Follow-Up (Months)	Pain	Relieved ≥50% (%)
Ferrante et al. [20]	Unspecified relief after a single SIJB	Bipolar	6	12/33	36 (Cl ₉₅ 20–52)
Cohen and Abdi [16]	80% relief SIJB, 50% after SLBBs	Unipolar	9	8/9	89 (Cl ₉₅ 69–100)
Yin et al. [14]	>70% relief after two deep lig. injects	Unipolar	6	9/14	64 (Cl ₉₅ 39–89)
Buijs et al. [21]	>50% relief after a single SIJB	Unipolar	3	24/43	56 (Cl ₉₅ 41–71)
Speldewinde [17]	>80% relief after each of 2 SIJBs	Unipolar	2	12/16	75 (Cl ₉₅ 54–96)
Kapural et al. [26]	>50% relief after each of 2 SIJBs	Cooled	3–4	13/27	48 (Cl ₉₅ 29–67)
Karaman et al. [19]	>75% relief after each of 2 SIJBs	Cooled	6	12/15	80 (Cl ₉₅ 60-100)
Stelzer et al. [22]	>50% relief after a single SIJB	Cooled	>4	70/126	56 (Cl ₉₅ 47–65).
Cohen et al. [23]	\geq 50% relief after one set of SLBBs	Cooled or unipolar	6	40/77	52 (Cl ₉₅ 41–63)
Cheng et al. [24]	\geq 50% relief after each of 2 SIJBs	Cooled or unipolar	6	28/88	32 (Cl ₉₅ 22–42)

SIJB = sacroilaic joint block; SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

nine of 14 patients or 64% (Cl₉₅ 39-89%) had >50% decrease in visual integer pain score and 36% (Cl₉₅ 11-61%) had complete relief, maintained for at least 6 months after treatment [14]. In the third study, also retrospective, five of the 43 patients were lost to follow-up at review 12 weeks after treatment: of the others, 24 or 56% (Clos 41-71%) reported at least 50% pain relief, and 10 or 23% (Cl₉₅ 10-36%) had complete pain relief [21]. A large case series was published in 2011 based on review of the records of unipolar RF treatments of cervical, lumbar, and sacroiliac pain over 10 years [17]. The series included 20 unipolar SLBTRFN procedures performed in 16 patients with sacroiliac pain, diagnosed by at least 80% relief of the index pain after each of two intra-articular SIJ blocks. A successful outcome was defined as at least 50% reduction of pain for at least 2 months after SLBTRFN. Categorical data were recorded by telephone contact between 6 and 36 months after treatment. The stated results were that 12 patients or 75% (Cl₉₅ 54–96%) reported having had at least 50% relief from pain for 2 months, and 7 or 44% (Cl₉₅ 20-64%) reported having had complete pain relief.

Cooled RF electrodes were used in three retrospective observational studies. In the first of these, 13 or 48% (Cl_{95} 29–67%) of patients reported at least 50% pain reduction

at follow-up 3–4 months after treatment, and three or 11% (CI_{95} 0–23%) had complete pain relief [26]. In the second, 12 of 15 patients or 80% (CI_{95} 60–100%) reported at least 50% decrease in pain scores at follow-up 6 months later [19]. In the third of these studies, the success rate for achieving at least 50% pain relief in the longer term (>4 months) was 77/126 or 61% (CI_{95} 52–70%) [22].

Both unipolar and cooled electrodes were employed, in different patients, in the other two observational studies, which were both retrospective. In the first study, 40 of 77 patients or 52% (Cl₉₅ 41–63%) achieved the set successful outcome of >50% pain relief at 6 months [23]. In the second of these studies, 58 patients underwent cooled RF techniques and 30 unipolar RF techniques; at review after 6 months, 28 of the patients or 32% (Cl₉₅ 22–42%) had >50% pain relief; analysis of the data showed no significant univariable relationship between RF technique and duration of pain relief [24].

The methods and data of these 10 observational studies are summarized in Tables 1 and 2.

Methodological issues cast some doubt on these results, as will be discussed later, but the observational

Table 2Success rates of observational studies of SLBTRFN for achieving 100% relief of the index painfor 6 months (or the period nearest to that for which data were reported)

Study	Selection	RF Treatment	Follow-Up (Months)	Pain	Relieved 100% (%)
Cohen and Abdi [16]	80% relief SIJB, 50% after SLBBs	Unipolar	9	2/9	22 (Cl ₉₅ 0–49)
Yin et al. [14]	>70% relief after 2 deep lig. injects	Unipolar	6	5/14	36 (Cl ₉₅ 11–61)
Buijs et al. [21]	>50% relief after a single SIJB	Unipolar	3	10/43	23 (Cl ₉₅ 10–36)
Speldewinde [17]	>80% relief after each of 2 SIJBs	Unipolar	2	7/16	44 (Cl ₉₅ 20–64)
Kapural et al. [26]	>50% relief after each of 2 SIJBs	Cooled	3–4	3/27	11 (Cl ₉₅ 0–23)
Stelzer et al. [22]	>50% relief after a single SIJB	Cooled	>4	29/126	23 (Cl ₉₅ 16–30)

SIJB = sacroiliac joint block; SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

Table 3 Success rates of SLBTRFN for achieving at least 50% relief of the index pain as shown by the explanatory study of Cohen et al. [18]

Group	RF Treatment	Follow-Up (Months)	Pain	Relieved \geq 50% (%)
Active group	Cooled	1	11/14	79 (Cl ₉₅ 58–100)
n = 14	Cooled	3	9/14	64 (Cl ₉₅ 39–89)
	Cooled	6	8/14	57 (Cl ₉₅ 31–83)
	Cooled	12	2/14	14 (Cl ₉₅ 0–32)
Control group	Sham	1	2/14	14 (Cl ₉₅ 0–32)
<i>n</i> = 14	Sham	3	0/14	0
	Sham	6	0/14	0
Cross-over group	Unipolar	1	7/11	64 (Cl ₉₅ 36–92)
<i>n</i> = 11	Unipolar	3	6/11	55 (Cl ₉₅ 26-84)
	Unipolar	6	4/11	36 (Cl ₉₅ 8–64)

Cohen	et al. [18]	Patients	Selected	bv>75%	Relief after a	a Sinale	SIJB
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SIJB = sacroiliac joint block; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

data do suggest that SLBTRFN can relieve sacroiliac complex pain, at least to some extent. The results of explanatory studies would be expected to clarify the issues.

Explanatory Studies

The two explanatory studies were randomized, controlled trials of SLBTRFN in which active treatment with cooled electrodes was compared to sham treatment.

The first explanatory study involved 28 adults, selected if they had at least 75% relief after a single intra-articular SIJ injection of bupivacaine and steroid [18]. They were allocated randomly to an active group of 14 patients and a control group of 14. Patients who did not respond to sham treatment were allowed to cross over and were offered treatment with RF denervation using unipolar technology. The patients were followed up at 1, 3, and 6 months after treatment, with the primary outcome measure being pain as assessed on a numeric rating scale (NRS). A successful outcome was defined as at least 50% pain relief at any stage. The categorical data provided for the primary outcome were as shown in Table 3.

These data suggest that SLBTRFN using cooled electrodes is more effective than placebo. They also show (again) that SLBTRFN using unipolar, thermal electrodes has outcomes similar to those of cooled RF. Overall, these data reinforce those of observational studies which show that SLBTRFN is effective for relieving pain arising in the sacroiliac complex, at least to some extent.

For the second explanatory study, patients were screened with two sets of single-site, single-depth local anesthetic blocks of the lateral branches of S1–S3 and of the L5 dorsal ramus. Patients who achieved 75% relief of their index pain after both blocks and had their index pain return were eligible for inclusion [13]. The 51 subjects enrolled were randomized on a 2:1 basis to receive SLBTRFN (n = 34) or a sham treatment (n = 17). Sham group subjects were allowed to crossover to SLBTRFN after 3 months. At follow-up reviews, patients

Table 4Success rates of SLBTRFN for achieving at least 50% relief of the index pain as shown by theexplanatory study of Patel et al. [13]

Group	RF Treatment	Follow-Lin (Months)	Pain	Believed > 50% (%)
Cioup			T all 1	
Active group	Cooled	3	16/34	47 (Cl ₉₅ 30–64)
n = 34	Cooled	6	13/34	38 (Cl ₉₅ 22–54)
	Cooled	9	20/34	59 (Cl ₉₅ 42–76)
Control group	Sham	3	2/17	12 (Cl ₉₅ 0–27)
n = 17				
Cross-over group	Cooled	3	7/16	44 (Cl ₉₅ 20–68)
<i>n</i> = 16	Cooled	6	7/16	44 (Cl ₉₅ 20–68)

Patel et al. [13] Patients	Selected by \geq 75%	Relief after Each of	Two Sets of S	ingle-Depth SLBBs
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SLBB = sacral lateral branch blocks; SLBTRFN = sacral lateral branch thermal radiofrequency neurotomy.

were assessed for pain, physical function, disability, global perceived effect, and quality of life using a number of instruments. Treatment success was defined as at least 50% decrease in the NRS pain score corroborated by either a 10-point decrease in the Oswestry Disability Index or a 10-point increase in the Short Form-36 scale for bodily pain. The results for pain were as set out in Table 4.

Prima facie, the raw data for the outcomes of active and sham treatment at 3 months seem to show that SLBTRFN using cooled electrodes is more effective than a placebo, although the 95% confidence intervals provided by the authors for the sham group outcomes (1-36%) overlap those of the active group (30-64%). The confidence intervals for sham treatment in Table 4 (0-27%) are as calculated by the authors of this review using the conventional, approximate formula, and they indicate that the active treatment was significantly more successful than the sham treatment at 3 months. The confidence intervals for the outcomes of the sham treatment group and those of the cross-over group at 3 months do overlap. Also, confidence intervals for the sham outcomes, calculated with adjustment for floor and ceiling effects on small proportions, results in a range of 2-34% which overlaps both the range for the active treatment at 3 months and the cross-over group at 3 months. If the figures in Table 4 for the results of active treatment and sham treatment at 3 months are taken in isolation, they do seem to show that SLBTRFN is better than a placebo, but the points outlined above leave that conclusion in doubt.

Taken overall, the evidence published to date suggests that SLBTRFN has some, although limited, effectiveness for the relief of pain arising in the sacroiliac complex. This evidence was found, in accordance with the GRADE system of rating quality of evidence, to be of moderate quality [10]. That rating was determined because the evidence includes data from two explanatory studies, with supporting evidence from observational studies. Readers can be moderately confident in the estimate of effect, and the true effect is likely to be close to that estimate, but there is a possibility that further research might show the effect is substantially different.

Discussion

The literature on SLBBs and SLBTRFN is not extensive. Although it is of moderate quality (in terms of GRADE ratings), it does not provide great endorsement for most of the sacral lateral branch interventions in current use.

The evidence on diagnosis by SLBBs is provided in two papers only. The summary of their findings is that multisite, multidepth SLBBs are target specific: They block the nerves they are intended to block. In other words, multisite, multidepth SLBBs have face validity for the diagnosis of posterior sacroiliac complex pain. There is no evidence of construct validity or predictive validity to augment the face validity of multisite, multidepth SLBBs.

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Single-site, single-depth SLBBs were shown not to have diagnostic validity, and no evidence of diagnostic validity was found for any other injections even though they are often used in practice.

The evidence on treatment by SLBTRFN comes from 15 studies. All used injections of local anesthetic, often with steroid, for patient selection, but none used multisite, multidepth SLBBs, which is the only injection technique shown to have any validity for the diagnosis of sacral lateral branch pain. It is not surprising, then, that in a substantial majority of cases, the relief after SLBTRFN was of limited degree and limited duration. A modal approximation of the outcomes is that about 50% of patients reported 50% relief 3 months after treatment, which is a far less than ideal outcome.

Thirteen of the 15 studies of effectiveness were observational studies which are all open to risks of bias because they lack control groups to account for confounding variables such as the placebo effect, the Hawthorne effect, the Rosenthal effect, regression to the mean, and effects of cointerventions (which were mentioned in six of the study reports); also, recall bias affects results recorded long after treatment (in one study, outcomes were elicited by telephone up to 3 years after treatment [17]), and losses to follow-up result in missing data which must be taken into account in calculating study results. All 13 observational studies could be criticized on methodological grounds, and their results must be interpreted as subject to resultant biases, the effects of which cannot be quantified.

Two of the effectiveness studies were explanatory, so their designs controlled for the risks of bias to which observational studies are subject. Unfortunately, neither used valid diagnostic injections. So, the sources of pains treated remain in doubt.

Nonetheless, despite the diversity of the 15 effectiveness studies in terms of patient selection criteria, treatment targets, and RF technologies applied, all patients had pains in the sacroiliac region, and those pains were relieved in many cases, at least to some extent. The data do not permit specific identification of the sources of the pains that were relieved, but the differences in selection criteria make it likely they were multiple. The known distributions of the S1, S2, and S3 lateral branches and the L4 and L5 dorsal rami suggest the structures from which they may transmit pain include the posterior elements of the sacroiliac complex (the posterior sacroiliac ligaments, the interosseous sacroiliac ligaments, inferior parts of the lumbar multifidus and erector spinae muscles, medial parts of the gluteus maximus muscle, and the posterior aspect of the sacroiliac joint) and the L5-S1 zygapophysial joint. Thus, on the evidence to date, pain relieved by SLBTRFN could be pain arising from any of those structures or a combination of them.

SLBTRFN would not be expected to abolish pain arising from the SIJ proper because anatomic [1-3] and

diagnostic [12] studies indicate that joint has both an anterior and posterior nerve supply. An intriguing conjecture is that perhaps SLBBs and SLBTRFN that produce partial but not total relief of pain may do so by blocking pain from the posterior capsule of the SIJ but not pain from the rest of the joint supplied by anterior nerves. Be that as it may, the authors of this review feel the best that can be said in the current state of knowledge is that pain relieved by SLBBs and SLBTRFN is likely to be pain from the posterior elements of the sacrolliac complex and its source(s) cannot be specified further, hence the title of this article.

Much of the literature reviewed reflected confusion of authors between pain generated from the SIJ and pain from other elements of the sacroiliac complex. This confusion should have been resolved, or at least reduced substantially, by the seminal diagnostic studies of Dreyfuss et al. who demonstrated clear differences between articular and extra-articular sacroiliac pain [12]. The confusion persists, however, and is still evident in papers published long after the Dreyfuss studies.

Further studies are required to enhance understanding of the roles that sacral lateral branch interventions may play in the management of sacroiliac complex pain. Future studies should explore the validity of multisite, multidepth SLBBs further using comparative local anesthetic agents and placebo controls to establish construct validity and the rates of false-positive and false-negative SLBBs, and precise therapeutic studies to establish their predictive validity or therapeutic utility. Future studies should also seek more information on the effectiveness of SLBTRFN, but if such studies are to be undertaken, it will be essential for the differences between the various potential sources of sacroiliac complex pain to be acknowledged and incorporated in their designs.

This review was undertaken as one contribution to a multisociety Appropriate Use Criteria Task Force convened by the ISIS. Its aim was limited to determining the scientific evidence of the validity of SLBBs for diagnosis and the effectiveness of SLBTRFN for treatment so these could be considered in the formulation of criteria for the appropriate use of interventions in the management of pain suspected of arising from the sacroiliac complex.

In addition to evaluating the quality of evidence on a given topic, the GRADE system assesses strength of recommendation for the use of interventions based not only on the quality of evidence but also on other factors such as risk-benefit analysis, cost-benefit analysis, access to services, and patient values and preferences [28]. The authors of this article have deliberately refrained from addressing strength of recommendations for use of SLBBs and SLBTRFN because they consider those recommendations will be more appropriately addressed by the appropriate use criteria to be published by the larger Task Force when it has considered all the findings of the various panels contributing to it.

Conclusions

The literature on sacral lateral branch interventions, as it stands in 2014, is sparse. The current body of knowledge is insufficient to support many interventions that are currently being used in practice.

The evidence that exists regarding the validity of SLBBs for the diagnosis of sacroiliac complex pain is rated as moderate in accordance with the GRADE system. In patients with sacroiliac pain, multisite, multidepth SLBBs have face validity for the diagnosis of pain arising from the posterior elements of the sacroiliac complex. Whether they also have construct validity and predictive validity remains to be seen.

The evidence to date of the effectiveness of SLBTRFN is also rated as moderate in accordance with the GRADE system. Fluoroscopically guided SLBTRFN seems effective for providing some relief of sacroiliac complex pain, but the evidence shows that relief is limited in extent and duration, and the indications for the procedure are unclear. SLBTRFN is not effective for blocking all pain from the SIJ itself because the joint is supplied by both anterior and posterior nerves; this latter point is not widely appreciated, and apparent confusion about it clouds the whole issue of interventions for sacroiliac complex pain.

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