



## RESEARCH ARTICLE

# Clinical results of lumbar sympathetic blocks in lower limb complex regional pain syndrome using infrared thermography as a support tool

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## Abstract

**Aim:** To describe the clinical outcomes for a group of complex regional pain syndrome patients using infrared thermography as an intraoperative support tool when undertaking fluoroscopy-guided lumbar sympathetic blocks.

**Subjects:** 27 patients with lower limb complex regional pain syndrome accompanied by severe pain and persistent functional impairment.

**Methods:** A series of three fluoroscopic-guided lumbar sympathetic blocks with local anesthetic and corticoids using infrared thermography as an intraoperative support tool were performed. Clinical variables were collected at baseline, prior to each block, and one, three, and six months after blocks in a standardized checklist assessing each of the clinical categories of complex regional pain syndrome stipulated in the Budapest criteria.

**Results:** 23.75% of the blocks required more than one chance to achieve the desired thermal pattern and therefore to be considered as successful. A decrease in pain measured on a visual analogic scale was observed at all time points compared to pre-blockade data, but only 37% of the cases were categorized as responders, representing a  $\geq 30\%$  decrease in VAS, with the disappearance of pain at rest. An improvement of most of the clinical variables recorded was observed, such as tingling, edema, perception of thermal asymmetry, difference in coloring and sweating. There was a significant decrease of neuropathic pain and improvement of functional limitation. Logistic regression analysis showed the main variable to explain the probability of being a responder was immobilization time (odds ratio of 0.89).

**Conclusion:** A series of fluoroscopy-guided lumbar sympathetic blocks controlled by infrared thermography in the treatment of lower limb CRPS showed a responder rate of 37%.

## KEY WORDS

Budapest criteria, complex regional pain syndrome, foot, pain, skin temperature, thermal image

## INTRODUCTION

Complex regional pain syndrome (CRPS) is a chronic pain condition characterized by the occurrence of multiple symptoms including chronic persistent pain, autonomic, sensory, motor, and trophic symptoms following trauma that cannot be explained by the trauma itself.<sup>1</sup> It is caused by a complex combination of different factors that start at the time of trauma and consist of sensitization of the nervous system, inflammatory changes, and dysfunction of the autonomic system,<sup>2</sup> which has led to the autonomic nervous system being considered a therapeutic target.<sup>3</sup> Pathophysiological changes result in different clinical symptoms. In its initial phase, the prevailing pathophysiology comprises a post-traumatic inflammatory reaction due to the activation of the immune system, with the appearance of redness, and edema,<sup>4</sup> as well as nociceptive sensitization that manifests itself clinically with hyperalgesia.<sup>5</sup> When CRPS does not improve within the acute phase, symptoms vary due to a series of pathophysiological changes, with central nociceptive sensitization and brain reorganization processes predominating,<sup>2</sup> whilst inflammation moderates.<sup>6</sup> In this phase, the predominant symptoms involve alterations in movement and body temperature, sensory loss, hyperalgesia, allodynia, along with body image disorders.<sup>2</sup>

Standardized therapy is mainly based on rehabilitation, early pharmacotherapy along with psychological treatment.<sup>7-9</sup> However, emphasis is increasingly being placed on tailored treatments focusing on the patient's dominant pathophysiology.<sup>10</sup> When sympathetic impairment is noticeable with changes in temperature and coloring within the affected limb, sympathetic blocks are a recommended option.<sup>11</sup> Although there is an aetiological rationale for sympathetic blocks to reduce the aberrant regional autonomic response, the scientific evidence regarding their analgesic efficacy is limited to one-third of patients.<sup>3,12</sup>

In clinical practice, lumbar sympathetic blocks (LSBs) are performed under fluoroscopic control,<sup>9</sup> targeting the anterolateral part of the lumbar vertebrae, but with no clear target regarding the specific point where the ganglion is located.<sup>13</sup> Moreover, fluoroscopic monitoring has limited accuracy as it is based only on a two-dimensional image. Implementing intraoperative monitoring to check in real-time whether the anatomical target has been reached may improve the accuracy of LSBs. Infrared thermography (IRT) is a validated tool, which may therefore improve the performance of the blocks.<sup>14</sup> In fact, a recent study has shown that 31.7% of the blocks performed, and simultaneously monitored with IRT, required needle repositioning as no thermal changes were observed within the plantar feet.<sup>15</sup>

Given that clinical results regarding the combined use of IRT during LSBs procedures are still unknown and due to the small number of studies related, the aim of this study was to describe the clinical outcomes of a group of CRPS patients using infrared thermography as an intraprocedural support tool when undertaking fluoroscopic guided LSBs.

## METHODS

### Patients

After receiving approval from the ethics committee (Spain, file number 1700292), a prospective observational study was carried out. The data were obtained from November 2019 to November 2021 at a hospital run by work accident insurance companies that treat patients with occupational injuries.

A calculation of the minimum sample size was estimated using the data of the visual analogue scale (VAS) of the first 10 patients with lower-limb CRPS type I of the present study. A minimum sample of 20 participants was estimated for Repeated Measures ANOVA using an effect size  $f$  of 0.3, an error of 5%, a power of 95%, and 6 measurements (three series of sympathetic blocks and subsequently, at one, three, and six months after the third block) (G\*Power 3 software, University of Düsseldorf, Düsseldorf, Germany). Then 35 correlative patients with lower-limb CRPS type I who fulfilled the Budapest criteria recommended by the IASP were selected.<sup>16</sup> Inclusion criteria were adults over 18 years, with time evolution of the disease of <2 years since the initial trauma, with symptoms affecting only one limb, pain intensity equal to or greater than 5 on the visual analogue scale (VAS) (0 being no pain and 10 being the worst pain imaginable),<sup>17</sup> with no significant reduction in pain or dysfunction after initiation of standard therapy, who did not receive previously sympathetic blocks, and who agreed to take part in the study by signing the informed consent form. Exclusion criteria were pregnant women, patients taking vasoactive drugs, patients with coagulopathies, systemic or local infections at the puncture site, patients with diabetic polyneuropathy or other diseases that may resemble CRPS, patients allergic to local anesthetic or iodinated contrast, patients with lumbar instrumentation, or patients with spinal cord stimulation systems.

Of the 35 patients enrolled initially in the study, 31 underwent the full block series (three planned LSBs). Three patients decided not to undergo the third block due to lack of felt progression and one patient underwent a single block since the COVID-19 lockdown made it impossible for the remaining procedures to be performed. Furthermore, thermographic recordings from four patients were not obtained due to technical problems. Thus, appropriate infrared recordings of the complete series of LSBs were finally obtained from 27 patients.

### Procedure

All 27 patients underwent a series of 3 lumbar sympathetic blocks at L4 level with local anesthetic and corticoids, ipsilateral to the affected limb, under radiosopic and thermographic control, and the interventions were performed by the same physician. Clinical variables were

collected previous to each block, and, at one, three, and six months after the third block.

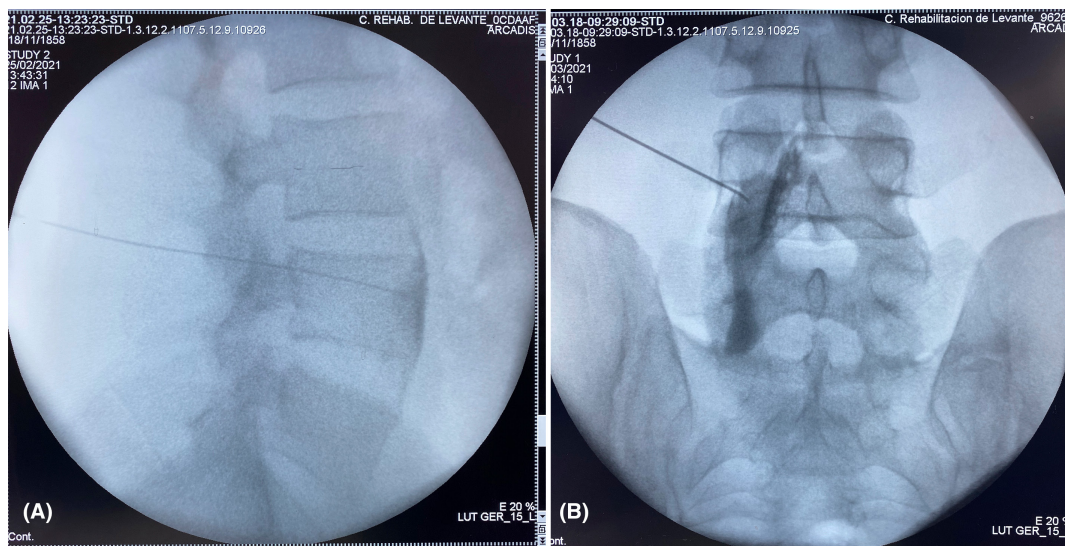
Patients had previously started a standard therapy, consisting of rehabilitation along with an adequate pharmacological treatment, which included anti-inflammatory drugs according to the following medical guideline: if they had a history of <3 months, prednisone in a 5-week regimen: 60–45–30–15–5 mg/day; bisphosphonates (alendronic acid 70 mg/week) for 3 months and calcium and vitamin D supplements (500 mg/400 IU daily); free radical scavengers (dimethyl sulfoxide 50% 3 times a day for 6 months); analgesics (paracetamol and/or tramadol according to requirements). When the pain was still persistent, gabapentin and/or amitriptyline were added. Rehabilitation was carried out by active mobilization, desensitization therapy, and motor imagery if required. Patients with high levels of anxiety or catastrophizing symptoms received psychological treatment.

When patients' pain did not improve (VAS decrease  $\leq 1$ ) after 2 months from the start of the rehabilitation and pharmacological treatment, a series of 3 LSBs with levobupivacaine 0.25% 10 mL with triamcinolone 80 mg, spaced 3 weeks apart, was proposed. During the period in which the blocks were performed, the medication was maintained. One month after the last block, the medication, both analgesics and coadjuvants, could be reduced based on demand.

Patients were asked to fast before the blocks. All procedures were performed in the same operating room with controlled ambient temperature of  $22.0 \pm 0.5^\circ\text{C}$ , and with the patient in prone position under aseptic conditions. The technique was performed under radioscopic control (Siemens Arcadis Orbic) under light sedation (midazolam 2 mg), directing the needle towards the anterolateral part of the vertebral body of the 4th lumbar vertebra. Then following steps were taken: First, the 4th lumbar

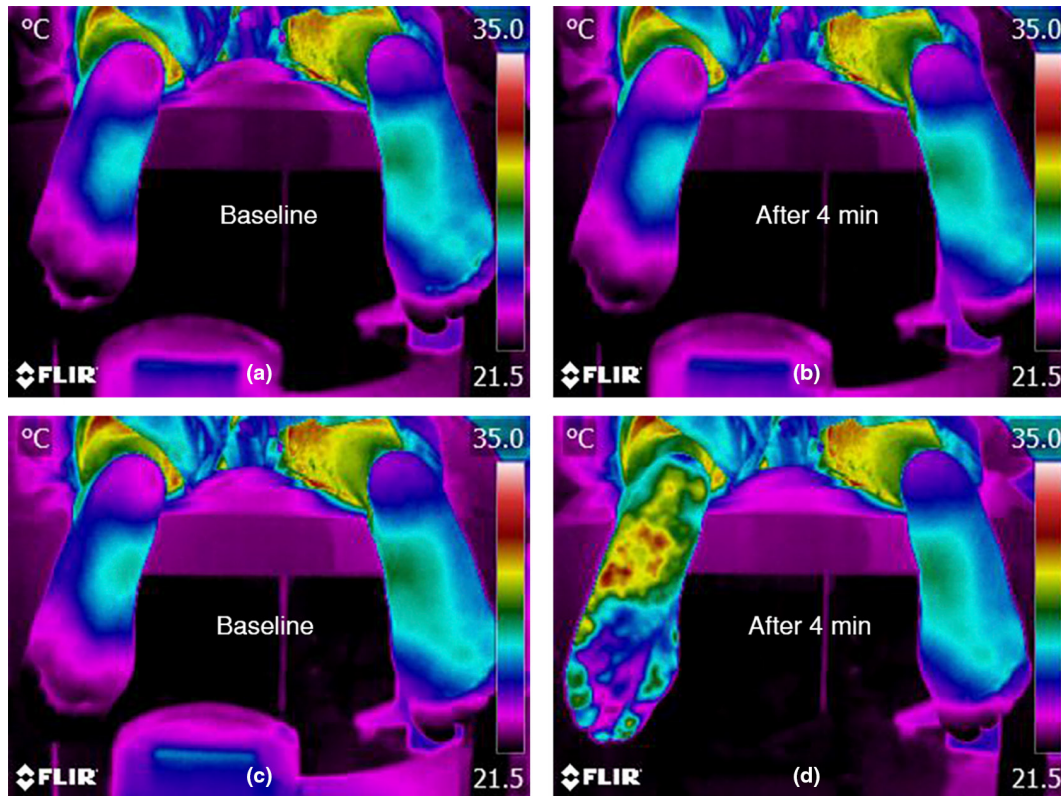
vertebra was located (adjusting the lower endplate of the target vertebral body to be aligned by moving the C-arm in a cephalocaudal direction), and the double contour of the vertebra was eliminated by moving the beam in a craniocaudal direction; an oblique projection was made ipsilateral to the limb to be treated until the transverse process was hidden in the vertebral body. After marking the target on the lateral margin of the vertebra, lidocaine 1% was injected and a 15 cm, 20-gauge needle was introduced in tunneled vision until bone contact was obtained, advancing the needle to the anterior part with a lateral projection of the beam. Adequate diffusion of the contrast (1.5 mL Omnipaque®) was checked in a caudocranial direction (Figure 1A) and inside the lateral margin of the vertebra with the anteroposterior projection (Figure 1B).

A test dose of 2 mL lidocaine 2% was injected, and since it induces vasodilation, the thermal changes taking place in the affected plantar foot were considered as a proper needle placement indicator. Thus, infrared images depicting the thermal alteration within the soles of both feet were recorded throughout the procedure with a FLIR E60 infrared camera (FLIR System, Inc.) placed on a tripod at a distance of 1.5 meters from the patient's feet. For the first four minutes after the lidocaine's test dose, the thermal images were evaluated by the medical team and when a thermal pattern consisting of hotspots within the ipsilateral plantar foot was detected (Figure 2D), the needle was considered correctly placed, and the full dose was injected: levobupivacaine 0.25% 10 mL with 80 mg de triamcinolone. The thermal patterns observed within the first minutes in the plantar feet were distinctive. In successful procedures, isolated warm small spots appeared in different parts of the sole and over the time they became enlarged and their temperature also progressively increased (Figure 2D).



**FIGURE 1** Radioscopic contrast control in the caudocranial direction (A) and in the anteroposterior projection (B).





**FIGURE 2** Infrared images of both plantar feet in a CRPS<sup>1</sup> patient (ipsilateral left) just after the lidocaine test (baseline) in (A) and (C), and 4 min after the lidocaine test in a: (B) failed and (D) successful intervention.

Otherwise, when the procedure was tagged as unresponsive, no thermal changes were observed within the plantar foot and neither these thermal patterns (Figure 2B). The 4-min time during which the infrared images were evaluated was determined based on both the short latency and onset of lidocaine action<sup>18</sup> and on previous studies using thermocouple probes<sup>19</sup> or infrared thermography.<sup>15</sup> When no thermal changes after the test dose were observed, the needle was repositioned in the cranio-caudal axis in a caudal direction, but when no changes were identified either, then, the most cranial part of the vertebra was approached. Thus, after each needle's reposition, the lidocaine test dose was injected along with confirmation of the adequate diffusion of the contrast, until infrared images confirmed the block was successful. At first a test dose was used instead of the full local anesthetic dose because, since it contains corticosteroid, there would be a limitation on repeating the procedure in case no thermal patterns were identified within the ipsilateral foot. On the other hand, since the extent of the ventrolateral part of the vertebra depends on the patient's anatomy and, due to the variability of the position of the sympathetic ganglion with respect to the height of the vertebra, there is no specific target point of the needle and, therefore there is no standardized protocol regarding the needle reposition. In this sense and considering the anatomy of the lumbar ganglia where the procedures were performed, only 3 consecutive repositioning

maneuvers were carried out at most to avoid complications in the patient. Furthermore, in light of the thermal variations observed within the plantar feet, all the samples included in this study were successful procedures.

### Clinical variables analyzed

Clinical variables were collected at baseline, prior to each block, and one, three, and six months after blocks in a standardized checklist that assessed each of the clinical categories of CRPS proposed in the Budapest criteria,<sup>16</sup> both by reported symptoms and by observation. Among the neurological symptoms, tingle, and allodynia (measured by brush-evoked pain) were considered. Whether there was edema and sweating (all these variables were categorized into two levels: yes/no) or not was also considered. Moreover, among the vasomotor symptoms, the existence of alterations in coloring (yes/no) and temperature were considered, which were then categorized as predominantly cold or hot, or without thermal asymmetry. Motor assessment, in turn, was performed by measuring passive (PJB) and active joint balance (AJB) (1—no movement, 2—partial mobility, 3—full mobility), Daniels and Worthingam muscle balance (MB) (0—no movement, 1—isometric contraction, 2—movement against gravity, 3—full movement against gravity without external resistance, 4—suboptimal

**TABLE 1** Evolutionary variables collected in a medical office.

Dolour Neuropathique (DN4) <sup>21</sup>	0 (no features of neuropathic pain) 10 (meets all the features of neuropathic pain)
Quality of life scale (QOL) <sup>22</sup>	0 patients who remained in bed all day and needed help with any activity 10 patients who were fully autonomous, socially, and occupationally active
Harden's severity scale <sup>23</sup>	Assesses the number of patient self-reported symptoms and signs present at the time of assessment, scoring from 0 to 17, with 17 being the most florid
Lower Limb Functional Index (LLFI) <sup>24</sup>	Validated scale to measure the percentage of functional limitation to their legs, with 100% being full mobility and no limitations and 0% being complete disability
Number of crutches required	0, 1 or 2 crutches
Likert scale at 1, 3 and 6 months after the blocks; and when the patient had been discharged from work during the follow-up time	7 points to measure subjective improvement (1—much worse, 2—much worse, 3—slightly worse, 4—the same, 5—slightly better, 6—much better, 7—much worse)

movement against resistance, and 5—normal movement),<sup>20</sup> and the presence or absence of myoclonus. The pain was also measured using the Visual Analogic Scale (VAS) on a numerical scale from 0 to 10 and the existence of rest pain (two levels: yes/no).<sup>17</sup>

The incidents that occurred during the performance of the blocks (vascular or root puncture) and the occurrence of side effects were also recorded.

Additionally, the following series of evolutionary variables described in Table 1 were collected in the medical office (at baseline, and one, three, and six months after the block).

The number of responding patients was evaluated in the assessment performed one month after the third LSB. Hence, responding patients were defined as those who presented a decrease in VAS  $\geq 30\%$  (numerical variable with values between 0 and 10) and disappearance of pain at rest (categorical variable with two levels, yes or no) compared to the evaluation undertaken prior to the first block (baseline).

## Statistical analysis

Statistical analysis was performed with RStudio (version 1.2.5033). The normality of the continuous variables was analyzed using the Shapiro–Wilk test, showing that the VAS, the LLFI, the QOL and the Likert showed a non-normal distribution ( $p < 0.05$ ), whereas both the Harden test and the DN4 showed a normal distribution at all measurement points ( $p > 0.05$ ). Hence, the differences between the moments measured in each of the continuous variables were analyzed with a one-way repeated measures ANOVA with Bonferroni post-hoc for both the Harden test and DN4, and on the other hand, the Friedman test with Wilcoxon post-hoc with Bonferroni correction was used for the non-parametric variables. The Chi-square test was used to analyze the differences between time points measured in categorical variables. Differences in clinical variables between the responder and non-responder groups were analyzed at follow-up, one month after the end of the series of LSBs using the

Student's *t*-test (for parametric variables), the Mann–Whitney *U* test (for non-parametric variables) and the Chi-square test (for categorical variables). Moreover, Cohen's effect size was analyzed for all tests, using for continuous variables the effect size for pairwise comparisons (ESd), and for categorical variables the effect size for assessing Chi-square (ESw). These effect sizes were classified as large (ESd  $> 0.8$ ; ESw  $> 0.5$ ), medium (ESd 0.5–0.8; ESw 0.3–0.5), and small (ESd 0.2–0.5; ESw 0.1–0.3). Finally, to analyze the factors associated with being a responder, a logistic regression model was performed to estimate the odds ratios (OR) and their 95% CI. Stepwise multiple regressions in both directions were performed to find the model with the best AIC (Akaike Information Criterion).<sup>25</sup> Final models were then adjusted to retain only variables yielding *p*-values  $< 0.05$ . Outcome variables of interest were age, body mass index, smoker (yes/no), location of the injury (knee/ankle/foot), fracture (yes/no), treatment (conservative/surgery), immobilization time in weeks, evolution time in months, and clinical variables obtained in the measurement before the first block (VAS, allodynia, tingle, myoclonus, edema, color asymmetry, temperature asymmetry, sweating, AIB, PJB, MB, crutches, DN4, QOL, Harden and LLFI). The significance limit was set at  $p < 0.05$ .

## RESULTS

Table 2 shows the descriptive data of the 27 patients analyzed in this study.

A total of 104 interventions were performed on the 27 patients, of which, 23 repositions were performed until the desired thermal changes were observed on the infrared images after the lidocaine test. Thus, the success rate of observing the desired thermal changes after the lidocaine test was 76.25% (the failure rate was 23.75%), considering all repositioning. During the procedures, in 5 cases, the patient complained of pain suggestive of radicular puncture and, on 8 occasions, a vascular spread of contrast was obtained, with immediate correction of the needle placement, prior to lidocaine administration.

It should be noted that, apart from transient lumbar discomfort after the puncture, in 44% of patients, no notable side effects were noticed.

The clinical results obtained in the interventions are presented below. Regarding VAS (Figure 3), a decrease was observed at all time points compared to pre-block data with a large effect size (vs. LSB2 95% CI of the difference [0.5, 1.5 points], vs. LSB3 95% CI [0.8, 2.0 points], vs. Month 1 post 95% CI [1.1, 2.4 points], vs. Month 3 post 95% CI [0.9, 2.4 points], vs. Month 6 post 95% CI [1.6, 3.1 points]) but no significant differences from the other time points were observed between them ( $p > 0.05$ ). A significant reduction in pain at rest was also observed ( $p < 0.001$ , Figure 4).

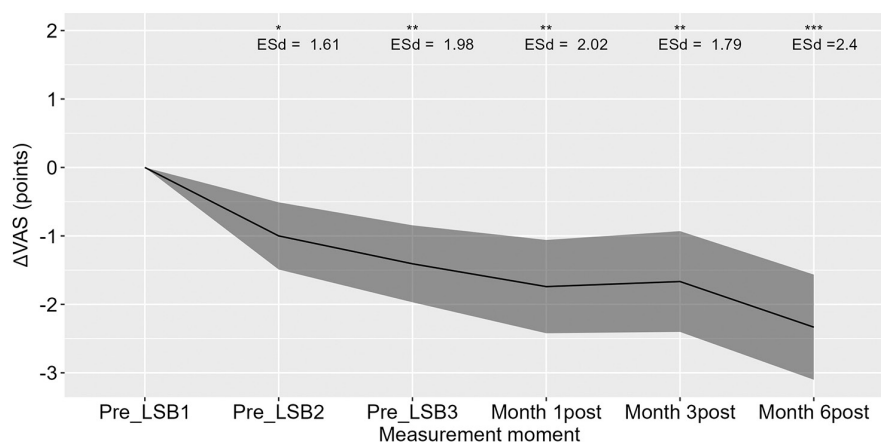
**TABLE 2** Demographic data and complex regional pain syndrome (CRPS) characteristics of the patients.

Variable	
Gender (male/female)	20/7
Age (years)	42±9
Body mass index (kg/m <sup>2</sup> )	26.9±3.2
Smokers (yes/no)	9/18
Characteristics of CRPS	
Side (right/left)	7/20
Location (foot/ankle/knee)	19/5/3
Fracture (yes/no)	11/16
Surgery: yes (fracture/no fracture)	8 (3/5)
Surgery: no	19
Temperature (cold/warm/no)	16/8/3
Immobilization time (days)	27±15
Evolution time (months)	9.3±5.2

Regarding the clinical variables recorded, a statistically significant difference was observed in the disappearance of some variables, such as tingling, edema, perception of thermal asymmetry, difference in coloring and sweating (Table 3).

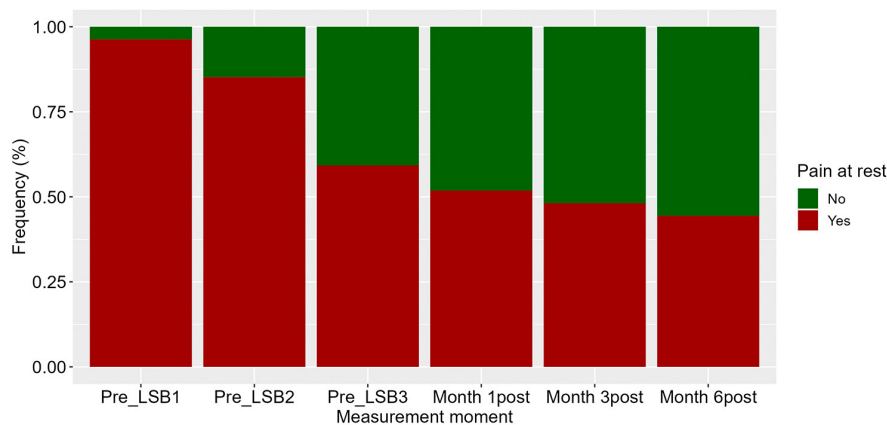
In the tests assessing global disease progression, the Harden test also showed an improvement in follow-up measures over the pre-first block measurement (vs. Month 1 post 95% CI [2.3, 5.2 points],  $p < 0.001$  and ESd=1.4; vs. Month 3 post 95% CI [3.0, 6.2 points],  $p < 0.001$  and ESd=1.6; vs. Month 6 post 95% CI [3.3, 6.7 points],  $p < 0.001$  and ESd=1.7), as well as the LFFI (vs. Month 1 95% CI [6.0, 17.0%],  $p < 0.01$  and ESd=0.6; vs. Month 3 post 95% CI [8.0, 27.0%],  $p = 0.04$  and ESd=0.6; vs. Month 6 post 95% CI [8.0, 30.0%],  $p = 0.01$  and ESd=0.7). DN4 also showed improvement in all follow-up measures compared to the measurement prior to the first block (vs. Month 1 post 95% CI [0.1, 1.8 points],  $p = 0.03$  and ESd=0.6; vs. Month 3 post 95% CI [0.4, 2.2 points],  $p < 0.01$  and ESd=0.8; vs. Month 6 post 95% CI [0.4, 2.4 points],  $p < 0.01$  and ESd=0.8). The QOL only showed an improvement in the measurement at 6 months after completion of the blocks compared to previous measurements (vs. Pre\_LSB1 post 95% CI [0.5, 2.3 points],  $p < 0.01$  and ESd=0.9; vs. Month 1 post 95% CI [0.1, 1.9 points],  $p = 0.04$  and ESd=0.6; vs. Month 3 post 95% CI [0.4, 1.8 points],  $p = 0.01$  and ESd=0.3). The Likert test resulted in a patient rating of  $5 \pm 1$  points, with no differences between measurements taken at follow-up at 1, 3 and 6 months after completion of the blocks ( $p > 0.21$ ).

Ten out of the 27 patients (37%) were categorized as responders. Differences between responders and non-responders are shown in Table 4. The multiple logistic regression model with stepwise selection of variables showed that the only variable related to being a responder



**FIGURE 3** Mean and CI95% (confidence interval 95%) of the variance of the 10-point Visual Analogue Scale ( $\Delta$ VAS) score. Difference from the time prior to the first lumbar sympathetic block (LSB1) was shown by symbols (\* $p < 0.05$ , \*\* $p < 0.01$ , \*\*\* $p < 0.001$ ) and effect size (ESd). Pre\_LSB1: basal value, Pre\_LSB2: previous to the 2nd sympathetic block, Pre\_LSB3: previous to the 3rd sympathetic block. Month 1 post: 1 month after the 3rd lumbar sympathetic block, 3 months after the 3rd lumbar sympathetic block, 6 months after the 3rd lumbar sympathetic block.





**FIGURE 4** Frequency of presenting pain at rest at the different times measured. The Chi-square test showed differences between the different times ( $p < 0.001$ ). Pre\_LSB1: basal value, Pre\_LSB2: previous to the 2nd sympathetic block, Pre\_LSB3: previous to the 3rd sympathetic block. Month 1 post: 1 month after the 3rd lumbar sympathetic block, 3 months after the 3rd lumbar sympathetic block, 6 months after the 3rd lumbar sympathetic block.

was immobilization time (coefficient  $-0.12 \pm 0.05$ ,  $p = 0.02$ ), with an odds ratio of 0.89 (95% CI [0.79, 0.96]).

## DISCUSSION

The aim of this study was to describe the clinical outcomes in a group of CRPS patients using infrared thermography as an intraprocedural support tool when undertaking fluoroscopy-guided LSBs. The main findings in this study were that, in general, most of the clinical variables improved compared to the pre-block moment (eg, VAS, pain at rest, Harden, tingling, edema, perception of thermal asymmetry, difference in coloring and sweating). However, only 37% of the patients were categorized as responders, and the variable that increases the probability to be a responder was immobilization time.

The results obtained regarding the LSBs performed and assessed with thermography in patients with CRPS in the lower limbs show a significant decrease with a large effect size in VAS from baseline to measurements at 1, 3, and 6 months after the LSBs intervention. In 13 out of 27 patients, the pain at rest faded away a month after the third LSB. Several studies analyze the efficacy of sympathetic blocks with variable protocols and a wide range of follow-up times.<sup>3,19,26</sup> However, there are no clinical guidelines that endorse a gold standard when undertaking LSBs. Clinical studies use protocols for LSBs with local anesthetics alone or in association with other drugs (clonidine, steroids, botulinum toxin, etc.) and in variable schedules.<sup>1</sup> In an online study conducted in the USA, among the interventional physicians asked about how they performed the blocks, 50% combined the local anesthetic with some adjuvant drug, usually corticosteroids to improve the block and to prolong the effect of symptomatic relief.<sup>27</sup>

Several predictive factors related to a positive response to sympathetic blocks have been described, such as allodynia, temperature asymmetry and color changes.<sup>28,29</sup>

However, Van Eijs et al.<sup>3</sup> found both allodynia and hypoesthesia to be negative predictors. In our series, the neurological symptoms measured were tingling, which was significantly reduced after the blocks with a medium effect size, and allodynia, which was not modified, but its presence did not determine a poor outcome either.

There is consensus on LSBs are not a first-line treatment and should be performed by experienced therapists.<sup>1,8,27</sup> In fact, the Cochrane database reveals no evidence of the efficacy of sympathetic blocks based on the lack of high-quality studies.<sup>30</sup> However, this does not mean that they must not be undertaken.<sup>1</sup> A review of the literature shows that sympathetic blocks with a local anesthetic in patients with CRPS resulted in pain relief in approximately one-third of patients.<sup>3,12</sup> Van Eijs et al.,<sup>3</sup> in a prospective observational study of 49 patients with upper and lower limb CRPS type I treated with sympathetic blocks with local anesthetics, found that 31% of patients presented a 50% improvement in their pain at a follow-up time of 7 days. Cepeda et al.<sup>12</sup> showed in a systematic review that sympathetic blocks with local anesthetic in CRPS patients reported a response rate of 30%. In our study, 37% of the cases were categorized as responders, meaning a decrease in VAS  $\geq 30\%$  with the disappearance of pain at rest (mean VAS of 2.8 in responders vs. 5.88 in non-responders) during the follow-up time. The higher response rate in this study compared to previous publications<sup>3,12</sup> may be due to the implementation of thermographic monitoring. Additionally, the definition of responders may also play a role, since previous publications<sup>3,12</sup> considered responders as those with more than 50% relief, but without taking into account the presence or absence of pain at rest and other clinical criteria or progression scales.

Although most of the qualitative clinical variables of the Budapest criteria analyzed improved significantly after the LSBs (edema, changes in coloring and temperature, sweating, tingle) (Table 3), there were no differences between responders and non-responders. Some

TABLE 3 Categorical clinical variables assessed.

Characteristic	Pre_LSBI <sup>a</sup>	Pre_LSB2 <sup>a</sup>	Pre_LSB3 <sup>a</sup>	Month 1post <sup>a</sup>	Month 3post <sup>a</sup>	Month 6post <sup>a</sup>	p-Value	Effect size <i>W</i>
Allodynia	15 (56%)	13 (48%)	8 (30%)	10 (37%)	9 (33%)	8 (30%)	0.3	0.200
Tingle	25 (93%)	17 (63%)	12 (44%)	11 (41%)	12 (44%)	8 (30%)	<0.001	0.409
Edema	24 (89%)	19 (70%)	15 (56%)	12 (44%)	15 (56%)	11 (41%)	0.003	0.331
Myoclonus	3 (11%)	2 (7.4%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	1 (3.7%)	0.9	0.123
Color asymmetry	23 (85%)	19 (70%)	16 (59%)	16 (59%)	14 (52%)	12 (44%)	0.037	0.270
Temperature asymmetry								
No	3 (11%)	5 (19%)	7 (26%)	11 (41%)	16 (59%)	14 (52%)	<0.001	0.322
Warm	8 (30%)	12 (44%)	13 (48%)	13 (48%)	5 (19%)	8 (30%)		
Cold	16 (59%)	10 (37%)	7 (26%)	3 (11%)	6 (22%)	5 (19%)		
Sweating	16 (59%)	9 (33%)	5 (19%)	3 (11%)	3 (11%)	3 (11%)	<0.001	0.412
AJB								
1	3 (11%)	–	–	2 (7.4%)	2 (7.4%)	2 (7.4%)	0.4	0.165
2	18 (67%)	–	–	14 (52%)	11 (41%)	12 (44%)		
3	6 (22%)	–	–	11 (41%)	14 (52%)	13 (48%)		
PJB								
1	0 (0%)	–	–	1 (3.7%)	1 (3.7%)	1 (3.7%)	0.9	0.108
2	12 (44%)	–	–	8 (30%)	8 (30%)	9 (33%)		
3	15 (56%)	–	–	18 (67%)	18 (67%)	17 (63%)		
MB								
1	2 (7.4%)	–	–	1 (3.7%)	2 (7.4%)	2 (7.4%)	0.8	0.145
2	1 (3.7%)	–	–	1 (3.7%)	1 (3.7%)	1 (3.7%)		
3	5 (19%)	–	–	6 (22%)	5 (19%)	4 (15%)		
4	16 (59%)	–	–	12 (44%)	10 (37%)	10 (37%)		
5	3 (11%)	–	–	7 (26%)	9 (33%)	10 (37%)		
Crutches								
0	10 (37%)	–	–	11 (41%)	14 (52%)	15 (56%)	0.8	0.126
1	12 (44%)	–	–	13 (48%)	10 (37%)	10 (37%)		
2	5 (19%)	–	–	3 (11%)	3 (11%)	2 (7.4%)		

Note: The *p*-value shows whether there are differences between the different assessment points.

Abbreviations: AJB, Active Joint Balance; MB, Muscle Balance; PJB, Passive Joint Balance.

<sup>a</sup>*n* (%).

clarifications on this respect should be considered, such as our categorization performed about responders and not responders, which may affect the results, along with the casuistry of this kind of patients, from whom multiple variables are collected due to the high variability in the response of their symptoms. In this sense, the Harden severity scale, which quantified the presence of symptoms and signs of the disease,<sup>23</sup> was not predictive of response to blocks and it showed no differences between the two groups. However, as might be expected, the scales measuring the neuropathic condition of the pain or the evolution of the disease do behave substantially differently in the group of respondent patients than in the non-respondents: DN4 5.41 vs. 3.20, subjective rating of improvement (Likert 4.53 vs. 5.70), quality of life (QOL 5.41 vs. 7). Moreover, QOL was improved only at 6 months, which can be explained on the basis

that the quality of life needs an important pain decrease and an improvement in the other associated symptoms, which consistently happens at 6 months. With regard to patients' mobility, measured through passive and active joint balance, as well as muscular balance and Lower Limb Functional Index, there is no significant improvement after the blocks. Obviously, there is a significant difference between the respondents and non-respondents in these variables, as well as in the need to walk with crutches (14 patients vs. 2) (Table 4).

Several studies assess the effectiveness of the blocks, either through temperature changes measured by palpation or by a thermometer attached to the skin, considering them successful when the temperature rises above 1.5–2°C.<sup>3,19,31</sup> Initially, the evaluation of skin temperature after sympathetic blocks was based on palpation of the affected area, substantiating the success



**TABLE 4** Differences in clinical variables assessed between responders and non-responders.

Characteristic	Non-responders <sup>a</sup>	Responders <sup>a</sup>	p-Value	Effect size <sup>b</sup>
VAS	5.88 (1.22)	2.80 (1.23)	<0.001	2.52
DN4	5.41 (1.54)	3.20 (1.03)	<0.001	1.68
LIKERT	4.53 (0.62)	5.70 (0.67)	<0.001	1.80
QOL	5.41 (1.00)	7.00 (1.25)	0.002	1.40
Pain at rest	13 (76%)	0	0.001	0.566
Harden	7.9 (2.7)	5.7 (3.3)	0.080	0.753
LFFI	27 (10)	57 (21)	<0.001	1.79
Allodynia	8 (47%)	2 (20%)	0.2	0.191
Tingle	10 (59%)	1 (10%)	0.018	0.402
Edema	10 (59%)	2 (20%)	0.11	0.300
Myoclonus	1 (5.9%)	0 (0%)	>0.9	0.000
Color asymmetry	12 (71%)	4 (40%)	0.2	0.223
Temperature asymmetry				
No	6 (35%)	5 (50%)	0.5	0.280
Warm	8 (47%)	5 (50%)		
Cold	3 (18%)	0 (0%)		
Sweating	3 (18%)	0 (0%)	0.3	0.149
AJB				
1	2 (12%)	0 (0%)	0.045	0.470
2	11 (65%)	3 (30%)		
3	4 (24%)	7 (70%)		
PJB				
1	1 (5.9%)	0 (0%)	0.13	0.383
2	7 (41%)	1 (10%)		
3	9 (53%)	9 (90%)		
MB				
1	1 (5.9%)	0 (0%)	0.007	0.664
2	1 (5.9%)	0 (0%)		
3	6 (35%)	0 (0%)		
4	8 (47%)	4 (40%)		
5	1 (5.9%)	6 (60%)		
Crutches				
0	3 (18%)	8 (80%)	0.007	0.620
1	11 (65%)	2 (20%)		
2	3 (18%)	0 (0%)		

Abbreviations: AJB, Active Joint Balance; DN4, Dolour Neuropathique; LFFI, Lower Limb Functional Index; MB, Muscle Balance; PJB, Passive Joint Balance; QOL, Quality Of Life; VAS, Visual Analogic Scale.

<sup>a</sup>n (%) for categorical variables and mean (SD) for continuous variables.

<sup>b</sup>Cohen *d* Effect size for numerical variables and Cohen *w* Effect size for categorical variables.

of the intervention based on the warming sensation.<sup>32</sup> Nonetheless, this technique may fail to distinguish subtle temperature differences. Hrabalek et al. reported that the ability to distinguish a difference in legs' temperature within an interval of 1.0–8.1°C after a lumbar sympathectomy by palpation was 32%. Still, palpation was unable to reveal differences in legs' temperature up to 4.3°C.<sup>33</sup> This explains the rejection of this “control” measure, as it offers a low level of precision. Accordingly, skin

temperature has been usually measured by contact thermal sensors, such as thermocouples or thermometers, yet these also entail some difficulties. For instance, there could be some issues with the way these devices are adhered to the skin, as it can lead to temperature changes.<sup>34</sup> In addition, the measurement is retrieved from a small area, so the temperature gradients in the measurement area cannot be properly recorded.<sup>35</sup>

Along with this, and according to previous studies, the IRT has been proved as a valuable technique in evaluating the performance of LSBs.<sup>15,36</sup> Apart from being a non-contact image technique compared with palpation or thermocouples<sup>19,32</sup> that are subjective or alter the skin temperature of the patient, thermal images provide much more thermal information allowing, in turn, straightforward interpretations.

There is controversy about whether the temperature increases following the blocks are related to their clinical efficacy. Hence, Tran et al.<sup>37</sup> described a direct relationship between the temperature increase and the relief of pain and allodynia. However, other authors deny this correlation.<sup>3,19,31,38</sup> Kim et al.<sup>14</sup> validated the accuracy of thermography to confirm the success of LSBs. In a preliminary study published by Cañada-Soriano et al., 44 LSBs were performed for the treatment of CRPS in lower limbs in 13 patients under radioscopic control and confirmation of block success by thermography. Although the blocks were performed by the same experienced interventional physician, in 32% of cases there were no temperature variations after lidocaine administration, thus requiring needle repositioning.<sup>15</sup> This study also increased the number of interventions up to 104, and when it was observed that the expected thermographic changes did not occur in 23.75% of cases, the needle had to be repositioned until it was confirmed that the block was effective. This led us to think that increasing the precision in the blocks' performance using a non-invasive method, which would measure more accurately the derived changes of the vascular flow increase and the subsidiary warming of the member, their clinical efficiency could be improved. In this sense, to date no study has yet analyzed the clinical evolution of sympathetic blocks performed under thermographic control.

The only variable related to being a responder was the immobilization time: the longer the immobilization time and the tingle, the worse the response to the blocks. Although prolonged immobilization time is considered an independent risk factor for the development of the disease,<sup>39</sup> no study correlates this finding as a negative predictive factor for blocks. On the other hand, traditionally, greater efficacy of blocks has been described for warm CRPS,<sup>40</sup> although Van Eijs et al.<sup>3</sup> found better results for cold ones. In this study, no difference was found in the response between initially warm or cold syndromes or in the evolution time of the condition when the pattern of the sympathetic blockade was initiated, as might be expected. The prognosis is typically better in the earlier stages of CRPS. Patients who did not respond to standardized conservative treatment for at least 2 months presented pain refractory to therapy and, therefore, an overall worse prognosis, which may explain the phenomenon mentioned above.

The great number of variables analyzed is intended to provide a global idea of patient evolution, given that a good response to treatment does not depend solely on the quantification of pain or its presence at rest, but also on the disappearance of other collateral symptoms, and

other indirect evaluations, such as improved functionality, quality of life and, ultimately, the ability to return to work. Another factor to take into account is the standardization of the procedure, with a well-defined approach performed by a single, experienced operator.

This study presents some limitations. The first is heterogeneity in terms of the time of evolution of the patients since there is a large number of factors involved in their development. In order to obtain conclusive results, a larger sample size should be evaluated, although in the normal clinical practice there are not so many patients with CRPS subsidiaries of LSBs. This study was carried out over 2 years and, what is more, it was concurrent with the COVID-19 pandemics, which resulted in a decrease in the number of patients diagnosed and treated due to the lockdown. Additionally, the differences in the care provided, until patients are referred to the pain unit where treatment is standardized, can also play a role.

In conclusion, a series of fluoroscopy-guided lumbar sympathetic blocks controlled by infrared thermography in the treatment of lower limb CRPS showed a responder rate of 37%. The favorable response is shown not only by the overall reduction in pain, but also by the disappearance of the satellite symptoms of CRPS along with the improvement of other scales that measure the evolution of the syndrome, and in the absence of notable complications. The use of thermography as a routine support technology in the performance of fluoroscopy-guided lumbar sympathetic blocks to certify temperature changes may reduce the likelihood of the patient receiving an anatomically inaccurate block, or sham block, and thus save valuable time in the treatment process.

## CONFLICT OF INTEREST STATEMENT

None.

## DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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**How to cite this article:** Bovaira M, Cañada-Soriano M, García-Vitoria C, Calvo A, De Andrés JA, Moratal D, et al. Clinical results of lumbar sympathetic blocks in lower limb complex regional pain syndrome using infrared thermography as a support tool. *Pain Pract.* 2023;00:1–11. <https://doi.org/10.1111/papr.13236>