American Pain Society
RESEARCH
EDUCATION
TREATMENT
ADVOCACY
PUBLISHED BY ELSEVIER

The Journal of Pain, Vol 17, No 5 (May), 2016: pp 569-576
Available online at www.jpain.org and www.sciencedirect.com

Paraspinous Lidocaine Injection for Chronic Nonspecific Low Back Pain: A Randomized Controlled Clinical Trial

Marta Imamura,[*,†] Satiko Tomikawa Imamura,[‡] Rosa Alves Targino,[†] León Morales-Quezada,[§,¶] Luis C. Onoda Tomikawa,[‖] Luis G. Onoda Tomikawa,[†] Fabio M. Alfieri,[†] Thais R. Filippo,[†] Ivan D. da Rocha,[**] Raul Bolliger Neto,[††] Felipe Fregni,[§] and Linamara Rizzo Battistella[‖]

**Physical and Rehabilitation Medicine Division, **Spine Group, [‡]Center for Pain, and [††]Musculoskeletal System Medical Research Laboratory-LIM 41, Orthopedics and Traumatology Institute, and [†]Clinical Research Center, [‖]Physical and Rehabilitation Medicine Institute (IMREA), Clinics Hospital, University of São Paulo Medical School, São Paulo, Brazil. [§]Spaulding Neuromodulation Center, Spaulding Rehabilitation Hospital, [¶]Placebo Studies Laboratory, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts.*

Abstract: **In this large, sham-controlled, randomized trial, we examined the efficacy of the combination of standard treatment and paraspinous lidocaine injection compared with standard therapy alone in subjects with chronic low back pain. There is little research-based evidence for the routine clinical use of paraspinous lidocaine injection for low back pain. A total of 378 subjects with nonspecific chronic low back pain were randomized to 3 groups: paraspinous lidocaine injection, analgesics, and exercises (group 1, LID-INJ); sham paraspinous lidocaine injection, analgesics, and exercises (group 2, SH-INJ); and analgesics and exercises (group 3, STD-TTR). A blinded rater assessed the study outcomes at 3 time points: baseline, after treatment, and after 3 months of follow-up. There were increased frequency of pain responses and better low back functional scores in the LID-INJ group compared with the SH-INJ and STD-TTR groups. These effects remained at the 3-month follow-up but differed between all 3 groups. There were significant changes in pain threshold immediately after treatment, supporting the effects of this intervention in reducing central sensitization. Paraspinous lidocaine injection therapy is not associated with a higher risk of adverse effects compared with conventional treatment and sham injection. Its effects on hyperalgesia might correlate with changes in central sensitization.**

Clinical Trial Registration: **NCT02387567.**

Perspective: ***There are few data to support paraspinous lidocaine injection use in patients with nonspecific chronic low back pain. Our results show that this therapy when combined with standard therapy significantly increases the number of responders versus standard treatment alone. Its effects on hyperalgesia might correlate with a change in central sensitization.***

Key words: *Randomized clinical trial, paraspinous lidocaine injection, nonspecific chronic low back pain, evidence-based medicine, central sensitization.*

Chronic low back pain is a leading cause of disability[28] and a major cause of health and socioeconomic problems in Western societies.[29] It is defined as low back pain that persists for ≥3 months. Whereas patients with chronic low back pain constitute a minority of low back pain cases, they are responsible for 70% to 80% of its annual costs, estimated at $50 billion.[9] Thus, in addition to being a major health problem in modern society, it is a significant socioeconomic challenge.[10]

Although there are several treatments for chronic nonspecific low back pain,[1] few have demonstrated efficacy, most of which have limited effects. There are 2 main

Received April 8, 2015; Revised November 18, 2015; Accepted January 6, 2016.

This study was supported by the Physical and Rehabilitation Medicine Institute, Clinics Hospital of University of São Paulo Medical School. Dr. Morales-Quezada received funding support from an Institutional National Research Service Award from the National Center for Complementary and Integrative Health grant T32AT000051, the Ryoichi Sasakawa Fellowship Fund, and by the Program in Placebo Studies at Beth Israel Deaconess Medical Center.

The authors have no conflicts of interest to declare.

Address reprint requests to Felipe Fregni, MD, PhD, Spaulding Rehabilitation Hospital, Spaulding Neuromodulation Center, 96 13th Street, Charlestown MA 02129. E-mail: felipe.fregni@mgh.harvard.edu

1526-5900/$36.00

http://dx.doi.org/10.1016/j.jpain.2016.01.469

categories of treatment: pharmacological and nonpharmacological. Although nonsteroidal anti-inflammatory drugs (NSAIDs) are effective for short-term symptomatic relief[24] there are insufficient data to suggest that they provide long-term pain relief.

Trigger point injections of lidocaine have been widely used in clinical settings for various chronic pain syndromes[8]; however, there are few data to support their use in nonspecific chronic low back pain. Proper but limited evidence comes from trials that have used this technique to treat fibromyalgia,[26] pelvic,[15] and myofascial[8] pain. Indeed, to our knowledge there are no randomized clinical trials testing lidocaine injections in patients with low back pain.

The principal goal of paraspinous lidocaine injection in patients with chronic low back pain is to induce spinal segmental desensitization. Recent studies have shown that plastic changes in the central and peripheral nervous systems mediate the genesis and maintenance of magnified chronic pain.

Thus, therapeutic approaches that modulate the nervous system, rather than merely interfere with inflammatory pathways, might be more effective in managing chronic pain. Similar to poststroke patients, in whom maladaptive plastic changes at the cortical level impair functional outcomes, mechanical nociceptive stimuli at the spinal segmental level can promote local spinal cord changes, as in cortical maladaptive plasticity. These changes sensitize facilitating pain of combined origin: musculoskeletal and neuropathic.[2,19]

On the basis of the mechanism of action of paraspinous lidocaine injection and its potential therapeutic effects, an evaluation of this intervention for nonspecific chronic low back pain in a properly powered and designed, controlled clinical trial is warranted. We conducted a randomized, single-blind, parallel (with an allocation ratio of 1:1:1), controlled trial to determine the analgesic and functional effects of paraspinous lidocaine injection in patients with chronic nonspecific low back pain, hypothesizing that lidocaine injections would effect greater reductions in pain compared with control treatments.

Methods

Study Population and Inclusion Criteria

This trial was conducted in the Department of Rehabilitation, Hospital das Clinicas, University, of Sao Paulo Medical School, one of the largest rehabilitation centers in Latin America. The trial was initiated in January of 2007 and closed to enrollment in January of 2013. We included 381 patients with a diagnosis of chronic nonspecific low back pain who were referred from various clinics in São Paulo that were linked to this rehabilitation center. Thus, patients were referred primarily by physiatrists, general practitioners, neurologists, orthopedic surgeons, and physiotherapists.

Patients were included if they had a diagnosis of nonspecific low back pain (defined as pain below the 12th rib and above the gluteal folds, with no other diagnosis for at least 6 months) per the following inclusion and exclusion criteria: 1) age between 20 and 60 years; 2) clinical symptoms of vertebral pain that is unresponsive to symptomatic treatment with anti-inflammatory drugs for 3 months[6]; 3) moderate to severe pain, with a visual analog scale (VAS) score >4[28]; 4) diagnosis of chronic nonspecific low back pain (as defined previously); 5) absence of severe psychiatric disease that requires psychiatric care[28]; 6) absence of neurological disorders (lumbosciatic pain); 7) absence of concurrent fibromyalgia, per the 1990 diagnostic criteria of the American Academy of Rheumatology[31]; 8) absence of concurrent rheumatic disease; 9) no history of allergy to lidocaine (used for blocks); 10) no history of surgery on the lumbar spine; 11) subjects seeking disability insurance from government due to pain were not included; and 12) informed consent to participate in the study and availability to visit the clinic for treatment and evaluations.

This study was approved by the Research Ethics Committee of the Clinics Hospital of University of São Paulo Medical School (CAPPesq 840/07). Patients were included after reading and signing an informed consent form. The trial was registered at the Brazilian National Registry (www.ensaiosclinicos.gov.br) and also at the World Health Organization International Clinical Trials Registry Platform (http://apps.who.int/trialsearch/Trial2.aspx?TrialID=NCT02387567).

Interventions and Randomization

Participants were randomized to receive 1) paraspinous lidocaine injection (LID-INJ) and standard treatment, or 2) sham lidocaine injection (SH-INJ) and standard treatment, or 3) standard treatment only (STD-TTR). Randomization was performed using a computerized random number generator. We performed a simple randomization, on the basis of the large number of subjects. The randomization list was prepared by an investigator who was independent of patient care and also recruitment of subjects. This list was sealed in opaque envelopes and was revealed only after receipt of the consent form and a baseline assessment.

In the lidocaine injection group (LID-INJ), paraspinous lidocaine was injected weekly at the affected spinal segmental level with 3 mL 1% diffuse lidocaine infusion, performed by experienced physicians (M.I., S.T.I., L.G.O.T., L.C.O.T., I.D.R.), for 3 consecutive weeks. We used the standard technique of identifying the most painful spot by palpation of a 'taut band.' The taut band was identified using the thumb and the index finger. Needling depth was approximately 3 to 3.5 cm.

We used 3.7-cm 27-gauge disposable needles for the injection and for infiltration and needling of the involved muscles. In addition, standard treatment was prescribed as described in the next paragraph.

In the sham injection group (SH-INJ), weekly stimulation of the nonsensitized thoracic territory was performed with the tip of a needle, without its introduction or the infusion of any local anesthetic. Standard treatment was prescribed.