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LETTER TO THE EDITOR

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OXFORD

Long-Term Efficacy of Ultrasound-Guided Injection of IncobotulinumtoxinA in Piriformis Syndrome

Dear Editor,

We present findings from a longitudinal, prospective study that examined the long-term efficacy of ultrasound-guided injection of incobotulinumtoxinA in six patients with piriformis syndrome. Characterized by buttock pain corresponding to the anatomical location of the piriformis muscle that varies according to patient position or activity, piriformis syndrome is a rare and poorly defined disorder—often still included in the broad definition of lower back pain [1]. While etiology is not well established, the most accepted pathophysiologic factor in piriformis syndrome is compression of the sciatic nerve, which passes below and through the piriformis muscle. In the absence of a specific test, piriformis syndrome is primarily diagnosed on the basis of clinical symptoms, physical examination, and a positive response to local injection of anesthetic into the muscle [2].

Conservative treatment of piriformis syndrome involves the use of analgesics, anti-inflammatory drugs and muscle relaxants, physical therapy, and intramuscular injection of corticosteroid and/or local anesthetics, guided by various imaging techniques. However, the operational complexity of guidance techniques such as fluroscopy and electromyography can limit their clinical usefulness [3]. Ultrasound-guided injection offers process simplification in tandem with efficient, localized delivery of the injected drug [4], although clinical evidence to support its efficacy, safety, and precision for performing piriformis injections is currently lacking.

Recently, injection of botulinum toxin into the piriformis muscle has shown promise in the management of piriformis syndrome [5–9]. We look to build upon this evidence base by establishing the long-term efficacy of incobotulinumtoxinA treatment, extending the duration of follow-up from the 12 to 16 weeks used in clinical trials to date [6,8,10] to six months. Our study, conducted at the Physical Medicine and Rehabilitation Department of the Hospital Virgen Macarena, Seville, Spain, assessed the efficacy, safety, and precision of a single ultrasound-guided injection of 100 U incobotulinumtoxinA (Xeomin; Merz Pharmaceuticals GmbH, Frankfurt am Main, Germany; in 2 mL saline) into the piriformis muscle of adults with chronic buttock or sciatic pain clinically compatible with piriformis syndrome. The study received relevant ethical approval.

IncobotulinumtoxinA dose selection was based on previous studies of botulinum toxin for piriformis syndrome, which have used doses of 40 U incobotulinumtoxinA (case study), 50 to 100 U onabotulinumtoxinA, 150 to 200 U abobotulinumtoxinA, and 5,000 to 12,500 U rimabotulinumtoxinB [11]. Patients were recruited on the basis of treatment-refractory buttock pain in the anatomical area of the piriformis muscle on selective finger palpation and at echopalpation, a pain score of 5 or higher out of 10 on a visual analog scale (VAS), and over three months of pain progression. Patients undergoing treatment with anticoagulants, with neurologic focality at the lower homolateral limb diagnosed as impairment of osteotendon reflexes or loss of strength, and the presence of other pathologies causing muscle weakness were excluded. In total, 24 patients (mean age = 57.0 years, SD = 12.6 years, 83.3% female) were recruited. Of these, only six (25.0%) attended with a correct diagnosis of piriformis syndrome, with sciatica (41.7% of patients) and chronic lower back pain (33.3%) accounting for misdiagnoses.

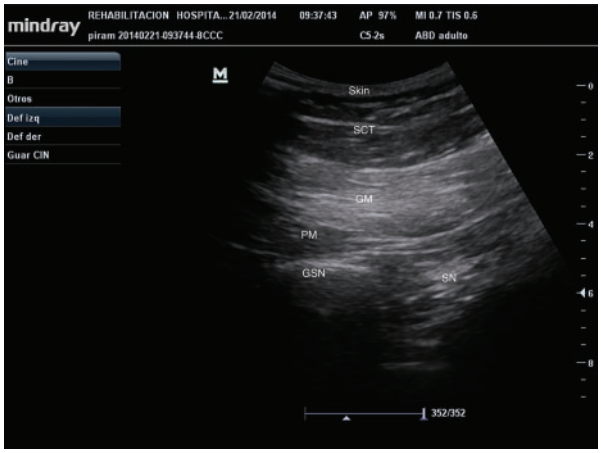

Figure 1 Ultrasound image of the piriformis muscle. A Mindray M–7 ultrasound with a convex transducer at 5 to 7.5 MHz frequency was used. The piriformis muscle appears as a hypoechoic band on a hyperechoic image corresponding to the iliac fossa. GM = gluteus maximus; GSN = great sciatic notch; PM = piriformis muscle; SCT = subcutaneous tissue; SN = sciatic nerve.

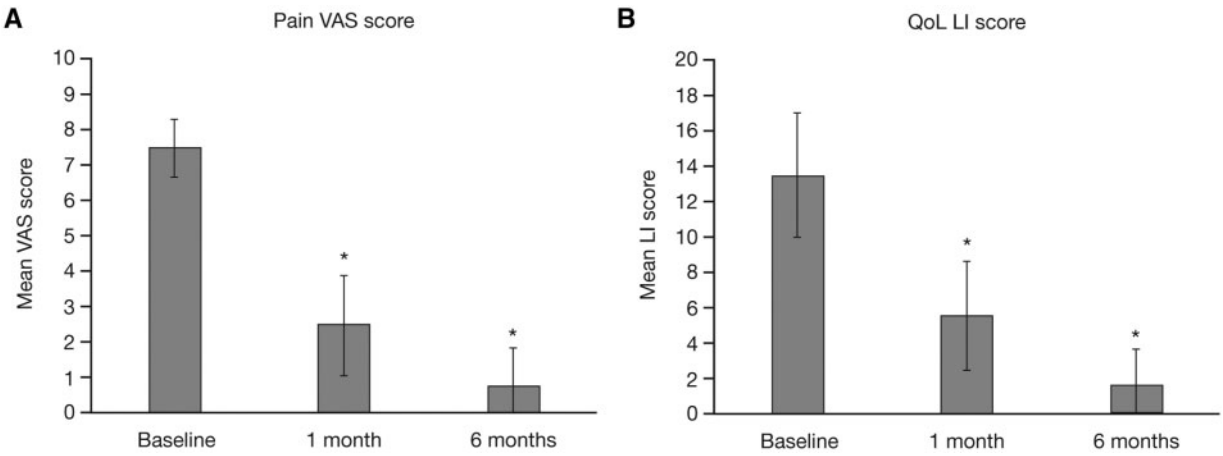

Figure 2 Pain and QoL improvements after botulinum toxin treatment. **A)** Mean (SD) VAS score, range from 0 (no pain) to 10 (severe pain). **B)** Mean (SD) LI score of QoL in chronic pain, range from 0 (no impairment) to 20 (severe effect on QoL by pain). *Significant reductions ($P < 0.05$ Bonferroni test for comparison of means) in VAS and LI scores were found between baseline and one month post-treatment and baseline and six months post-treatment. LI = Lattinen Index; QoL = quality of life; VAS = visual analog scale.

Localization of the injection site was determined as described previously [12]. The piriformis muscle appeared as a hypoechoic band-shaped mass on a hyperechoic image that corresponded to the sciatic recess (Figure 1). Poor needle imaging due to depth and inclination, an acknowledged difficulty with ultrasound-guided injection techniques, and limited visualization of the sciatic nerve (six cases, 25.0%) were the main technical difficulties encountered. Complications associated with the injection procedure were acute, self-limiting sciatica (one patient) and postinjection pain (four patients).

Patients perceived an improvement in chronic pain intensity and quality of life (QoL) for up to six months after treatment with 100 U incobotulinumtoxinA, as evidenced by statistically significant reductions in VAS pain scores and significant improvements in pain-related QoL based on the Lattinen Index (LI; validated in Spanish [13]) at one and six months following treatment ($P < 0.05$, Bonferroni test for comparison of means) (Figure 2). At six months, all patients achieved predefined responder thresholds (≥50% score reduction from baseline) for both VAS and LI scores, with a significant correlation between the two (Spearmann correlation coefficients of 0.80 and 0.90 for

months 1 and 6, respectively). The LI items that showed the greatest reduction in scores were degree of disability and sleep duration, suggesting that these were directly related to patient-perceived improvement in QoL. Six months after incobotulinumtoxinA injection, half of the patients were asymptomatic and the remainder reported feeling better; no patients reported unchanged or worsening symptoms. IncobotulinumtoxinA injections were well tolerated, and no adverse reactions were reported.

The use of ultrasound guidance for incobotulinumtoxinA injection into the piriformis muscle reduced the technical complexity of the injection procedure in comparison with other conventionally used guidance techniques without increasing the incidence of complications or reducing the overall effectiveness of the procedure. That the procedure required only a single consultation without any need for irradiation has positive implications with respect to resource utilization in clinical practice. However, such promise must be countered by the fact that accurate localization of the piriformis muscle requires expertise in order to avoid injury to the sciatic nerve. Given the higher cost of botulinum toxin compared with that of local anesthetics [14] and the risk of muscle atrophy and fat generation that has been reported following botulinum toxin injection in piriformis syndrome [15], we acknowledge that this treatment approach may be most relevant for those patients with a level of disease that has proven refractory to previous treatment approaches.

In conclusion, these results support the use of ultrasound-guided injection of 100 U incobotulinumtoxinA for the long-term management of treatment-refractory piriformis syndrome, suggesting that, with adequate clinical examination, the diagnostic need for an initial conservative injection of anesthetics may be eliminated. However, given the limited sample size, we acknowledge that further investigation is warranted before firm conclusions can be drawn, particularly regarding the lowest effective dose of incobotulinumtoxinA and the cost-effectiveness of such an approach.

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LETTER TO THE EDITOR

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One Step Further in "Sono-Palpation" During Ultrasound Imaging: "Self-Palpation"

Dear Editor,

A 58-year-old man was seen for pain in his right hand for the last few months. He denied any trauma, and the medical history was unremarkable for rheumatic, orthopedic, and metabolic disorders. Physical examination was normal, except for a painful region on the ulnar side of his right 5th metacarpal bone. Ultrasound (US) imaging was performed as the extension of physical examination. While "sono-palpation" was being used to better/precisely localize the pathology; interestingly, the patient asked whether we allowed him to take the probe and place it on the most painful area. Eventually, a small hypoechoic avascular lesion—consistent with a ganglion—was visualized next to the digital artery exactly at the place where the patient indicated (Figure 1). It was decided that the patient would be followed conservatively (with simple analgesics when necessary), and he was called for a control visit after three months. Indisputably, US imaging has already taken its place in the clinical practice of musculoskeletal physicians [1]. One of its several advantages would be the possibility of interactive scanning with the patient, that is, "sono-palpation" or "sono-auscultation." Especially while trying to localize the exact place of pathology, one can easily move the probe over/nearby the painful region and ask the patient to show the most painful area. Likewise, it is quite straightforward that the diagnosis cannot/can never be more precise if US uncovers a pertinent lesion over the place where the patient indicates.

In our patient, we have encountered a more interesting scenario, whereby he suggested placing the probe himself on the painful area [2]. Since we were able to easily visualize the small ganglion thereafter, we deemed this issue noteworthy and named it as "self-palpation." For sure, we do not intend to say that patients can do "self-sonography," but instead that, on certain occasions, physicians might ask their patients to indicate the place while holding the probe.

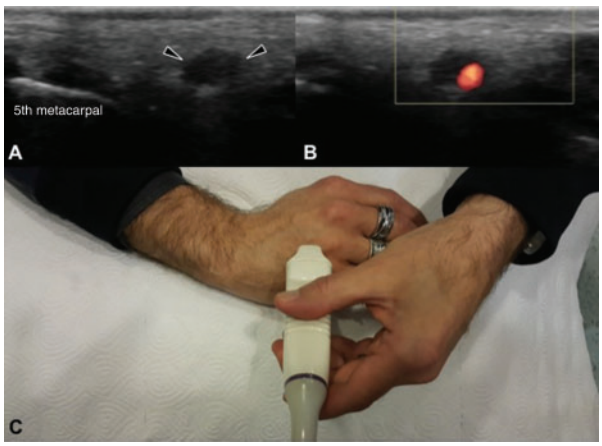

Figure 1 Longitudinal B-mode **(A)** and power Doppler **(B)** images show the small anechoic/cystic lesion (arrowheads) immediately next to the palmar digital artery (flow signal in the power Doppler image) and close to the 5th metacarpal bone. Photograph demonstrates the patient's "self-palpation" using the ultrasound probe **(C)**.

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