Long-term efficacy of ultrasound-guided injection of incobotulinumtoxinA (XEOMIN®) in piriformis syndrome

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INTRODUCTION AND OBJECTIVES

Piriformis syndrome (PS) is caused by prolonged or excessive contraction of the piriformis muscle associated with pain in the buttocks, hips, and lower limbs because of the close proximity to the sciatic nerve. Conservative strategies include hip extensor, abductor, and adductor muscle stretching exercises, massage, physical therapies and drug treatments. In recent years, several published studies showed the employment of botulinum toxin type A (BoNT-A) injection as a new therapeutic option to reduce buttocks and low back pain induced by PS by inhibiting substance P release and other inflammatory factors. BoNT-A injection technique is important considering the difficult access of the needle for deep location, the small size of the muscle, and the proximity to neurovascular structures. Ultrasound guidance is easy to use and painless and several studies have described its use during BoNT-A administration in PS. This longitudinal, prospective study assessed the efficacy and safety of ultrasound (US)-guided incobotulinumtoxinA (IncoBoNT-A, Xeomin®) injections into the piriformis muscle for 6 months after treatment.

METHODS

Patients (18–65 years) with chronic buttock or sciatic pain clinically compatible with PS refractory to other conventional treatments received a single US-guided injection of IncoBoNT-A 100U into the piriformis muscle (see Figure1). Outcomes assessed at baseline, 1 and 6 months post treatment included pain (visual analogue scale [VAS], range 0 [no pain] to 10 [severe pain]) and quality of life (QoL) in chronic pain (Lattinen Index [LI], range 0 [no impairment] to 20 [severe impairment]). Response to treatment was defined as a decrease compared to baseline scores of ≥40% in VAS and LI scores at 1 month post-treatment and of ≥50% at 6 months post-treatment. Patients' subjective treatment response and adverse events (AEs) were also recorded.

RESULTS

A total of 24 patients were assessed (Table 1). Of them, only 6 (25.0%) had a correct initial diagnosis of PS, 10 (41.7%) presented with an initial diagnosis of sciatica and 8 (33.3%) of lower back pain. For all 24 patients VAS score improved significantly ($p<0.05$) after IncoBoNT-A injection, from 7.5 (0.8) at baseline to 2.5 (1.4) at 1 month and 0.75 (1.1) at 6 months. The corresponding mean relative reduction in VAS scores from baseline to 1 month and 6 months were 66.7% and 90% respectively. Mean (SD) LI QoL scores also improved significantly ($p<0.05$) from 13.5 (3.5) at baseline to 5.6 (3.1) at 1 month and 1.7 (1.8) at 6 months post treatment. The corresponding mean relative reduction in LI scores from baseline to 1 and 6 months were 58.5% and 87.4%,respectively. Six months post-treatment all patients improved ≥50% in VAS and LI scores (Fig.2). Assessment of the subjective treatment response showed that 1 month after treatment 50% of patients reported being asymptomatic and 50% reported feeling better; no patients reported feeling unchanged or worse. These results were maintained at 6 months. AEs, reported in 5 patients (20.8%), included acute self-limiting sciatica (n=1; 4.2%) and post-injection pain (n=4; 16.7%). No technique-derived complications were reported. All patients described the discomfort during the injection procedure as tolerable.

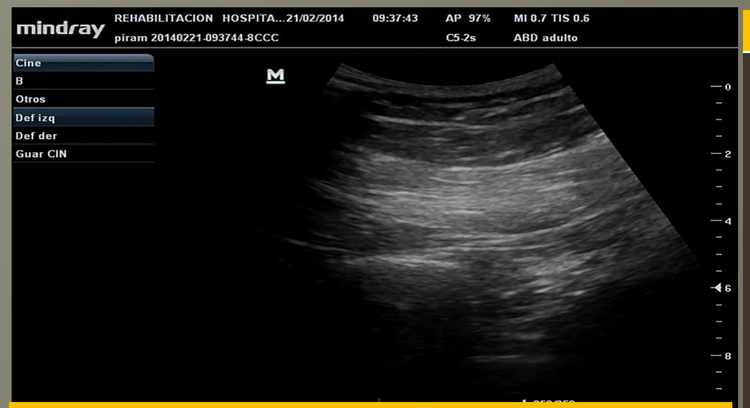

Figure 1. Ultrasound image of the piriformis muscle

Table 1. Patient characteristics (Standard deviation)	Patients (n=24)
Gender, n (%)	
Male / Female	4 (16.7) / 20 (83.3)
Age, years; mean (SD) [range]	57.0 (12.6) [36–72]
Treated side, n (%)	
Left / Right	8 (33.3) /16 (66.7)
Symptom progression time, months; mean (SD) [range]	14.3 (8.9) [5–36]
Initial diagnosis, n (%)	
Piriformis syndrome	6 (25%)
Sciatica	10 (41.7%)
Chronic lower back pain	8 (33.3%)
Pain radiating to lower limb, n (%)	16 (66.7)
Positive pain provocation test, n (%)	
Beatty	24 (100)
FAIR	24 (100)
Pace	20 (83.3)
Freiberg	4 (16.7)

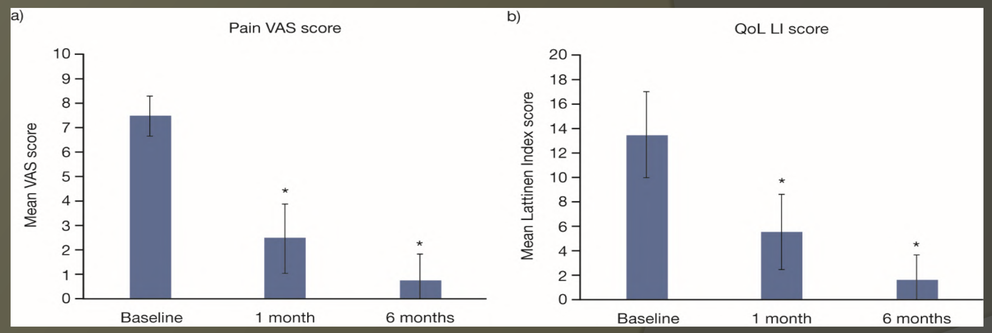

Figure 2. Pain and QoL improvements after botulinum toxin treatment. Bars show mean (a) VAS score, range 0 (no pain) to 10 (severe pain); (b) Lattinen Index score of QoL in chronic pain, range from 0 (no impairment) to 20 (severe effect on QoL by pain). Error bars denote standard deviations. *Significant reductions ($P < 0.05$ Bonferroni test for comparison of means) in VAS and Lattinen Index scores were found between baseline and 1 month post-treatment and baseline and 6 months post-treatment. VAS = visual analog scale; QoL = quality of life.

DISCUSSION

The results of this study support the use of botulinum toxin injections into the piriformis muscle for the treatment of PS. All patients treated experienced symptomatic pain relief, with a statistically significant reduction in VAS pain scores and significant improvements in QoL based on the LI, an instrument developed specifically to assess QoL in patients with chronic pain. Six months after a single IncoBoNT-A treatment half of the patients reported feeling asymptomatic and the remainder reported feeling better. This study demonstrated that the use of ultrasound guidance for botulinum toxin injection into the piriformis muscle reduced the technical complexity of the injection procedure in comparison to other conventionally used guidance techniques without increasing the incidence of complications or reducing the effectiveness of the procedure. Furthermore, the ultrasound-guided technique has other advantages such as facilitating the use of a single consultation with lower cost in resources, eliminating the need for irradiation and reducing the total time for completion of the treatment. However, a limitation of the technique is that accurate localization of the piriformis muscle is difficult and requires expertise in order to avoid injury to the sciatic nerve. IncoBoNT-A injections for PS were well tolerated and no adverse reactions were recorded.

CONCLUSIONS

Results suggest that US-guided injections of IncoBoNT-A 100U were an effective, well-tolerated treatment option for the management of PS, and improved pain intensity and patients' QoL. Further studies are required to assess the lowest effective dose of IncoBoNT-A, as well as the cost-effectiveness of ultrasound-guided botulinum toxin injection in PS.

REFERENCES

1. Santamato A, Micello MF, Valeno G, Beatrice R, Cinone N, Baricich A, Picelli A, Panza F, Logroscino G, Fiore P, Ranieri M. Ultrasound-Guided Injection of Botulinum Toxin Type A for Piriformis Muscle Syndrome: A Case Report and Review of the Literature.. Toxins (Basel). 7 (8):3045-56 (2015)