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Research Article

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Therapeutic Response Rate for Those with Piriformis Muscle Syndrome Treated by Fluoroscopy Guided Botulinum Toxin Injection

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Background

Piriformis syndrome presents as pain in the low back, buttock, groin, and/or posterior thigh due to excessive contraction of the piriformis muscle irritating the sciatic nerve [1-13]. It predominantly is reported to occur in the middle-aged and in women [7,14]. Diagnosis of piriformis syndrome is established using palpation, special tests, and/or local anesthetic and steroid injection [5, 15-17]. Once diagnosed, conservative treatment involving physical therapy, lifestyle modifications, non-steroidal anti-inflammatory agents, other medications, and psychotherapy are usually effective [18]. If those are not successful in alleviating piriformis syndrome, interventional strategies may be indicated. One such intervention is botulinum toxin type A (Botox) injections [2,19-21].

Botox injection accuracy influences both treatment effectiveness and the risk of sciatic nerve sensorimotor nerve block. Consequently, a number of injection guidance modalities have been proposed. These guidance modalities seek to mitigate the possibility of complications due to the location and size of the piriformis muscle and the proximity of neurovascular structures [22]. Those that have been described include CT, MRI, ultrasound, fluoroscopy, electrical stimulators, or electromyogram guidance [2,19,23-25]. This clinic employs a sacral technique with palpation and fluoroscopy guidance of their Botox injections. Our aim is to ascertain the effectiveness of this technique by retrospectively determining the rate at which patients who receive these injections experience a 50% or greater improvement in their piriformis syndrome pain.

Materials and Methods

This study is a retrospective chart review. In total, the charts of 12 patients who received an aggregate of 46 Botox injections were reviewed for inclusion in this study. We excluded four injections due to lack of visual analog scale (VAS) or percent improvement information. Analysis was performed on data from the 12 patients and 42 injections.

Patients were included if they had presented to our pain center within the past three years with evidence of piriformis tenderness upon physical exam. Additional inclusion criteria included two or more of the following: pain with the FAIR test, low back or buttock pain, pain with palpation of the piriformis muscle, or pain radiating down the leg without radiographic evidence of radiculopathy. Eligible subjects then had to have received at least one Botox injection to the piriformis muscle as part of their treatment regimen. Those that progressed to this level of treatment had to have had a prior diagnostic response to treatment with steroid piriformis injections (20 mg of Triamcinolone, 2 ml 1% lidocaine, 2 ml of 0.25% bupivacaine) via a sacral approach. A diagnostic response was defined as having at least a fifty percent reduction in pain and improvement in function anywhere between three hours and several weeks following treatment.

Therapeutic response to Botox was also assessed. Per manufacturer guidelines, a patient was defined as failing treatment only if they had had three injections without a diagnostic response [26]. Patients who obtained a diagnostic response following either their first, second, or third round of Botox injection were considered to be therapeutic responders.

Description of Injection Technique

All procedures were performed per sterility standards. The patients were placed, draped, and prepped in the prone position on a fluoroscopy table. The medial inferior aspect of the sacroiliac joint was visualized using the fluoroscope. It served as a landmark. The lateral angle of the sacrum was palpated for use as a landmark as well. The needle was inserted down to this point and then retracted 2-3 cm. Once in position, the needle was angled 45 degrees laterally and 45 degrees caudad; going down 2-5 mm farther than the previous depth depending on patient size. Location of the piriformis was then confirmed via fluoroscopy using ISOVUE-200. Once the piriformis muscle was visualized, 100 units of Botox was injected in 10-15 unit increments into the Piriformis muscle followed by a mixture of 2mL of 0.25% bupivacaine and 2 mL of 1% Lidocaine.

Data Analysis

Pre- and post-procedure VAS scores and percent improvement were evaluated. Statistical analysis was performed using the

Wilcoxon rank-sum test for ordinal dependent variables (change in VAS scores) and the Chi-squared test for nominal dependent variables (number of patients who achieved a diagnostic response). P values < 0.05 were considered significant. Values are presented as averages ± standard deviation.

Results

The medical records of five men and seven women were analyzed for this study. Mean age was 62.3 ±14.6. Mean BMI was 25.7 ± 5.42 **(Table 1)**.

Table 1: Study Demographics

Men	Women	Age	BMI	Steroid Injections	Botox Injections
5	7	62.3 ± 14.6	25.7 ± 5.42	2.17 ± 0.84	3.83 ± 3.43

The patients received an average of 2.17 ± 0.84 steroid piriformis injections for a total of 26 piriformis injections prior to transitioning to Botox (**Table 1**). Of those 26 injections, 84.6% (22) resulted in a diagnostic response or a 50% or better improvement (**Figure 2**). Patients on average experienced a significant (P<0.05) 65.6% ± 70.8 improvement in their piriformis pain relative to baseline immediately following their injection (**Figure 1**). Twenty-three of these injections had adequate follow-up information for analysis. Follow-ups were scheduled for three weeks following the injection. Of those that reported visual analog scale data, 21.7% of the injections resulted in a lingering diagnostic response at that juncture(**Figure 2**). On average, patients reported to have improved by 9.89% ± 36.9 relative to baseline at their follow-up visit (**Figure 1**). This finding was not significantly different from baseline (P: 0.074).

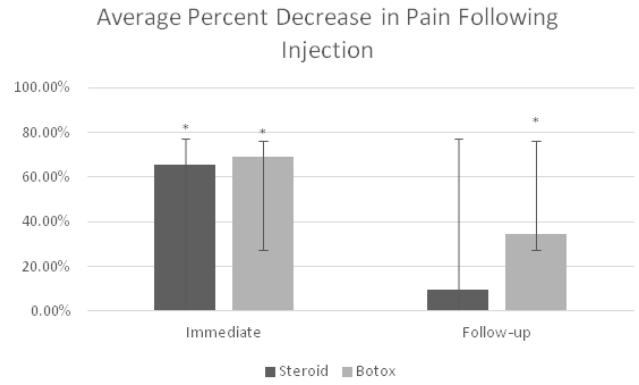

Figure 1: A total of 26 steroid piriformis injections and 42 Botox injections had VAS data at the time of injection. A total of 23 steroid piriformis injections and 28 Botox injections had VAS data at the time of follow-up. The average reduction in pain at the time of injection was 65.6% ± 70.8 and 69.3% ± 36.6 for the steroid and Botox injections respectively. At follow-up, pain level was 9.89% ± 36.9 and 34.6% ± 36.9 less than baseline for steroid and Botox respectively. Average reduction in pain was found significant using Wilcoxon rank-sum test for both steroid and Botox at the time of injection and for Botox at the time of follow-up (P<0.05) Significant findings are indicated by *. Error bars are presented as standard deviation.

The twelve patients analyzed then went on to receive a total of 46 Botox injections in treatment of their piriformis syndrome. On average, patients had received 3.83 ± 3.43 Botox injections at the time of analysis (**Table 1**). Forty-two of those injections had sufficient information for analysis. Overall, 73.8% (31) of those injections resulted in a diagnostic response or a 50% or greater improvement(**Figure 2**). Patients reported an average improvement of 69.3% ± 36.6 immediately following their Botox injections (**Figure 1**). The percent improvement in VAS scores was significant (P: 0.00). Information for twenty-eight injections were available at follow-up. Follow-ups were scheduled for four weeks following injection. Of those that reported visual analog scale data, 32.1% of the injections resulted in a lingering diagnostic response at that juncture (**Figure 2**). On average, patients reported to have significantly improved (P<0.05) by 34.6% ± 36.9 relative to baseline at their follow-up visit (**Figure 1**).

Using a Chi-squared test, it was determined that there was no statistically significant difference between the number of Botox injections that resulted in a diagnostic response and the number of steroid piriformis injections that resulted in a diagnostic response. This finding applied to both the immediate VAS data (P: 0.300) and the follow-up data (P: 0.412). No adverse effects from the Botox injections were reported.

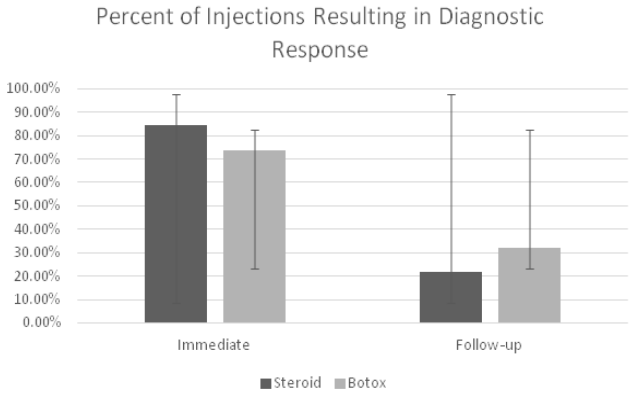

Figure 2: A total of 26 steroid piriformis injections and 42 Botox injections had VAS data at the time of injection. A total of 23 steroid piriformis injections and 28 Botox injections had VAS data at the time of follow-up. 84.6% of steroid injections and 73.8% of Botox injections resulted in a diagnostic response at the time of injection. 21.7% of steroid injections and 32.1% of Botox injections resulted in patients still reporting a 50% or greater reduction in pain relative to baseline at the time of their follow-up. There was no significant difference between steroid and Botox injections as determined using a Chi-squared test (p>0.05). Error bars are presented as standard deviation.

Ten of the patients studied experienced a therapeutic response to their Botox regimen. Eight of those experienced that response after the first injection. One met the criteria only after receiving a second injection. An additional one experienced that response

only after receiving a third injection. One patient never met the criteria for a therapeutic response after four injections and was considered to have failed the protocol. One patient was excluded from consideration here because they did not meet the criteria nor had they received three or more injections. Overall, 90.9% of the patients who received Botox injections experienced a therapeutic response (**Figure 3**).

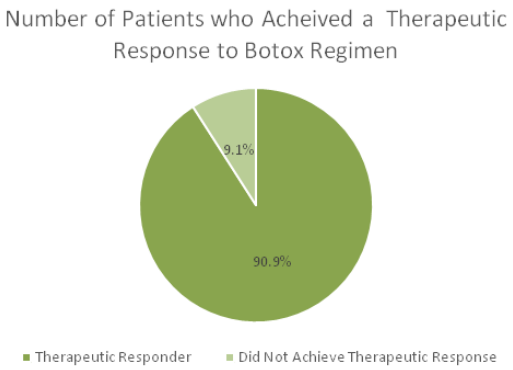

Figure 3: A total of ten patients (90.9%) had a therapeutic response to their series of Botox injections. Eight of those patients (72.7%) met this criterion after their first injection. One additional patient (9.09%) met this criterion after two injections. One additional patient (9.09%) met this criterion after three injections. One patient (9.09%) never achieved a therapeutic response after four injections. One patient was not considered because they did not have a diagnostic response nor did they have three or more injections.

Concomitant treatments were reported to have occurred in conjunction with the injections. Patients reported physical therapy (2 instances), acupuncture (1 instance), Lidoderm patches (2 instances), aquatherapy (1 instance), ibuprofen (1 instance), TENS unit (2 instances), a multidisciplinary pain therapy regimen (1 instance), and osteopathic manipulation therapy (1 instance) whilst receiving injection treatments. Nine of the Botox injections occurred in conjunction with trigger point injections.

Discussion

The present study sought to explore sacral approach fluoroscopy guided Botox injections as treatment for piriformis syndrome. Our data suggests that treating piriformis syndrome in this manner may be efficacious for our patients. Piriformis syndrome presents as pain in the low back, buttock, groin, and/or posterior thigh due to excessive contraction of the piriformis muscle irritating the sciatic nerve [2-13, 27]. Treatment modalities aim to relax this contraction. Conservative treatments that accomplish this include physical therapy, lifestyle modifications, non-steroidal anti-inflammatory agents, other medications, and psychotherapy [18]. Interventional strategies, including the corticosteroid with local anesthetic injections employed in this study, aim to lessen the irritation by decreasing inflammation in the area and temporarily stopping piriformis spasms. Botox has been shown to similarly influence muscle contraction.

The mechanism of action of Botox is to inhibit release of acetylcholine from peripheral cholinergic, motor, and autonomic nerve endings contributing to marked reduction in muscle spasms. The toxin may also have antinociceptive mechanisms [10, 21,28-30]. These features of Botox have been taken advantage of to alleviate pain associated with various conditions both dependent and independent of excessive muscle contractions [27,31]. Other studies include Piriformis syndrome as a condition that can be successfully treated with Botox [2,19-21]. Our study aims to add to this evidence of its efficacy.

Prior studies into Botox utilized various guidance techniques for their injections. CT, MRI, ultrasound, fluoroscopy, electrical stimulators, and electromyogram guidance have all been shown to result in safe and effective administration of Botox [2, 19, 23-25]. To our knowledge, however, no prior study illustrates the effectiveness of administering Botox by a sacral approach using fluoroscopy guidance. This methodology has been shown efficacious by a previous study for guiding steroid piriformis injections [32]. We hypothesized that performing Botox injections in this manner would be effective as well.

Our twelve study subjects underwent an average of 2.17 ± 0.84 standard piriformis injections prior to receiving treatment using Botox. Previous studies indicated that patients should find relief using this modality as treatment for piriformis syndrome [5]. As anticipated, these injections resulted in significant decreases in pain for our patients. A diagnostic response was achieved 84.6% of the time. On average, patients experienced a significant ($P<0.05$) 65.6% ± 70.8 decrease in their piriformis pain relative to baseline immediately following their injection. At follow-up, 21.7% of injections resulted in a lingering diagnostic response. On average, patients experienced 9.89% ± 36.9 less pain at this juncture. These findings affirmed steroid piriformis injections as an effective treatment modality for piriformis syndrome.

Our twelve study subjects underwent an average of 3.83 ± 3.43 Botox injections following treatment with steroid piriformis injections. Overall, 73.8% of Botox injections resulted in a diagnostic response. Patients reported a significant (P: 0.00) average improvement of 69.3% ± 36.6 immediately following injection. At follow-up, 32.1% of the injections resulted in a lingering diagnostic response. On average, patients reported to have significantly improved ($P<0.05$) by 34.6% ± 36.9 relative to baseline at their follow-up visit. These findings were not significantly different than those obtained by the standard piriformis injections. What these results suggest is the potential for Botox injections to be at least as effective as the standard piriformis injections in alleviating pain from piriformis syndrome.

While 73.8% of individual Botox injections resulted in a diagnostic response for our patients, 90.9% of our patients were determined to be therapeutic responders to Botox. What this finding suggests is that a patient who fails to respond after one injection may become a responder after subsequent injections.

Further breakdown of this data found that 72.7% of patients were responders after the first injection. An additional 9.09% became responders after their second injection and an additional 9.09% became responders after their third injection. This pattern mirrored the findings of a study into Botox treatment for migraine headaches. Their findings resulted in a recommendation that patients who do not respond to treatment should receive three injections before being considered to have failed the protocol [26]. Our results suggest that this may hold true for treating piriformis syndrome with Botox as well. Those that receive Botox injections but do not experience a diagnostic response after the first injection may become therapeutic responders after subsequent injections. Further studies are necessary to affirm this treatment guideline for piriformis syndrome.

Our study is moderated by the limitations of a retrospective chart review with low sample size. A greater sample size and comparisons to other published techniques of piriformis syndrome treatment would garner more robust conclusions. Additionally, the results were confounded by concomitant treatments. None, however, occurred at a frequency or clarity outstanding enough for statistical analysis of their influence. Previous studies have shown that pairing Botox injections with other treatment modalities, like active or passive self-administered physical therapy, influence their efficacy [9,33]. Additional studies will be needed to ascertain the influence of these concomitant treatments on treating piriformis syndrome with Botox.

Lastly, our study focused on pain using visual analog scales as a reference. However, these were not always available in the medical record. Some patient information was reported as percent improvement without pre-or post-treatment visual analog scale reporting. This influenced both statistical analysis and our presentation of the data. Furthermore, visual analog scales are not the only means of assessing injection efficacy. Quality of life or functionality metrics may be an interesting exploration as well.

Overall, our findings suggest the potential for sacral technique Botox injections guided by palpation and fluoroscopy to be an effective treatment modality for patients with piriformis syndrome. It also provides some support to a recommendation that three injections may be necessary before a patient experiences a diagnostic response. Therefore, patients should only be considered to have failed the treatment protocol only if they do not respond after three injections. However, further information and testing will be necessary for confirmation of both Botox efficacy and of this treatment recommendation.

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