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Research Article

Improving the Quality of Life and Decreasing the Healthcare System Burden for Chronic Pelvic Pain Patients Via an Office based Neuromuscular Treatment

Allyson Shrikhande[1,2*], Neha James[1], Marjorie Mamsaang[1], Tayyaba Ahmed[1], Christian Reutter[1], Kimberlee Leishear[1], Rucha Kapadia[1], Janaki Natarajan[1], Yogita Tailor[1], Sandra Sandhu-Restaino[1], Monica Zirolli[1], Myesha Banks[1], Jessica Ray[1], Katherine Wolfrum[1], Lolarasi Rampally[1], Jasmine Ross[1], Laura Brott[1], Zita Anigbogu[1], Gautam Shrikhande[1]

[1]Pelvic Rehabilitation Medicine Clinical Research Foundation, West Palm Beach, FL, USA

[2]The Feinstein Institute for Medical Research, Northwell Health, Manhasset, NY, USA

[*]**Corresponding author:** Allyson Shrikhande, Pelvic Rehabilitation Medicine Clinical Research Foundation, West Palm Beach, FL, USA

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Abstract

Introduction: The complex and poorly understood nature of Chronic Pelvic Pain (CPP), which affects up to 1 in 4 adults and significantly impacts their quality of life, poses diagnostic and therapeutic challenges, and this study aims to assess the impact of a peripheral nerve block and trigger point injection protocol on Patient Reported Outcomes. **Methods:** In the one-year follow-up, patient-reported outcomes were collected from a total of 128 respondents, comprising 73 participants in the treatment group (those who completed the peripheral nerve block and trigger point injection protocol) and 55 participants in the control group (those who did not complete the peripheral nerve block and trigger point injection protocol). The analysis encompassed the examination of occurrences of surgeries, treatments, diagnostic procedures, pain management interventions, opioid utilization, and Emergency Room (ER) visits in both groups. **Results:** The treatment group demonstrated remarkable reductions in surgeries ($p<0.01$), medical treatments ($p<0.01$), diagnostic procedures ($p<0.01$), pain management interventions ($p<0.01$), opioid usage ($p<0.01$), and ER visits ($p<0.01$) in comparison to the control group. VAS pain levels decreased by 28%. Opioid use decreased from 26% to 14%. ER visits decreased from 23% to 11%. **Conclusion/Implications:** The findings of this study underscore the remarkable effectiveness of the peripheral nerve block and trigger point injection protocol in alleviating the burden on healthcare systems. The substantial reductions in surgeries, medical treatments, diagnostic procedures, pain management interventions, opioid consumption, and ER visits signify both clinical and economic advantages. Integrating this office-based protocol into healthcare practices presents a transformative opportunity to enhance patient care while optimizing resource allocation.

Introduction

Chronic Pelvic Pain (CPP) is a distressing and intricate medical condition that has confounded healthcare professionals and significantly impaired the quality of life for a substantial portion of the adult population. This elusive condition affects up to 1 in 4 adults, making it a prevalent and burdensome health concern [1]. It is characterized by the presence of persistent pelvic pain, typically lasting for more than six months, and can result from a complex interplay of gynaecological, gastrointestinal, urological, musculoskeletal, neurological, and psychosocial factors [2]. The multifaceted and poorly understood nature of CPP presents a formidable challenge, hindering both diagnosis and treatment.

The diagnostic and therapeutic complexities associated with CPP have given rise to a pressing need for innovative approaches to alleviating the suffering experienced by affected individuals. The condition's impact extends beyond the physical realm, taking a toll on the emotional and psychological well-being of those it afflicts. Despite its prevalence and the profound quality-of-life implications, there is a dearth of comprehensive research on effective treatment modalities for CPP. Therefore, this study is designed to address this knowledge gap by assessing the impact of a peripheral nerve block and trigger point injection protocol on Patient Reported Outcomes, aiming to offer new hope to those burdened by the persistent discomfort of CPP [3].

Furthermore, neuropathic factors, including peripheral sensitization, central sensitization, and cross-sensitization, contribute to a heightened sensitivity to pain in CPP patients [4,5]. Patients often experience hyperalgesia, where the pain that would normally be mild becomes more intense while experienced over a longer time, and allodynia, where non-painful touches cause discomfort. The intricate and not fully understood nature of CPP makes it challenging to diagnose and treat, leading to increased healthcare usage among CPP patients [1]. Treatment approaches often target various sources of pain, both through medications like anti-inflammatories, pain relievers, and other drugs affecting the nervous system, as well as non-drug therapies like physical therapy, acupuncture, lifestyle adjustments, dietary changes, cognitive-behavioral therapy, and yoga [6]. This study assesses the effectiveness of an office-based neuromuscular ultrasound-guided procedural treatment protocol targeting myofascial pain, peripheral sensitization, and central sensitization in female and male CPP patients.

Materials and Methods

Participants included in this study were 128 patients (92 women and 36 men) aged 18-76 years old diagnosed with CPP and presented to an outpatient pelvic rehabilitation practice between June 2022 and September 2023. Of the 128 patients, 73 participants were in the treatment group (those who completed the office-based ultrasound-guided peripheral nerve block and trigger point injection protocol) and 55 participants were in the control group (those who did not complete the peripheral nerve block and trigger point injection protocol). Patient demographics and clinical characteristics are depicted in Figures 1-3.

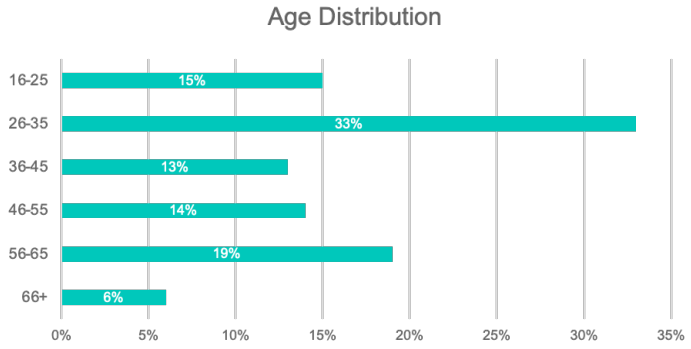

Figure 1: Age Distribution of Participants with CPP.

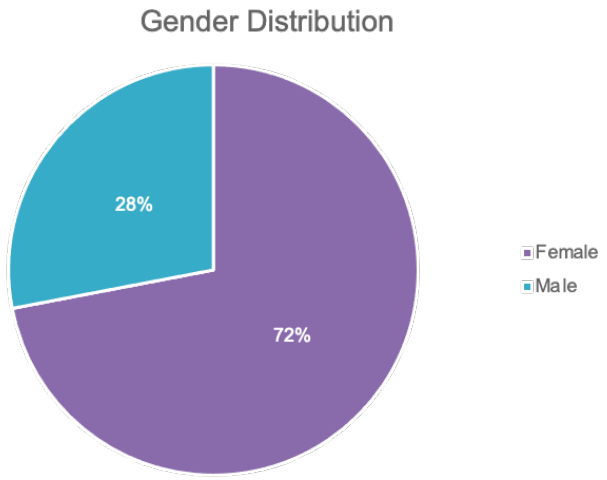

Figure 2: Gender Distribution of Participants with CPP.

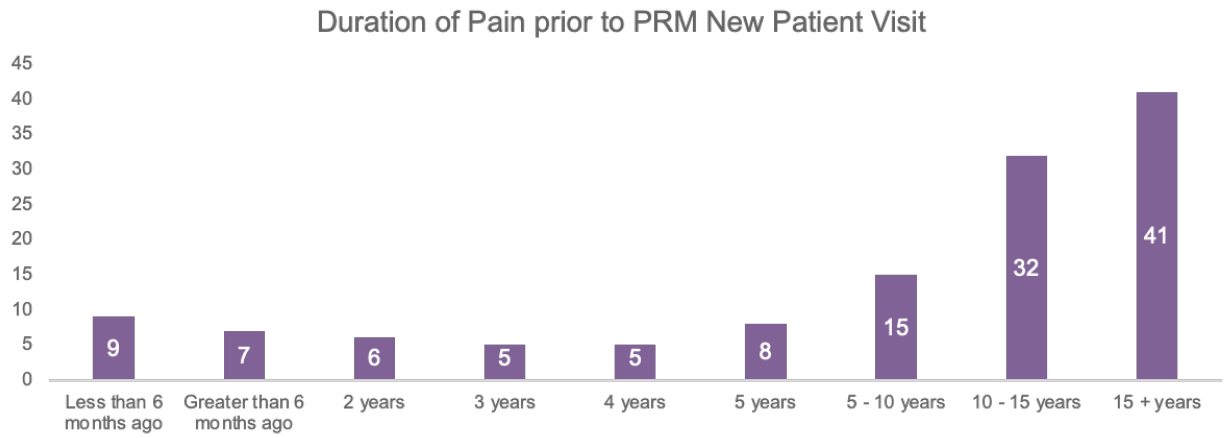

Figure 3: Duration of Pain before PRM New Patient Visit.

To perform the research, the data was accessed on 16 January 2024 from the health portal and authors had access to information that could assist identify individual participants during or after data collection for any necessary follow-up. The protocol for this research project has been approved by a suitably constituted Ethics Committee of the institution and it conforms to the provisions of the Declaration of Helsinki. Committee of The Feinstein Institutes for Medical Research, Approval No. IRB# 17-0761. This study does not have a clinical trial number and consent forms were waived due to study design. This IRB-approved (IRB# 17-0761) treatment was designed for patients whose symptoms persisted after participating in pelvic floor physical therapy, the first-line treatment typically recommended for CPP. All participants underwent the following 6-week treatment protocol. For the purposes of this paper, a retrospective chart review of the protocol was performed (Figure 4).

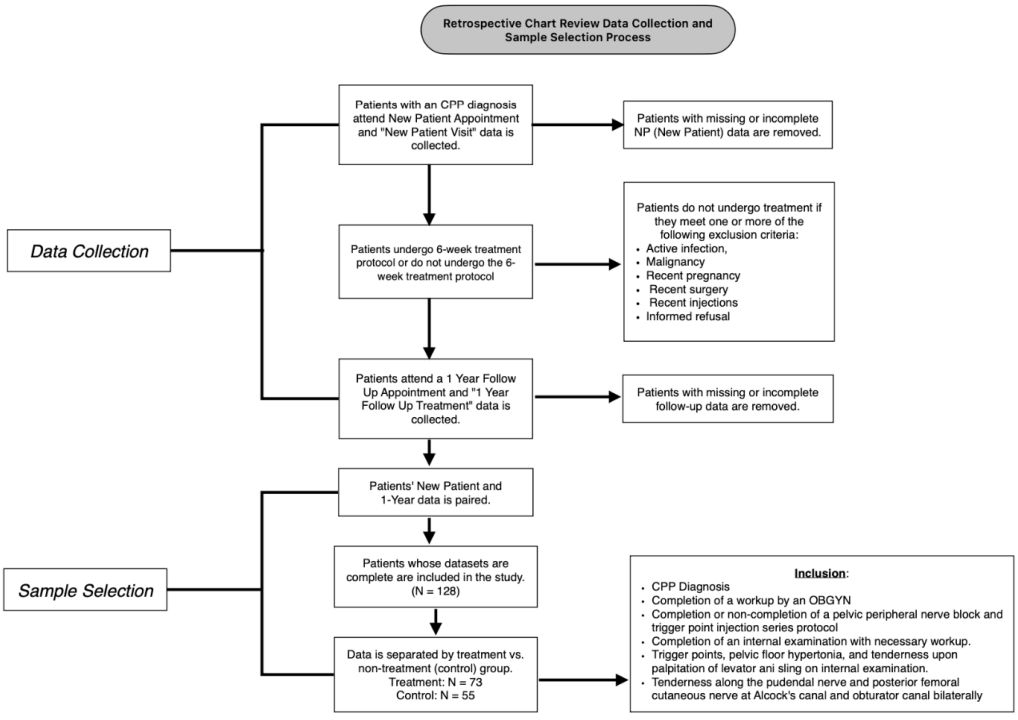

Figure 4: Retrospective Chart Review Data Collection and Sample Selection Process.

Patients were pre-medicated with diclofenac 75 mg PO and pre-treated with a 27-gauge needle with topical anaesthetic spray. Once weekly, participants received external ultrasound-guided trigger point injections, each delivering 1 cc of Lidocaine 1% to the pelvic musculature. A global injection was administered into the iliococcygeus, pubococcygeus, or puborectalis muscles one side at a time, targeting each muscle of the levator ani sling. This was accomplished using a flexible, 6-inch, 27-gauge needle inserted into the specific muscle from the subgluteal posterior approach. The procedure followed aseptic techniques under ultrasound guidance, with patients lying in a prone position. Notably, myofascial trigger points were identified on ultrasound as focal, hypoechoic zones with a diminished vibration amplitude on vibration sonoelastography, indicating the presence of a local rigid nodule [5].

Concurrently, while in the supine position, participants underwent ultrasound-guided peripheral nerve blocks of the pudendal nerve at Alcock's canal with a subgluteal approach (Figure 5). The patient was then switched to the prone position, where a nerve block of the posterior femoral cutaneous nerve was administered 4 cm inferior to the ischial tuberosity. This occurred during each appointment, alternating between the right and left sides throughout the treatment. The initial treatment involved the placement of 2 ml of dexamethasone with 7 ml of 1% Lidocaine around each nerve on both sides. In subsequent appointments, normal saline was used for the nerve blocks instead of dexamethasone. Following the procedure, participants were able to resume their normal activities and return to work on the same day after sitting on ice for 10 minutes.

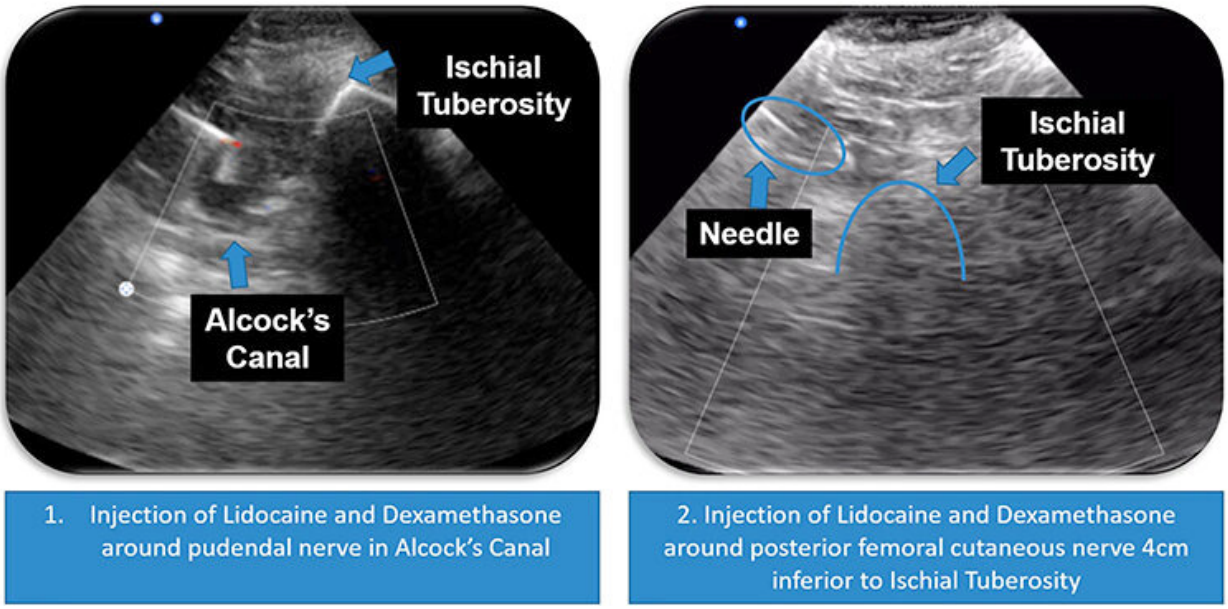

Figure 5: Ultrasound images of Alcock's Canal and Obturator Canal.

Participant response to treatment was measured 1 year after their final treatment procedure. Differences in overall surgeries, treatments, and diagnostic procedures for patients were recorded through phone calls. The primary outcome measure is a Visual Analog Scale (VAS) score to calculate pelvic pain concentration. Patients reported their mean pain intensity from 1-10 during the previous 24 hours for the VAS score. Also, patient-reported frequency of opioid use and Emergency Room (ER visits) are utilized for a more well-rounded account of a patient's well-being. A retrospective medical records review was conducted to analyse the above outcome measures. VAS scores are analyzed using a Wilcoxon signed-rank test, due to non-normal distribution, for paired samples. Differences in opioid use and ER Visits were tested using a McNemar test for paired proportions.

Results

Statistically significant results were achieved across several outcome variables. A VAS (Visual Analog Scale), Opioid use, and Emergency Room attendance were measured at participants' initial appointment (New Patient Visit) and their appointment held 1 year after completion of a pelvic peripheral nerve block and trigger point injection series protocol (1 Year Follow Up).

In the treatment group, 16% of patients reported a decrease in abdominal-pelvic hernia surgeries post peripheral nerve block and trigger point injection protocol and 11% of patients reported a decrease in abdominal-pelvic hernia surgery in the control group. In the treatment group, 11% of patients reported a decrease in endometriosis surgeries post peripheral nerve block and trigger point injection protocol while 9% of patients reported a decrease in endometriosis surgery in the control group. In the treatment group, 43% of patients reported a decrease in endoscopy procedures. In the control group, 28% of patients reported a decrease in endoscopy procedures.

For the treatment group, VAS pain levels decreased by 28% from New Patient Visit with an average of 7.682 (SD 1.182; α=0.05, CI=7.175-7.684) to 1-year Follow-up average of 5.564 (SD 2.174; α=0.05, CI=5.528-5.569) ($p<0.01$), as shown in Figure 6. For the control group, VAS pain levels decreased by 10% from New Patient visits with an average of 7.158 (SD 1.176; α=0.05, CI=7.143-7.162) to 1-year Follow-Up average of 6.473 (SD 2.138; α=0.05, CI=6.384-6.482), also shown in Figure 6.

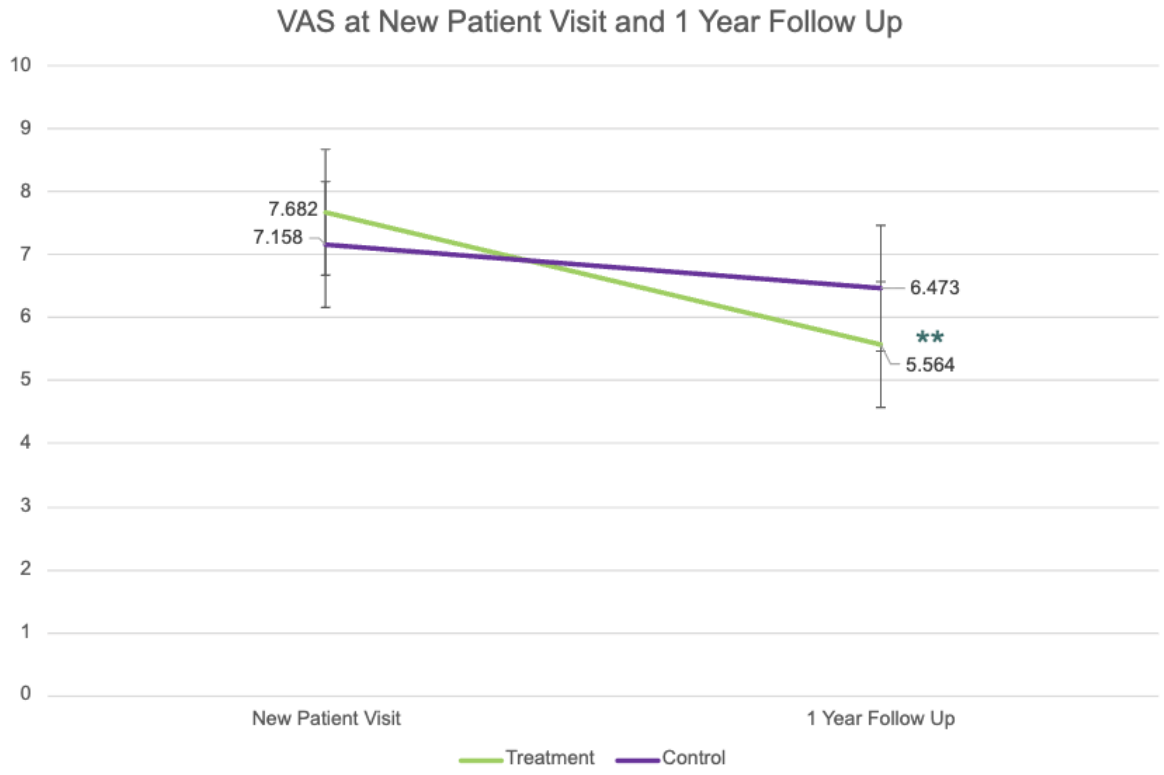

Figure 6: VAS Score at NPV and 1 Year Follow Up across Sample Groups.

For the treatment group, 26% of patients reported using opioids for their CPP-related pain at New Patient Visit appointment and 23% reported having gone to the Emergency Room for their CPP-related pain at New Patient Visit, shown in Figures 7 and 8. These proportions reduced to 14% and 10%, respectively, at their 1 Year Follow Up appointment, also as shown in Figures 7 and 8. This is a 12% decrease in opioid use and a 13% decrease in patients visiting the ER (both $p<0.01$) for the treatment group. For the control group, 15% of patients reported using opioids for their CPP-related pain at New Patient Visit appointments while 18% of patients reported using opioids for their CPP-related pain at their 1 Year Follow Up appointment. Similarly, 15% of patients reported having gone to the Emergency Room for their CPP-related pain at a New Patient Visit while 9% of patients reported having gone to the Emergency Room for their CPP-related pain at their 1 Year Follow Up appointment. This is a 3% increase in opioid use and a 6% decrease in patients visiting the ER for the control group. The treatment group also demonstrated remarkable reductions in surgeries ($p<0.01$) as seen in Figures 9 and 10, medical treatments ($p<0.01$) as seen in Figures 11 and 12, and diagnostic procedures ($p<0.01$) as seen in Figures 13 and 14, in comparison to the control group.

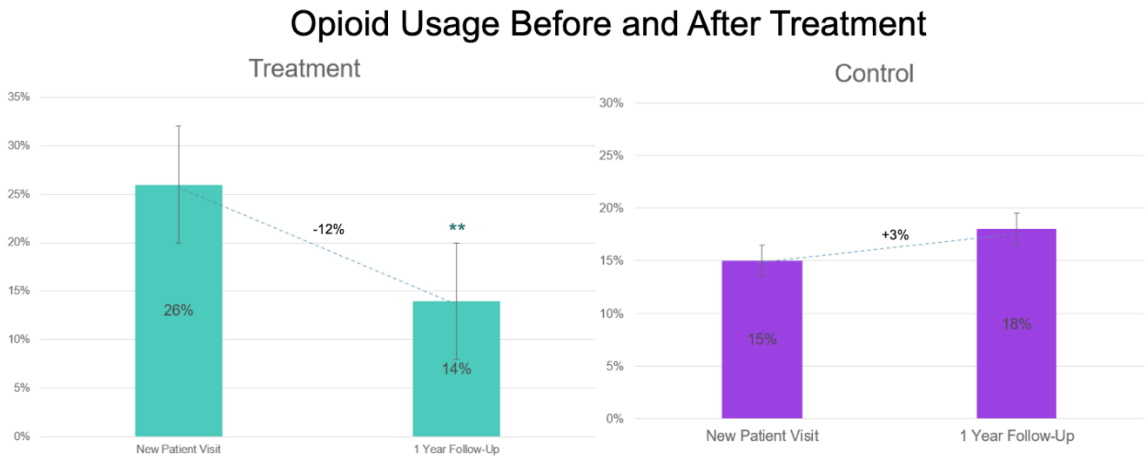

Figure 7: Opioid Usage Score at NPV and 1 Year Follow Up across Sample Groups.

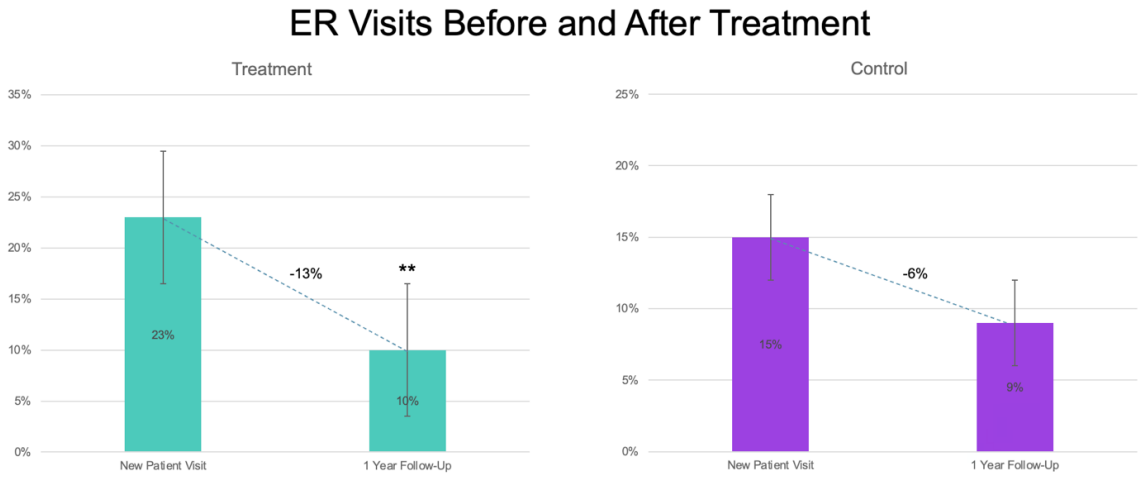

Figure 8: ER Visits at NPV and 1 Year Follow Up across Sample Groups.

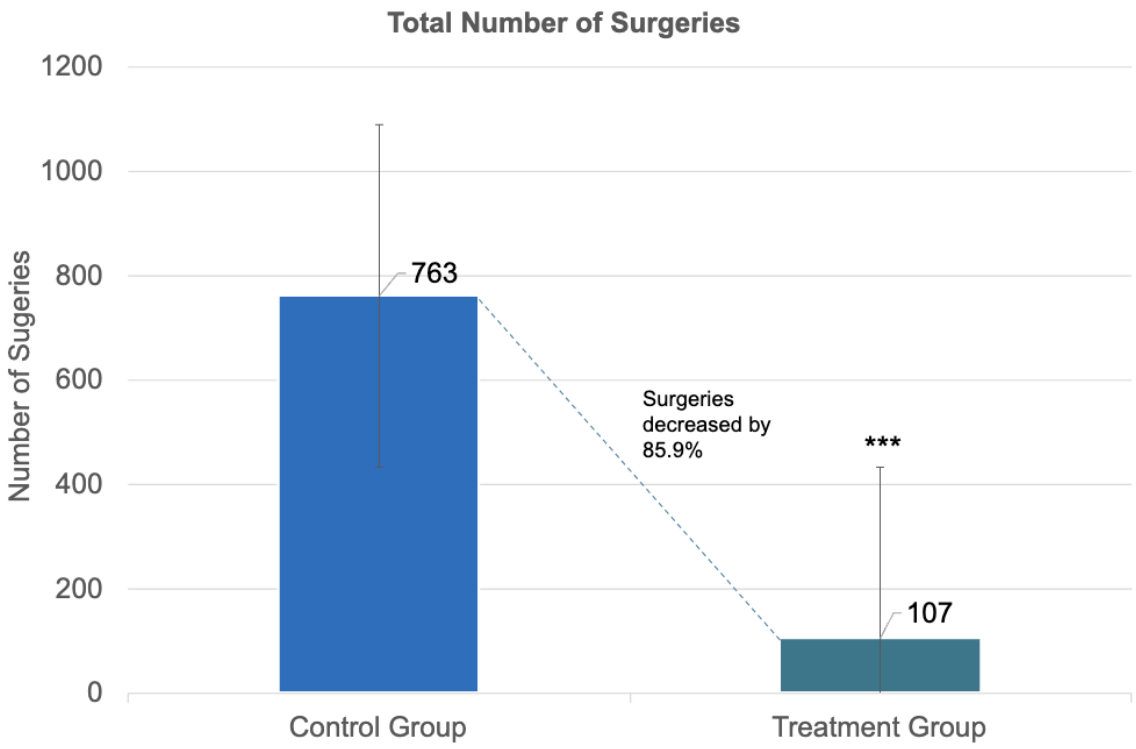

Figure 9: Total Lifetime Surgeries across Sample Groups.

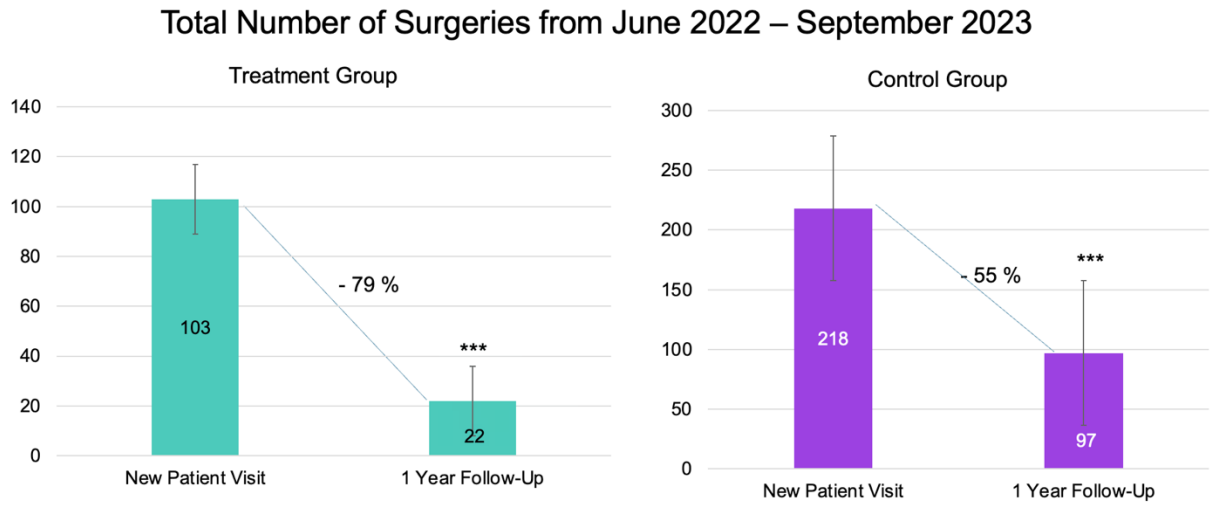

Figure 10: Total Surgeries from June 2022 to September 2022 across Sample Groups.

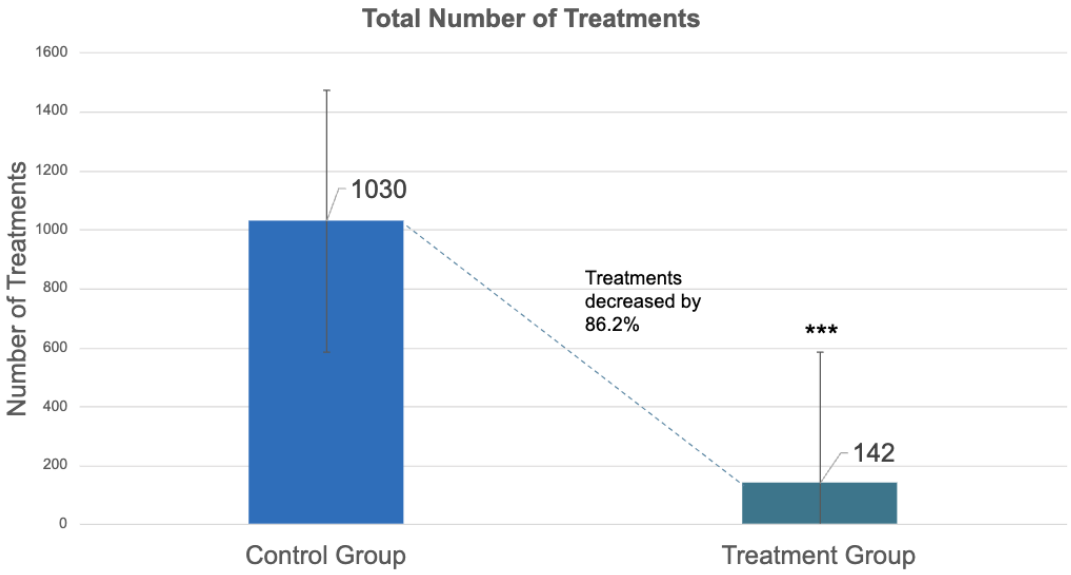

Figure 11: Total Lifetime Treatments across Sample Groups.

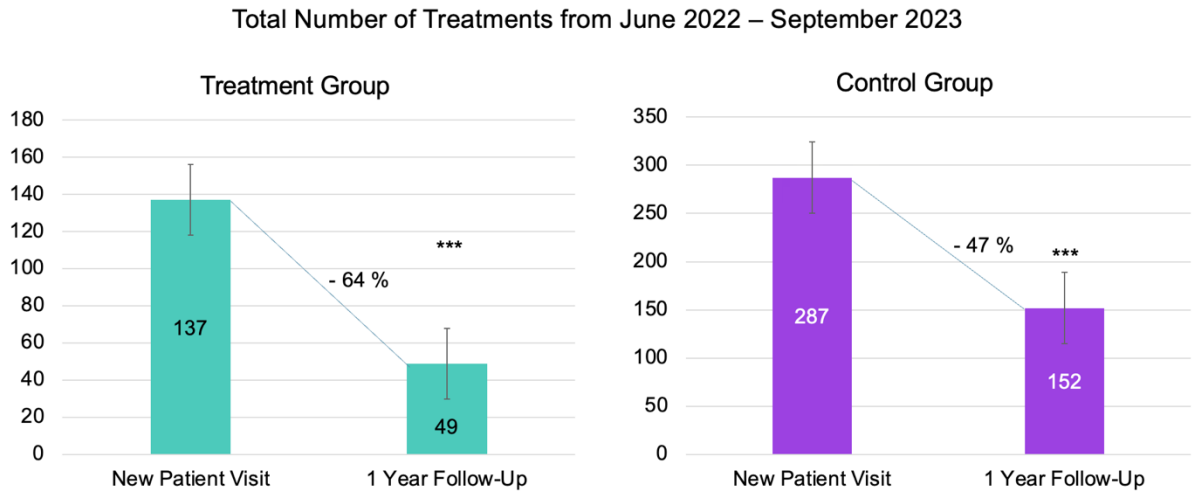

Figure 12: Total Number of Treatments from June 2022 to September 2022 across Sample Groups.

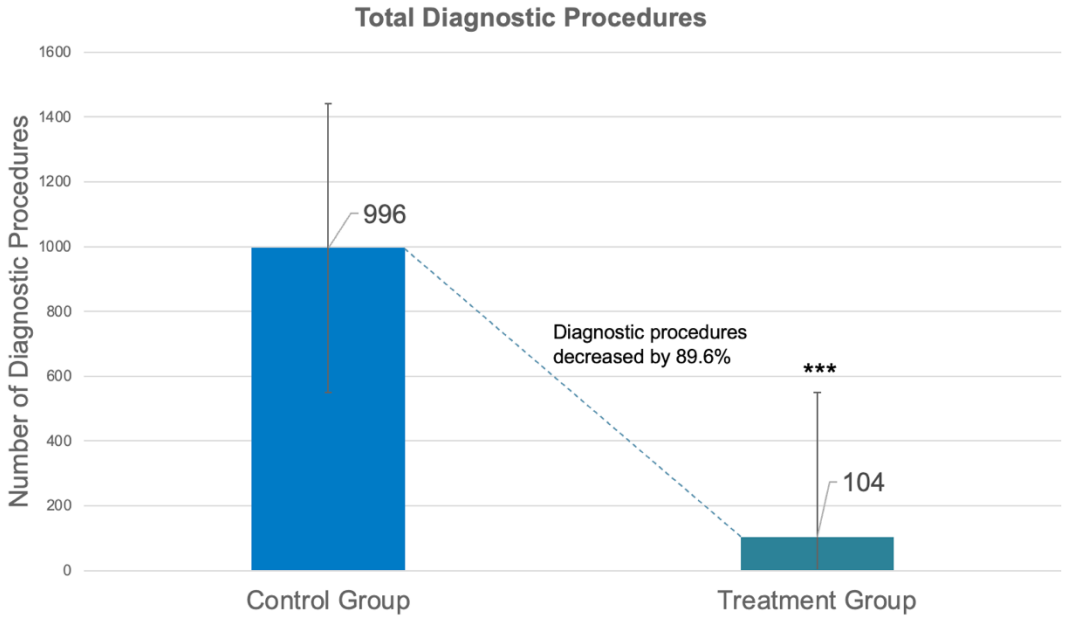

Figure 13: Total Lifetime Diagnostic Procedures across Sample Groups.

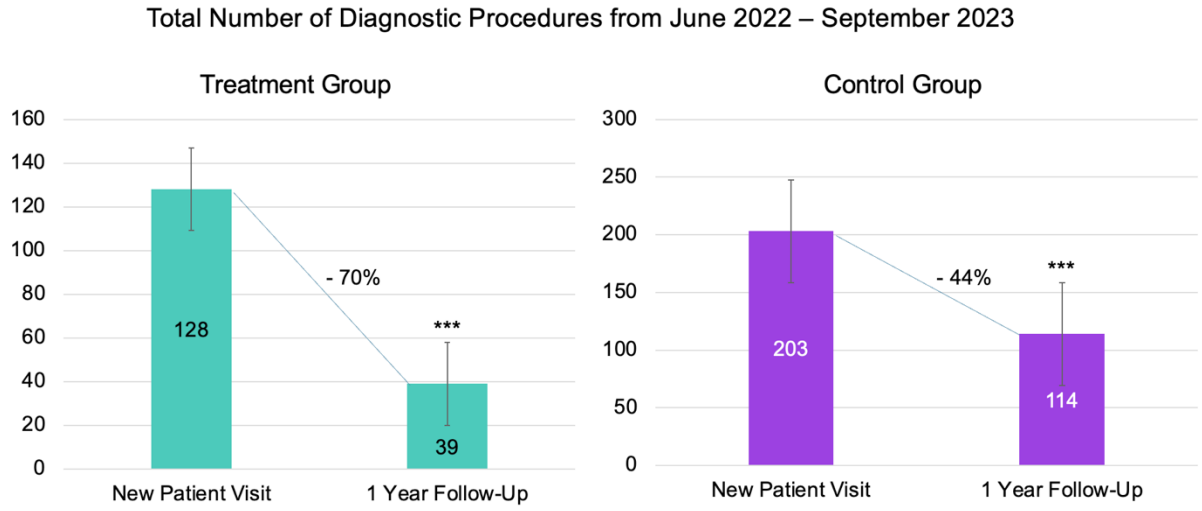

Figure 14: Total Diagnostic Procedures from June 2022 to September 2022 across Sample Groups.

Discussion

The primary aim of this research was to assess the effects of the office-based pelvic peripheral nerve block and trigger point injection protocol on a broad spectrum of outcome parameters, encompassing pain, functionality, work productivity, quality of life, mental health, sexual health, and healthcare system utilization. It is worth noting that the average duration of pain experienced by the 128 participants in this study was 10.5 years, underscoring the chronic and debilitating nature of CPP. Patients in the treatment group, who had undergone the peripheral nerve block and trigger point injection protocol, experienced a reduction in the number of surgeries, medical treatments, and diagnostic procedures when compared to patients in the control group.

The outpatient protocol scrutinized in this investigation is designed to concurrently address the underlying pain and dysfunction within the myofascial and nervous systems, which are often observed in CPP patients. Furthermore, statistically significant improvements in Visual Analog Scale (VAS) pain levels were observed in both female and male participants, highlighting the effectiveness of this approach in targeting the root causes of nerve and muscle pain. Myofascial dysfunction within the pelvis is closely associated with bowel, bladder, and sexual dysfunction, and it contributes to pelvic pain via myofascial trigger points [7]. By treating this underlying myofascial pain and pelvic floor dysfunction through ultrasound-guided trigger point injections to each muscle of the levator ani sling, the source of ongoing nociception is alleviated, and enhanced blood circulation to the pelvic floor musculature occurs [8]. The protocol also addresses peripheral and central sensitization, aiming to reduce neurogenic inflammation, inhibit feedback loops from the peripheral to central nervous systems, and prevent cross-sensitization between the pudendal and posterior femoral cutaneous nerves [9]. Peripheral sensitization is managed using consecutive peripheral nerve blocks targeting the pudendal and posterior femoral cutaneous nerves to 1) reduce neurogenic inflammation by locally administering dexamethasone to deplete pro-inflammatory cytokines such as substance P [10] and employing repeated exposure to lidocaine 1%, which diminishes the release of histamine release from mast cells [11], and 2) desensitize hyperactive peripheral nociceptors through repeated exposure to lidocaine 1% [12]. In addition to addressing peripheral sensitization, the protocol also targets central sensitization by reversing the pelvic neurogenic inflammation. This approach effectively inhibits the feedback loop from the peripheral nervous system to the central nervous system [13]. Notably, the overlap in pain patterns and innervation between the pudendal and posterior femoral cutaneous nerves can lead to cross-sensitization, a phenomenon observed in the pelvis where a sensitized structure can upregulate an adjacent, otherwise normal structure [14]. Consequently, the protocol concurrently addresses both peripheral pelvic nerves to prevent cross-sensitization from occurring.

Chronic Pelvic Pain patients frequently face underdiagnosis and inadequate treatment, stemming from a lack of awareness, limited understanding, simplistic diagnostics, and effective treatment options within the medical community. Consequently, these patients often navigate a convoluted medical journey, seeking relief in the Emergency Room during severe pain episodes, undergoing numerous unnecessary diagnostic procedures, and experiencing a series of unsuccessful therapeutic surgical and non-surgical treatments. It is imperative for the medical community to collaboratively establish a streamlined diagnostic and treatment protocol for CPP patients, which would greatly benefit both the individuals suffering from CPP and the burden on the healthcare system. The study presents several noteworthy limitations, with the primary constraint being its retrospective nature, which precludes the use of randomized control groups. This design restricts our ability to evaluate the effectiveness of our protocol when compared to placebo control groups, as we deliberately refrain from treating control group CPP patients who are actively seeking relief from their pain. Furthermore, ongoing research is essential to better understand the causes, mechanisms, and optimal treatment strategies for CPP. Advances in imaging techniques, genetic research, and the development of targeted therapies offer hope for improved outcomes, however, the office-based procedural protocol described in this paper addressing the pelvic floor nerves and muscles denotes a safe, simple procedural option for the common disease process Furthermore, raising awareness about CPP among healthcare providers is crucial to expedite diagnosis and intervention [15-17].

Conclusion

CPP affects 25% of women of reproductive age, 15% of women in a lifetime, and 10% of men [4]. This study highlights the effectiveness of addressing the pelvic floor in CPP patients with a simple, safe office-based procedural approach. This retrospective review demonstrated the long-term effectiveness of a procedural protocol on both patient pain and function but also on decreasing the healthcare utilization for CPP patients. The notable reductions in surgeries, medical treatments, diagnostic procedures, pain management interventions, opioid consumption, and emergency room visits represent significant clinical and economic benefits. The incorporation of this protocol into healthcare practices offers a transformative opportunity to improve patient care and optimize resource allocation.

Disclosure

The authors report no conflicts of interest in this work.

Author Contributions Statement

All authors contributed to the design and implementation of the research, to the analysis of the Results, and to the writing of the manuscript.

Ethics Approval and Consent to Participate

The protocol for this research project has been approved by a suitably constituted Ethics Committee of the institution and it conforms to the provisions of the Declaration of Helsinki. Committee of The Feinstein Institutes for Medical Research, Approval No. IRB# 17-0761. Our study does not have a clinical trial number and consent forms were waived due to study design.

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References

1. Hutton D, Mustafa A, Patil S, Rathod S, Shrikhande G, et al. (2023) The burden of Chronic Pelvic Pain (CPP): Costs and quality of life of women and men with CPP treated in outpatient referral centers. PLoS One 18: e0269828.
2. Polackwich AS, Shoskes DA (2016) Chronic prostatitis/chronic pelvic pain syndrome: a review of evaluation and therapy. Prostate Cancer Prostatic Dis 19: 132-138.
3. Coutaux A, Adam F, Willer JC, Le Bars D (2005) Hyperalgesia and allodynia: peripheral mechanisms. Joint Bone Spine 72: 359-371.
4. Carey ET, Till SR, As-Sanie S (2017) Pharmacological management of chronic pelvic pain in women. Drugs 77: 285-301.
5. Stanford EJ, Koziol J, Feng A (2005) The prevalence of interstitial cystitis, endometriosis, adhesions, and vulvar pain in women with chronic pelvic pain. J Minim Invasive Gynecol 12: 43-49.
6. (2020) Chronic Pelvic Pain: ACOG Practice Bulletin, Number 218. Obstet Gynecol 3: e98-e109.
7. Prendergast SA, Weiss JM (2003) Screening for musculoskeletal causes of pelvic pain. Clin Obstet Gynecol 46: 773-782.
8. Prather H, Camacho-Soto A (2014) Musculoskeletal etiologies of pelvic pain. Obstet Gynecol Clin North Am 41: 433-442.
9. Malykhina AP (2008) Neural mechanisms of pelvic organ cross-sensitization. Neuroscience 149: 660-672.
10. Bowden JJ, Schoeb TR, Lindsey JR, McDonald DM (1994) Dexamethasone and oxytetracycline reverse the potentiation of neurogenic inflammation in airways of rats with *Mycoplasma pulmonis* infection. Am J Respir Crit Care Med 150: 1391-1401.
11. Ballyns JJ, Shah JP, Hammond J, Gebreab T, Gerber LH, et al. (2011) Objective sonographic measures for characterizing myofascial trigger points associated with cervical pain. J Ultrasound Med 30: 1331-1340.
12. Nickel JC, Moldwin R, Lee S, Davis EL, Henry RA, et al. (2009) Intravesical alkalinized lidocaine (PSD597) offers sustained relief from symptoms of interstitial cystitis and painful bladder syndrome. BJU Int 103: 910-918.
13. Staud R, Nagel S, Robinson ME, Price DD (2009) Enhanced central pain processing of fibromyalgia patients is maintained by muscle afferent input: a randomized, double-blind, placebo-controlled study. Pain 145: 96-104.
14. Ustinova EE, Fraser MO, Pezzone MA (20210) Cross-talk and sensitization of bladder afferent nerves. Neurourol Urodyn 29: 77-81.
15. Wespes E, Nogueira MC, Herbaut AG, Caufriez M, Schulman CC (1990) Role of the bulbocavernosus muscles on the mechanism of human erection. Eur Urol 18: 45-48.
16. Furuta A, Kita M, Suzuki Y, Egawa S, Chancellor MB, et al. (2008) Association of overactive bladder and stress urinary incontinence in rats with pudendal nerve ligation injury. Am J Physiol Regul Integr Comp Physiol 294: R1510-R1516.
17. Yanagi H, Sankawa H, Saito H, Iikura Y (1996) Effect of lidocaine on histamine release and Ca2+ mobilization from mast cells and basophils. Acta Anaesthesiol Scand 40: 1138-1144.