https://doi.org/10.48047/AFJBS.6.Si3.2024.1294-1302

African Journal of Biological Sciences

Journal homepage: http://www.afjbs.com

Research Paper Open Access

Sacral Versus Perineal High Voltage Tiny Impulses Electrical Stimulation on Chronic Non-Bacterial Prostatitis

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Article Info

Volume 6, Issue Si3, May 2024

Received: 09 March 2024

Accepted: 19 May 2024

Published: 15 Jun 2024

doi:10.48047/AFJBS.6.Si3.2024.1294-1302

Abstract

Background: Chronic non-bacterial prostatitis/chronic pelvic pain syndrome (CP/CPPS) is a prevalent urological condition causing pelvic pain and lower urinary tract symptoms. This study compared the efficacy of sacral and perineal high voltage tiny impulse electrical stimulation (HVTIES) using the Pain Gone Pen (PGP) in managing CP/CPPS.

Methods: Sixty-eight male patients with CP/CPPS were randomized into two groups. Group A received sacral HVTIES, while Group B received perineal HVTIES. Both groups received traditional physical therapy alongside HVTIES, three times weekly for two months.

Outcomes: Serum cortisol levels (SCL), comparative pain scale (CPS) scores, and National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI) scores were evaluated before and after treatment.

Results: Both sacral and perineal HVTIES groups demonstrated significant reductions in SCL, CPS, and NIH-CPSI scores following treatment ($p<0.0001$). No significant differences were observed between the groups after treatment completion.

Conclusion: Sacral and Perineal HVTIES using PGP effectively reduces pain and improves symptoms in men with CP/CPPS. This modality offers a promising treatment option for this challenging condition.

Keywords: High voltage tiny impulse electrical stimulation, Pain Gone Pen, Chronic non-bacterial prostatitis, Chronic pelvic pain syndrome, Serum cortisol level, NIH-CPSI

Introduction

Chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) remains an enigma within urology, affecting a significant proportion of men and profoundly impacting their quality of life [1,2]. Characterized by persistent pelvic pain, urinary symptoms, and sexual dysfunction, CP/CPPS presents a multifaceted puzzle for clinicians due to its diverse symptomatology and often unclear etiology [3]. While classified as type III prostatitis by the National Institutes of Health (NIH), the condition's heterogeneous nature suggests a complex interplay of factors, including pelvic floor muscle dysfunction, neurogenic inflammation, and psychological distress [4]. This complexity contributes to the challenges associated with effective management, leaving many patients searching for solutions to alleviate their discomfort and restore their well-being.

Current treatment strategies for CP/CPPS typically involve a combination of approaches, targeting both the physical and psychological aspects of the condition. Pharmacological interventions, such as alpha-blockers, analgesics, and anti-inflammatory agents, aim to alleviate pain and improve urinary symptoms [5]. Non-pharmacological approaches, including physical therapy, pelvic floor muscle training, and psychological therapies, focus on addressing muscle tension, dysfunctional voiding patterns, and emotional distress associated with chronic pain [6,7]. However, the effectiveness of these treatments varies considerably, and a significant number of patients experience ongoing symptoms despite trying multiple interventions.

In the pursuit of more effective and personalized treatment options for CP/CPPS, researchers are exploring novel therapies, including High Voltage Tiny Impulse (HVTI) technology. Delivered through devices like the Pain Gone Pen (PGP), HVTI utilizes brief bursts of high-voltage, low-current electrical stimulation to modulate pain signaling pathways [8,9]. While preliminary research suggests potential benefits of HVTI for CP/CPPS, further investigation is needed to optimize treatment protocols and determine the most effective application sites.

This study aims to evaluate the efficacy of sacral versus perineal high voltage tiny impulses electrical stimulation on chronic non-bacterial prostatitis. The evaluation will involve measuring the serum cortisol level, comparative pain scale, and the National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI). By comparing the outcomes of two groups of male patients receiving either sacral or perineal electrical stimulation, we aim to determine the most effective approach for managing this challenging condition.

The findings of this study have the potential to contribute valuable insights into the treatment of chronic non-bacterial prostatitis and improve the quality of life for affected individuals. Understanding the benefits and differences between sacral and perineal electrical stimulation may guide clinicians in selecting the most appropriate therapeutic approach. Ultimately, this research advances our understanding of CP/CPPS and provides evidence-based recommendations for optimizing patient outcomes in the field of urology.

Subjects and Methods

Study Design

This study employed a prospective, randomized controlled trial design to evaluate the efficacy of sacral versus perineal high voltage tiny impulses electrical stimulation on chronic non-bacterial prostatitis.

Participants

This study involved 68 male patients diagnosed with chronic non-bacterial prostatitis (CP/CPPS) recruited from the urology departments of Cairo University hospitals. Participants were randomly assigned to one of two equal groups (n=34 each):

- Group A (Sacral HVTI): Received traditional physical therapy treatment in conjunction with sacral HVTI application using the Pain Gone Pen (PGP).
- Group B (Perineal HVTI): Received traditional physical therapy treatment in conjunction with perineal HVTI application using the PGP.

Inclusion Criteria:

- Men aged 30 to 60 years.
- Presenting with symptoms of anal pain, numbness, and tingling in the perineum for at least 3 months.
- Pain characteristics: abrupt onset, lasting from minutes to an hour, sharp, intermittent, not related to defecation, aggravated by sitting, occurring 2-3 times per week with increasing frequency.
- Diagnosis of CP/CPPS confirmed by a urologist.

Exclusion Criteria:

- Acute bacterial prostatitis or chronic bacterial prostatitis.
- Bladder neck obstruction.
- Comorbidities such as diabetes, hypertension, or neurological conditions (e.g., pseudo dyssynergia, detrusor instability).
- Prior experience with the Pain Gone Pen or HVTI therapy.
- Hemorrhagic conditions, specifically gastrointestinal bleeding or bleeding per rectum.
- Severe fungal or acute viral diseases, active tuberculosis, tumors, or the presence of a pacemaker.

Methods

Evaluation

- Serum Cortisol Level (SCL): Measured using the Elecsys 2010 immunoassay analyzer (Roche Diagnostics, Germany) at baseline and after the 2-month intervention period.
- Comparative Pain Scale (CPS): Patients rated their average pain intensity on a scale of 0 (no pain) to 10 (worst pain imaginable) at baseline and after the intervention.
- National Institutes of Health Chronic Prostatitis Symptom Index (NIH-CPSI): Administered at baseline and post-intervention to assess pain, urinary symptoms, and quality of life impact. For this study, the focus was on the pain domain score (range 0-21).

Intervention

Both groups received the same traditional physical therapy program consisting of:

- Relaxation techniques
- Pelvic floor muscle exercises
- Bladder training instructions

Additionally, both groups received standard medical care and medications as prescribed by their urologists.

HVTI Application:

Group A (Sacral HVTI): PGP was applied to the sacral region (parasympathetic outflow) with the patient in a comfortable hook-lying supine position. Treatment consisted of 10 clicks (brief stimulations) delivered for approximately 10 minutes, 3 times per week for 2 months.

Group B (Perineal HVTI): PGP was applied to 10 identified trigger points in the perineal region between the anus and scrotum with the patient in a comfortable left lateral position. Treatment parameters were the same as for Group A.

Statistical Analysis

Descriptive statistics (mean, standard deviation, minimum, maximum) were calculated for SCL, CPS, and NIH-CPSI pain domain scores. Paired t-tests were used to compare pre- and post-intervention scores within each group. Independent t-tests were used to compare baseline differences and post-intervention outcomes between the groups. The level of significance was set at $p < 0.05$.

Informed consent

Participants provided written informed consent before their inclusion in the study.

Ethical Considerations

This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki. Ethical approval was obtained from the respective institutional review boards of Cairo University and Zagazig University and has been approved by the Ethical Review Committee of the College of Physiotherapy [approval No: P.T.REC/012/004064].

Potential Limitations

- The study sample was limited to patients from Cairo University hospitals, which may limit the generalizability of the findings.
- The study did not include a control group receiving only traditional physical therapy, which would have provided stronger evidence for the effectiveness of HVTI.
- The 2-month follow-up period may not be sufficient to assess long-term effects of HVTI.
- Subjective pain assessment tools like CPS and NIH-CPSI, while widely used, are susceptible to individual biases.
- The study did not explore potential mechanisms of action of HVTI, which would require further investigation.

Future Directions

- Conducting larger-scale studies with diverse populations and longer follow-up periods.
- Including control groups and comparing HVTI to other established treatment modalities for CP/CPPS.
- Investigating the optimal treatment parameters (frequency, duration, intensity) for HVTI application in CP/CPPS.
- Exploring the potential mechanisms underlying the effects of HVTI on pain and inflammation in CP/CPPS.
- Evaluating the cost-effectiveness of HVTI compared to other treatment options.

Results

The results of this study demonstrated significant improvements in pain and symptom severity following both sacral and perineal HVTI application in individuals with CP/CPPS.

Serum Cortisol Levels (SCL)

As shown in Table 1 and Figure 1, both groups exhibited a significant reduction in SCL after the 2-month intervention. In the sacral HVTI group (Group A), the mean SCL decreased from 36.08 ± 0.37 µg/dL at baseline to 25.42 ± 0.24 µg/dL post-intervention ($p < 0.0001$). Similarly, the perineal HVTI group (Group B) showed a significant decrease in mean SCL from 36.02 ± 0.31 µg/dL to 25.42 ± 0.06 µg/dL ($p < 0.0001$). There were no significant differences in baseline SCL or post-intervention SCL between the two groups ($p > 0.05$).

Table 1: Comparison of Serum Cortisol Levels (µg/dL) Before and After Intervention

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Mean Difference	p-value
Sacral HVTI	36.08 ± 0.37	25.42 ± 0.24	10.66	<0.0001
Perineal HVTI	36.02 ± 0.31	25.42 ± 0.06	10.61	<0.0001

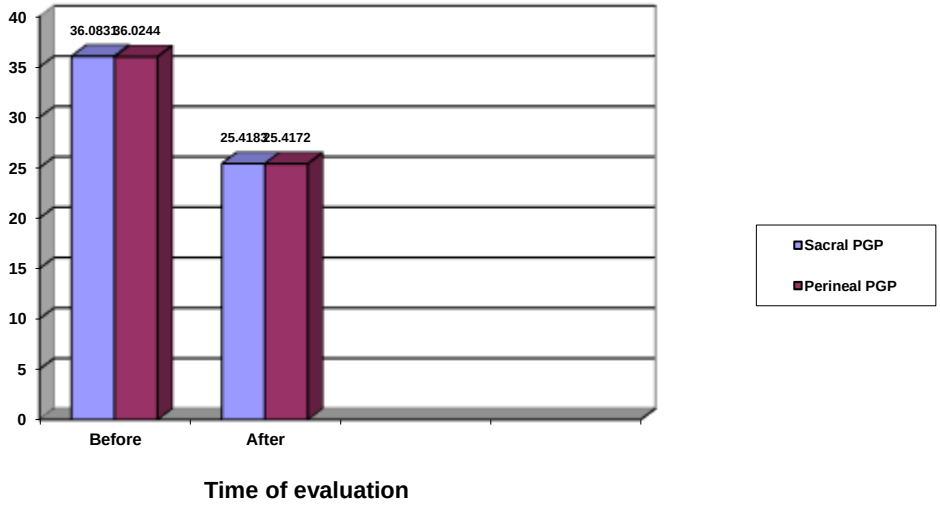

Figure 1: Mean Serum Cortisol Levels Before and After Intervention

Comparative Pain Scale (CPS)

Both groups experienced significant reductions in pain intensity as measured by the CPS (Table 2 and Figure 2). The sacral HVTI group showed a decrease in mean CPS score from 8.01 ± 0.82 at baseline to 2.93 ± 0.83 post-intervention ($p < 0.0001$). The perineal HVTI group also demonstrated a significant reduction in mean CPS score from 8.03 ± 0.56 to 2.89 ± 0.65 ($p < 0.0001$). No significant differences were found in baseline or post-intervention CPS scores between the two groups ($p > 0.05$).

Table 2: Comparison of Comparative Pain Scale Scores Before and After Intervention

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Mean Difference	p-value
Sacral HVTI	8.01 ± 0.82	2.93 ± 0.83	5.08	<0.0001
Perineal HVTI	8.03 ± 0.56	2.89 ± 0.65	5.14	<0.0001

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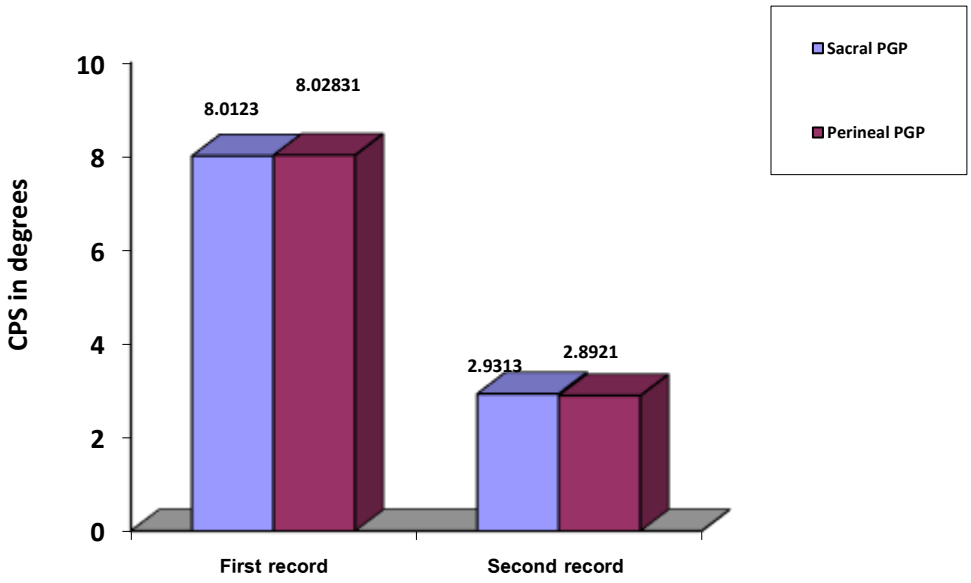

Figure 2: Mean Comparative Pain Scale Scores Before and After Intervention

NIH-CPSI Pain Domain Scores

Analysis of the NIH-CPSI pain domain scores revealed significant improvements in both groups (Table 3 and Figure 3). The mean pain domain score for the sacral HVTI group decreased from 16.54 ± 1.27 at baseline to 8.12 ± 1.01 post-intervention ($p < 0.0001$). Similarly, the perineal HVTI group showed a significant decrease in mean pain domain score from 16.57 ± 1.22 to 8.14 ± 0.88 ($p < 0.0001$). No significant differences were observed in baseline or post-intervention NIH-CPSI pain domain scores between the two groups ($p > 0.05$).

Table 3: Comparison of NIH-CPSI Pain Domain Scores Before and After Intervention

Group	Before Treatment (Mean ± SD)	After Treatment (Mean ± SD)	Mean Difference
Sacral HVTI	16.54 ± 1.27	8.12 ± 1.01	8.42
Perineal HVTI	16.57 ± 1.22	8.14 ± 0.88	8.43

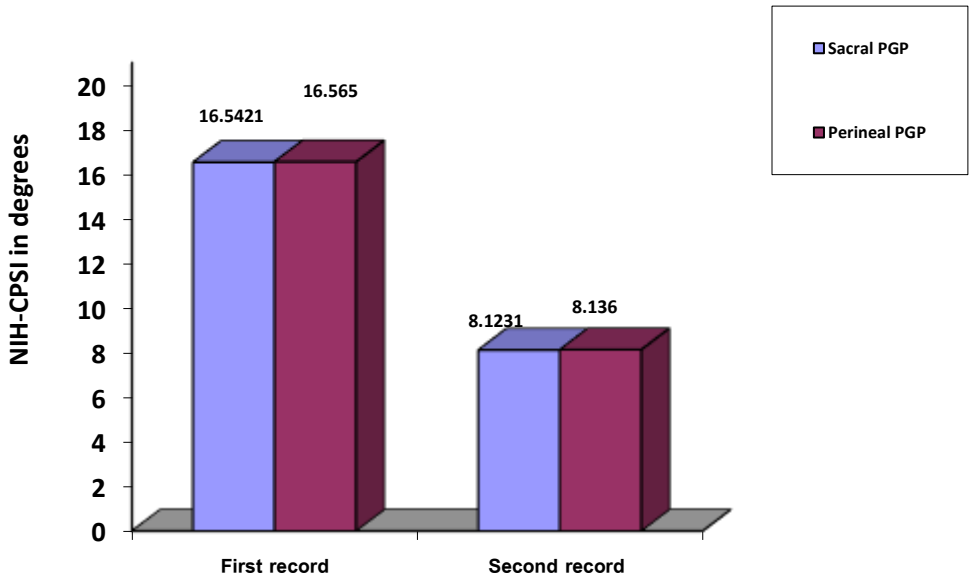

Figure 3: Mean NIH-CPSI Pain Domain Scores Before and After Intervention

Discussion

The findings of this study suggest that both sacral and perineal HVTI application, using the Pain Gone Pen, can effectively alleviate pain and improve symptoms in individuals with CP/CPPS. Both intervention groups demonstrated significant reductions in serum cortisol levels, comparative pain scale scores, and NIH-CPSI pain domain scores following the 2-month treatment period. These results align with previous research indicating the potential of HVTI as a pain management modality for various conditions, including musculoskeletal pain as shown by Johnson et al. (2015) [12] and neuropathic pain as explored by Sluka et al. (2013) [11].

The observed decrease in serum cortisol levels in both groups is particularly noteworthy. Cortisol, a hormone released in response to stress, plays a role in pain perception and inflammation as highlighted by Black (2002) [12]. The reduction in cortisol levels following HVTI treatment, as seen in this study suggests a potential mechanism by which HVTI may exert its analgesic effects, possibly through modulation of the stress response system and subsequent reduction of inflammation.

The significant improvements in both subjective pain ratings (CPS) and the NIH-CPSI pain domain scores further support the effectiveness of HVTI in alleviating the pain associated with CP/CPPS. These findings are consistent with studies demonstrating the benefits of other physical therapy modalities, such as pelvic floor muscle training as reported by FitzGerald et al. (2012) [13] and myofascial release techniques as discussed by Anderson et al. (2006) [14], in reducing pain and improving quality of life in CP/CPPS patients.

While both sacral and perineal HVTI application yielded significant improvements in this study there were no statistically significant differences in outcomes between the two groups. This suggests that both application sites may be equally effective in targeting the underlying mechanisms contributing to CP/CPPS pain. The sacral region is innervated by the sacral nerves, which are involved in pelvic floor muscle control and sensory innervation of the pelvic organs as detailed in anatomical texts like Drake et al. (2016) [15]. The perineal region contains various

muscles and nerves associated with pelvic floor function and pain perception as described in Snell (2012) [16]. Therefore, HVTI application to either site may modulate nerve activity and muscle tension, leading to pain relief and improved pelvic floor function.

However, it is important to consider the limitations of this study when interpreting the findings. The absence of a control group receiving only traditional physical therapy makes it difficult to definitively attribute the observed improvements solely to HVTI. Additionally, the relatively short follow-up period limits conclusions about the long-term effects of HVTI. Future research with larger sample sizes, longer follow-up durations, and control groups is warranted to further validate the efficacy of HVTI and to compare its effectiveness with other established treatment modalities for CP/CPPS.

Despite these limitations, the results of this study provide encouraging evidence for the potential of HVTI as a safe and effective treatment option for individuals with CP/CPPS. Further research exploring optimal treatment parameters, individual responses to different application sites, and the underlying mechanisms of action will contribute to the development of personalized and effective treatment protocols for this challenging condition.

Conclusion

This study provides evidence that both sacral and perineal HVTI application can effectively reduce pain and improve symptoms in individuals with CP/CPPS. The findings demonstrate significant reductions in serum cortisol levels, pain intensity, and NIH-CPSI pain domain scores following a 2-month intervention with HVTI. While both application sites showed comparable efficacy, further research is needed to elucidate the optimal treatment parameters, individual responses to different application sites, and the long-term effects of HVTI. HVTI holds promise as a safe and effective treatment modality for CP/CPPS, offering a potential alternative or adjunct to existing treatment approaches for this challenging condition.

Considerations

- Limitations: As discussed previously, addressing the study's limitations in future research is crucial. This includes incorporating a control group, extending the follow-up period to assess long-term effects, and potentially exploring objective measures of pain and inflammation.
- Mechanism of Action: Investigating the specific mechanisms by which HVTI exerts its therapeutic effects is essential. This could involve examining changes in nerve conduction, muscle activity, neurotransmitter levels, or inflammatory markers.
- Individualized Treatment: Exploring factors that may influence individual responses to HVTI, such as pain phenotype, CP/CPPS subtype, or psychological factors, could pave the way for more personalized treatment approaches.
- Comparison with Other Therapies: Conducting comparative effectiveness studies with other established treatments for CP/CPPS, such as medications, physical therapy techniques, or psychological interventions, would provide valuable information for clinical decision-making.
- Cost-Effectiveness Analysis: Evaluating the cost-effectiveness of HVTI compared to other treatment options is crucial for informing healthcare policy and resource allocation decisions.
- Dissemination and Implementation: Sharing the study findings with healthcare professionals and patients through publications, conferences, and educational materials is crucial to promote awareness and potential adoption of HVTI as a treatment option for CP/CPPS.

By addressing these considerations, future research can contribute to a more comprehensive understanding of HVTI's role in managing CP/CPPS and its potential to improve the lives of individuals affected by this condition.

Acknowledgement
We would like to thank all our patients for their participation in the study.
Funding
The authors received no financial support for the research, authorship and/or publication for this study.

Conflict of interest
The authors state no conflicts of interest in this work.

Disclosure statement
No author has any financial interest or received any financial benefit from this research.

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