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Effect of High Voltage Tiny Impulses Electrical Stimulation on Chronic Prostatitis

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Abstract

Background: Chronic pelvic pain syndrome (CPPS) or National Institutes of Health (NIT) type IIIA/IIIB prostatitis is characterized by pelvic pain and voiding symptoms. The source of the symptoms is still poorly understood, but pain associated with chronic tension and spasm of the pelvic floor muscles (pelvic floor tension myalgia) has been hypothesized to be a contributing factor.

Aim of Study: To evaluate the therapeutic efficacy of the perineal high voltage tiny impulses electrical stimulation of pain gone pen (PGP) in decreasing pain and improving the pelvic floor tension myalgia.

Material and Methods: 70 male patients with chronic non-bacterial prostatitis and pelvic floor tension myalgia, were divided into two groups. Group (A) received the perineal high voltage tiny impulses electrical stimulation of pain gone pen (PGP) plus the traditional physical therapy. Group (B) received the traditional physical therapy only, PGP stimulation was applied (for a brief period) one (10 clicks) in about 10 minutes on the exaggerated perineal trigger points between anus and scrotum, 3 times weekly for 3 months as a total period of treatment. Methods of assessment (Measurement of the serum cortisol level and the vasual analouge scale).

Results: Result showed that PGP was effective and beneficial in improving the chronic non-bacterial prostatitis and pelvic floor tension myalgia as evidenced by the highly significant decrease in the serum cortisol level and the visual analouge scale.

Conclusion: PGP was effective and beneficial in improving the chronic non-bacterial prostatitis and pelvic floor tension myalgia as evidenced by the highly significant decrease in the serum cortisol level and the visual analouge scale.

Key Words: *High voltage tiny impulses electrical stimulation – Pain gone pen (PGP) – Chronic non-bacterial prostatitis – Pelvic floor tension myalgia – Serum cortisol level – Visual analouge scale.*

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Introduction

ALTHOUGH some studies find a minority of men with chronic pelvic pain have little inflammation (as measured by white blood cells, or pus cells, in their expressed prostatic secretions), other studies that look at more subtle markers of inflammation (cytokines) find inflammation in the majority of sufferers. The mystery is what is causing this inflammation? Infection is ruled out, although work still goes on, fruitlessly at this stage, to prove that perhaps nonbacterial or a stealth virus may be to blame. But recently work with mast cells and nerves points to a more likely culprit: Neurogenic inflammation triggered by muscle spasm that is called the "pelvic myoneuropathy" which is the descriptive new label for CP/CPPS) **[1-4]**.

Chronic pelvic pain syndrome (CPPS) or National Institutes of Health (NIT) type IIIA/IIIB prostatitis is characterized by pelvic pain and voiding symptoms. The source of the symptoms is still poorly understood, but pain associated with chronic tension and spasm of the pelvic floor muscles (pelvic floor tension myalgia) has been hypothesized to be a contributing factor, patients with chronic pelvic pain syndrome frequently exhibit tenderness of the levator ani muscles on rectal examination and that measures that decrease pelvic floor muscle tension such as sitz baths and relaxation techniques, may be used to treat CPPS with anecdotal success **[5-8]**.

Patients with chronic pelvic pain syndrome including pelvic floor tension myalgia may be either inflammatory chronic pelvic pain syndrome (NIH type III A prostatitis) or non-inflammatory CPPS (NIT type III B prostatitis). Inflammatory chronic pelvic pain syndrome is differentiated from

the non-inflammatory CPPS by the presence or absence of white blood cells in the expressed prostatic fluid **[9-12]**.

Chronic prostatitis has been a perplexing problem for urologists for decades, the perils and pitfalls that urologists encounter with epidemiology, etiology, classification and treatment of this syndrome are tremendous. Patients with CCPS exhibits genitourinary voiding complications, pain and sexual dysfunctions, so most urologists acknowledge that prostatitis, especially the chronic type is frustrating and difficult clinical problem to deal with in urology as etiology is unclear **[13-16]**.

Recent epidemiological studies for the major male health issue revealed that, in the early 1990s, 2 million urologists office visits per year in the United States were for prostatitis, while 38% of the Canadian urologist's office visits per year were for the newly prostatitis. Incidence and prevalence of CPPS and prostatitis in Egypt is tremendous and life of patients with chronic prostatitis is similar to that of patients with infarction unstable angina or active Crohn's disease **[2-6,17]**.

Treatment alternatives for the inflammatory and non-inflammatory chronic pelvic pain syndrome includes antibiotics, alpha-adrenergic blockers, anti-cholinergic agents, pentosan polysulfate and the trans-urethral resection of the prostate and the suitable physical therapy modalities **[1,4,9,10]**.

Since the discovery of electricity, and before, current has been applied to the human flesh by a variety of methods to cure a multitude of afflictions. Electrical discharges from the black torpedo fish (Electric eels) were known to the Ancient Egyptians as well as to Hippocrates, for the treatment of headache and gout **[18-22]**.

The word electric was first used by William Gilbert (1544-1630), who was the first to classify and generalize the phenomenon of electricity in his book De Magnete. Kratzenstein (1746) wrote the first report on the use of electricity in medical therapy, so William Gilbert considered as the electricity father, while Kratzenstein considered as the electrotherapy father **[22-27]**.

The mobility of charged particles in a conductive medium causes micro vibration of these particles. The vibration and the associated frictional forces lead to the production of heat. There are many published reports on the effectiveness of the ES for wound healing. But, it is difficult to determine the most effective protocol since researchers report on a variety of currents (high voltage pulsed galvanic, low voltage electrical stimulation, biphasic pulsed current, monophasic pulsed current, direct current, low intensity direct current (LIDC), low intensity stimulation, micro-amperage, or micro-current and the high voltage tiny impulses electrical stimulation in the form of the pain gone pen (PGP) **[22,23,24,27]**.

The electrical charge causes ionic movements. The best-known physiological consequences of such ionic movements include the excitation of peripheral nerves. Electrolytes including calcium, magnesium and other ions such as free amino acids and proteins are also forced to move in response to electromotive force provided by the stimulator. Recently, the evidence supporting electrical stimulation as a treatment modality for pain inhibition and wound healing and soft tissue injury has been evaluated. Although the authors concluded that electrical stimulation can affect wound healing the mechanism is unclear **[18-24]**.

Aim of the study:

Purposes of the present study were the following:

To evaluate the therapeutic efficacy of the perineal high voltage tiny impulses electrical stimulation of pain gone pen (PGP) in decreasing pain and improving the pelvic floor tension myalgia.

To gain knowledge about the perineal high voltage tiny impulses electrical stimulation of pain gone pen (PGP) application as well as its implementation in urology and physical therapy fields.

To share in designing the optimal and ideal protocol for the treatment of chronic non-bacterial prostatitis and pelvic floor tension myalgia.

Subjects and Methods

Subjects:

70 patients who had chronic non-bacterial prostatitis and pelvic floor tension myalgia were participated in this study. The patients were selected from the Urology Departments in Cairo University hospitals, Duration of this study was from June to September 2022. They were randomly divided into 2 equal groups in number, group (A) and group (B). Patients were not familiar with the techniques of the high voltage tiny impulses electrical stimulation and they were divided equally in number into two groups. They were consented to receive the high voltage tiny impulses electrical stimulation for the experimental group. All patients were carefully assessed by a urologist and received the same and necessary physiotherapeutically regimen, drugs, medical and nursing care **[2,4,17,19]**.

The patients were chosen under the following criteria:

Inclusive criteria:

The patients ages ranged from 35 to 50 years, patients who had chronic non-bacterial prostatitis and pelvic floor tension myalgia and all patients were conscious.

Exclusive criteria:

The patients were examined by an urologist before the study and patients who excluded from this study were patients who had acute bacterial prostatitis or acute bacterial pelvic pain syndrome (Category I); Patients who had chronic bacterial prostatitis or chronic bacterial pelvic pain syndrome (Category II); patients who had bladder neck obstruction, patients who were diabetic or hypertensive; patients who had pseudodyssynergia and detrusor muscle instability; patients those familiar with of the high voltage tiny impulses electrical stimulation; patients with hemorrhage specially hemorrhage of digestive system and those with bleeding per rectum; patients with severe fungal diseases and acute viral diseases and patients with active tuberculosis and tumors as well as those with peacemakers.

Instrumentation:

Pain gone pen unit: It is a new pain relief device which has lately become available. The piezoelectronic crystal placed in the product works by producing a high voltage, low frequency pulse for a brief period. Clicking on the painful area, the device transmits electrical impulses to the skin surface and then to the body's pathway for pain relief.

Pain gone pen unit (it has been manufactured in UK for medi-direct international Ltd. Unit 17; Wilford industrial estate and business park, Ruddiington Lane, Nottingham, NG 11 7EP. UK) with the following technical specifications; hand-held, pen-like, piezoelectric stimulator, Pain ®Gone. Class IIa medical device (CE0086), 132mm in length, 20mm in diameter, 2.6mJ at 2000. Operating life: 2-3 years under normal application of three treatments per day of 30-40 clicks per treatment. Voltage: High voltage of 15.000V. Low frequency of 1-2Hz with intensity: 0.006mA **[22,23,26]**.

Procedures:

A- *Evaluation:*

I- Elexcess twenty ten device for blood serum analysis was used for the measurement of serum cortisol level (SCL) for the assessment of pain. (Manufactured by Roch Company, Germany). Normal cortisol level ranged from 9-25µg/dL at morning and patients with painful conditions tended to have higher than normal SCL, A venous blood sample of 8 CC was taken at the morning, centrifuged and stored at 20ºC till analyzed. The pain level was assessed by serum cortisol level (SCL) before starting treatment (first record) then after 3 months (as second final record) **[21,22]**.

II- Visual Analogue Scale (VAS): The pain level was assessed by visual analogue scale (VAS) before starting treatment (first record) then after 3 months (as second final record) The pain level was assessed by visual analogue scale (VAS) before starting treatment (first record) then after 3 months (as second final record). consisted of a line, usually 10 cm long, whose ends are labeled as the extremes of pain (e.g., no pain to unbearable pain).

Patient was asked to place a mark at the point on the line which best represent he or her experience of pain between two "no pain" to "worst pain", then the operator measured the distance from the zero "no pain" in centimeters.

Visual analogue scale (VAS) is a psychometric response scale that can be used in questionnaires. It is a measurement instrument for subjective characteristics or attitudes that cannot be directly measured. When responding to a VAS item, respondents specify their level of agreement to a statement by indicating a position along a continuous line between two end point **[1,3,6,11]**.

B- *Treatment:*

All patients in the 2 groups (A) and (B) received the same traditional physical therapy and home exercise in the form of relaxation techniques, and pelvic floor exercise and instructions for bladder training. Also all patients received the same medical care and medications.

Procedures of PGP for the experimental group (A):

According to the previously mentioned characteristics and specifications of the PGP stimulation. With the patient in the comfortable left lateral position for sigmoidoscopy (long axis of the patient's trunk at 45º to the long axis of the couch, feet level with far edge of couch, buttocks raised on sandbag, and buttocks extending about 10cm beyond the couch near edge), area of treatment was cleaned, and then PGP stimulation was applied (for a brief period) one (10 clicks) in about 10 minutes on the exaggerated perineal trigger points between anus and scrotum. The PGP stimulator

was applied according to the following parameters, high voltage of 15.000V, amplitude (intensity) 0.006mA, 1-2HZ for frequency. The frequency of this treatment protocol for each patient of this group was three sessions per week, every other day, for three months. All patients received the same traditional physical therapy in the form of Relaxation techniques, biofeedback-assisted techniques of neuromuscular reeducation and pelvic floor exercises with interval bladder training **[21,24-27]**.

Data analysis:

SCL and VAS records were measured before treatment and after cessation of the treatment program in both groups. Collected data were fed into computer for the statistical analysis; descriptive statistics as mean, standard deviation, minimum and maximum were calculated for each group. The *t*-test was done to compare the mean difference of the two groups before and after application and within each group. Alpha point of 0.05 was used as a level of significance **[28,29,30]**.

Results

In the present study, the effect of PGP on SCL and VAS in chronic non-bacterial prostatitis and pelvic floor tension myalgia was investigated.

As shown in Table (1) and Fig. (1), the mean value of the SCL before treatment was (36.230± 0.420) g/dL in the experimental group, while after treatment was (25.960±0.435) g/dL. These results revealed a highly significant reduction in SCL, (p<0.0001). But in the control group, the mean value of the SCL, before treatment was (36.210± 0.270) g/dL, while after treatment was (33.209± 5.640) g/dL, and these revealed significant difference in SCL, (p<0.003).

Table (1): Comparison of the mean values of the SCL, before and after treatment in both groups.

	Before treatment		After treatment				
	Mean in microgram/ dl//dl	± SD	Mean microgram/ dl/ dl	± SD	Mean difference	*t*-value	*p*-value
Study group (PGP group)	36.230	0.420	25.960	0.435	10.2700	100.48	<0.0001
Control group (Traditional P.T group)	36.210	0.270	33.209	5.640	3.00100	3.14	0.003

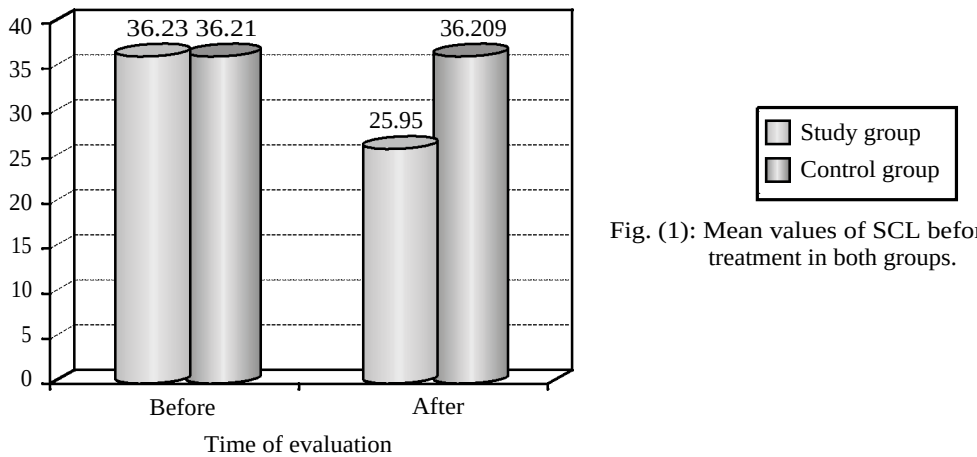

Fig. (1): Mean values of SCL before and after treatment in both groups.

Also as shown in Table (2) and Fig. (2), the mean value of VAS scores, before treatment was 9.0750±0.221 in the experimental group, while after treatment was 2.0745±0.220. These results revealed a highly significant reduction in VAS degrees, (p<0.0001). But in the control group, the mean value of the VAS degrees, before treatment was 9.0744±0.220, while after treatment was 8.8740±0.0506, and these revealed significant decrease in VAS degrees, (p<0.05).

Table (2): Comparison of the mean values of the VAS scores before and after treatment in both groups.

	Before treatment		After treatment		Mean difference	*t*-value	*p*-value
	Mean in degrees	± SD	Mean in degrees	± SD			
Study group (PGP group)	9.0750	0.221	2.0745	0.220	7.00050	75.13	<0.0001
Control group (Traditional P.T group)	9.0744	0.220	8.8740	0.506	0.200400	2.15	0.037

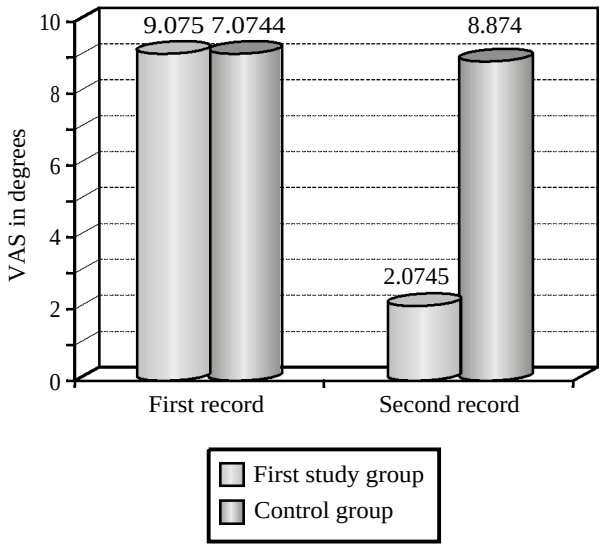

Fig. (2): Mean values of VAS degrees before and after treatment in both groups.

Discussion

The purpose of this study was to determine the effect of high voltage tiny impulses electrical stimulation on chronic prostatitis.

It was observed that there was a significant improvement in both groups with more improvement in study group compared with control group showing that 12 weeks that used pain gone pen (PGP) yielded a positive result in patients with chronic non-bacterial prostatitis and pelvic floor tension myalgia. In this study, the effect of PGP on SCL and VAS in chronic non-bacterial prostatitis and pelvic floor tension myalgia was investigated.

The pain and symptoms of ('abacterial') prostatitis have little or nothing to do with the prostate may be foreign to many urologists". Pelvic floor muscle spasm may be largely responsible for the symptoms of abacterial 'prostatitis' or CPPS. Indeed, many men are now reporting significant improvements in their symptoms as a result of treating pelvic floor muscle spasm. So, there is exactly a relationship between pelvic floor muscle spasm and the symptoms of CPPS. The underlying causes of muscle dysfunction are myofascial trigger points, which are defined as a hyperirritable spot in the muscles that refer pain and are tender to touch. These can be a source of pain as well as cause the muscle not to function properly. Trigger points are "usually caused by a muscle that is being overloaded and worked excessively. It appears that when the muscle is overworked, either by unconscious tensing of the muscle (usually because of anxiety) or due a protective/splinting muscle spasm, trigger points develop in the muscle. These can then cause pain in any part of the pelvic floor, creating wide ranging pain from the pubic bone to the perineum and coccyx. Pelvic muscles become chronically tightened in a trigger point (contracture), giving irritated tissues little or no chance to heal. This in turn, can lead to the symptoms commonly associated with CPPS **[1,2,3,5,6]**.

Cycling, prolonged erection and prolonged sitting all involve significant perineal compression forces which starve the urethra, bladder and prostate of blood. Sitting puts pressure on the prostate, and pressure is a mast cell degranulation trigger. Sitting also compresses the pudendal nerve, possibly leading to Pudendal Nerve Entrapment. Blood starvation is known as "ischemia". When the blood returns to the area it is known as "reperfusion". As a result of this, one can suffer an "ischemia-reperfusion injury", which has long been known to result in inflammation in the area affected. This injury may also lead to inflammation through nerve damage. That's the whole concept in a nutshell. It's a well-known and much-studied concept in medicine, where transplanted organs may become inflamed after blood deprivation, for instance. To make matters worse, the prostate is a poorly blood-perfused gland anyway, so the ischemia caused by excessive sitting may make a gland with a marginal blood supply even more susceptible to this kind of injury **[1,3,5,7]**.

Pelvic floor muscle spasm may be the main cause of symptoms in over 90% of CPPS patients. Everyone with the lack of any clear problem within the prostate itself has caused several researchers to look elsewhere for an underlying cause of CPPS. Urologists at the University of Colorado studied

103 patients with 'a bacterial prostatitis'. When they palpated their patients' pelvic floor muscles, they found that 88% of these patients had "myofascial tenderness" in the rectal area which was associated with the inability to relax the pelvic floor efficiently. When they measured these patients' voiding behaviour with invasive urodynamics, they found that a whopping 92.2% of these patients had "dysfunction of the pelvic floor muscles" **[2,4,12,17]**.

Therefore, two key points to arise are (1) Few CPPS patients have any evidence of infection in the prostate itself; and (2) The majority does have pelvic floor muscle spasm. The next question that arises is this: How does chronic spasm of the pelvic floor muscles lead to the pattern of pain and voiding dysfunction typically seen in CP/CPPS should have a pelvic floor examination as part of a complete urological work-up by someone expert in trigger point/myofascial evaluation **[1,2,4,5,6]**.

Electrical stimulation may mimic the current of injury restarting or accelerating the wound healing process and decreasing pain perception (e.g., cells may be stimulated to move along the path of the electrical current, and this migration of cells may be important in the inflammatory and proliferative stage of the healing process). Electrical currents are believed to stimulate several cell activities (e.g., deoxyribonucleic acid [DNA] synthesis, cell proliferation, synthesis of extracellular matrix, collagen, expression of growth factors and receptors). The flow of electrical current through a biological conductive medium result in three basic effects; electrochemical, electro physical and electrothermal, theoretically, every time electrical current flows through the body, all three effects occur. Electrochemical effects: The unidirectional flow of the direct current (DC) redistributes sodium and chlorine to form a new chemical compound in the tissue under the electrodes **[19,20,22]**.

The mobility of charged particles in a conductive medium causes micro vibration of these particles. The vibration and the associated frictional forces lead to the production of heat. There are many published reports on the effectiveness of the ES for wound healing. But, it is difficult to determine the most effective protocol since researchers report on a variety of currents (high voltage pulsed galvanic, low voltage electrical stimulation, biphasic pulsed current, monophasic pulsed current, direct current, low intensity direct current (LIDC), low intensity stimulation, micro-amperage, or micro-current and the high voltage tiny impulses electrical stimulation in the form of the pain gone pen (PGP). The electrical charge causes ionic movements. The best-known physiological consequences of such ionic movements include the excitation of peripheral nerves. Electrolytes including calcium, magnesium and other ions such as free amino acids and proteins are also forced to move in response to electromotive force provided by the stimulator. Recently, the evidence supporting electrical stimulation as a treatment modality for pain inhibition and wound healing and soft tissue injury has been evaluated. Although the authors concluded that electrical stimulation can affect wound healing the mechanism is unclear **[18,21, 22,26]**.

The findings of the present study showed non-significant difference in the pre-treatment records of the SCL, between the experimental and the control groups, as well as in the pre-treatment records of the VAS, between the mean values of both groups.

Results of this study revealed a highly significant reduction in the mean values of SCL (2) and VAS (2) of the experimental group after the application of the PGP compared with the mean value of SCL (1) as well as VAS (2).

Comparing mean values of the post-treatment records of both SCL and VAS in the control group with the mean values of the pre-treatment records of both SCL and VAS revealed only significant decreased ($p<0.05$).

Significant differences showed in this study, were consistent with those observed and recorded by Akai and Hayashi, 2006; Alexander, 2004; Anthony, 2006; Capodice et al., 2005; Cesaro, 2006; Chen et al., 2008; Cornel et al., 2005; Demir et al., 2004 as well as Hargreaves and Lander, 2012.

Results of this study supports the expectation that perineal high voltage tiny impulses electrical stimulation of pain gone pen (PGP) was effective in improving chronic non-bacterial prostatitis and pelvic floor tension myalgia as manifested by the highly decreased SCL and VAS.

Conclusion:

Perineal high voltage tiny impulses electrical stimulation of pain gone pen (PGP) was effective in improving chronic non-bacterial prostatitis and pelvic floor tension myalgia as manifested by the highly decreased SCL and VAS.

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تأثير التنبيه الكهربى ذو النبضات الصغيرة عالية الفولتية على الالتهاب المزمن للبروستاتا

الخلفية : متلازمة آلام الحوض المزمنة (CPPS) أو المعاهد الوطنية للصحة (NIT) من النوع IIIA/IIIB يتميز التهاب البروستات بألم فى الحوض وإفراغ الأعراض. لا يزال مصدر الأعراض غير مفهموم جيداً، ولكن يفُترض أن يكون الألم المرتبط بالتوتر المزمن وتشنج عضلات قاع الحوض (ألم عضلى قاع الحوض) عاملاً مساهماً.

الهدف من الدراسة : لتقييم الفعالية العلاجية للنبضات العجان ذات الجهد العالى والتحفيز الكهربائى للألم المنقطع (PGP) فى خفيف الألم وتحسين آلام عضلات قاع الحوض.

تم تقسيم ٧٠ مريضاً مصاباً بالتهاب البروستاتا المزمن غير الجرثومى وألم عضلى فى قاع الحوض إلى مجموعتين. تلقت المجموعة (أ) النبضات الكهربائية الدقيقة للعجان ذات الجهد العالى لتحفيز الألم بالقلم (PGP) بالإضافة إلى العلاج الطبيعى التلقيدى. تلقت المجموعة (ب) العلاج الطبيعى التقليدى فقط، وتم تطبيق تحفيز PGP (لفترة وجيزة) واحد (١٠ نقرات) فى حوالى ١٠ دقائق على نقاط الزناد العجانى المبالغ فيها بين فتحة الشرج وكيس الصفن، ٣ مرات أسبوعياً لمدة أشهر كإجمالى فترة العلاج. طرق التقييم (قياس مستوى الكورتيزول فى الدم ومقياس التناظرية الوعائية).

النتائج : أظهرت النتائج أن PGP كان فعالاً ومفيداً فى تحسين التهاب البروستاتا المزمن غير الجرثومى وآلام عضلات قاع الحوض كما يتضح من الانخفاض الكبير فى مستوى الكورتيزول فى الدم ومقياس النظير البصرى.

الخلاصة : كان فعالاً ومفيداً فى تحسين التهاب البروستاتا المزمن غير الجرثو مى و ألم عضلى قاع الحوض كما يتضح من الانخفاض الكبير فى مستوى الكورتيزول فى الدم ومقياس النظير البصرى.