

Pulsed Electromagnetic Fields in the Treatment of Prostatic Hyperplasia

Summary:

In order to evaluate the effect of treatment with pulsed electromagnetic fields on benign prostatic hyperplasia, a randomized, prospective, longitudinal study was performed in 120 patients; with clinical and radiological diagnosis of benign prostatic hyperplasia with moderate symptomatology according to the International Scale of Prostatic Symptoms; who went to the Natural and Traditional Medicine clinic of the Rampa polyclinic, in the period from September 2016 to February 2017. The sample was divided into two groups of 60 patients each: 1) Control: Did not receive specific treatment only behavior expectant with hygienic dietary indications. 2) 30 sessions of pulsed electromagnetic fields were applied in the perineal area with the patient in a seated position, with a daily frequency. In the two groups, the following variables were evaluated before and after three months of treatment: the International Scale of Prostatic Scale (IPSS) scores, the score obtained in the Erectile Dysfunction Questionnaire IIEF-5, the prostate specific antigen (PSA) values and the degree of prostatic hypertrophy in relation to the volume calculated by abdominal ultrasound. When applying the analysis of covariance for comparison of means (ANOVA) $p = 5.9 \cdot 10^{-8}$, it was found that there was no difference between the groups before treatment, it behaved homogeneously. As a result, the group treated with pulsed electromagnetic fields was statistically ($p = 0.00$) higher than the group that received only expectant management, in the IPSS, in the IPSS quality of life assessment, in the IIEF- 5 and prostate volume. No adverse events were reported in the group treated with pulsed electromagnetic fields. It is concluded that therapy with pulsed electromagnetic fields in the treatment of benign prostatic hyperplasia with moderate symptomatology according to the International Scale of Prostatic Symptoms is a safe and effective method.

Key words: benign prostatic hyperplasia, Erectile Dysfunction, prostate specific antigen, pulsed electromagnetic fields.

Introduction

Benign prostatic hyperplasia (BPH) is one of the most common diseases in men, and is a major health problem with very high economic costs. The etiology of this disease is multifactorial, and the actual factors associated with its development are age, prostate-specific antigen (PSA), and prostate volume.¹ In most patients, initial assessment, follow-up, and treatment may from primary care.²

The most common symptoms in the lower urinary tract in benign prostatic hyperplasia can be classified as irritative and obstructive. The irritants are polaquiuria, nocturia, urinary urgency and incontinence. With regard to obstructive symptoms, we have a weak urine stream, difficulty initiating urination, intermittent blushing, incomplete emptying sensation, post voiding drip and urine retention.³ The volume of the prostate has been reported to be an indication of obstruction of the tract urinary volume in studies of pressure flow.⁴

Treatment goals are to reduce symptoms, improve quality of life and avoid complications.² Therapeutic options are: watchful waiting, pharmacological treatment and surgical treatment.⁵

In patients with mild to moderate symptoms and little affectation of their quality of life is recommended an expectant behavior that consists in giving to the patients advice on the lifestyle and it is recommended that they must be controlled annually to evaluate the progression of the sintomatologia.⁶

A therapeutic scale has been proposed that recommends starting with conservative treatments that do not include drugs or surgical interventions. They may include: pelvic floor muscle training alone or associated with biofeedback, electrical stimulation by surface electrodes (patches) or intraanals, lifestyle adaptations, magnetotherapy, external penile compression devices (external clamp), or a combination of methods.⁷ Low-frequency magnetotherapy has been used in prostatic adenoma because of its analgesic, anti-inflammatory, tissue regeneration, local and general circulation improvement, as well as to improve the function of peripheral nerve endings.⁸

PEMF therapy has been successfully applied in diverse diseases such as musculoskeletal disorders,⁹ neurological manifestations¹⁰ and urological disorders¹¹. Analgesic, anti-inflammatory, and vascularization effects are reported¹². several clinical studies have recommended the use of magnetic fields to stimulate healing processes more quickly.¹³ The efficacy of PEMF on BPH in dogs has been reported in the literature with no side effects. the hypothesis that impairment of blood supply in the lower urinary tract may be a causal factor in the development of BPH.¹⁴ PEMF therapy has been shown to have had encouraging results in the treatment of Benign Prostatic Hyperplasia in humans.¹⁵

The symptoms of the lower urinary tract and erectile dysfunction are pathologies of high prevalence with a significant negative impact on the quality of life of these patients; there is a strong epidemiological incidence that evidences the existence of a link between the presence of both pathologies, which is supported by theories of common pathogenesis.¹⁶ In this study we propose to evaluate the effects of PEMF therapy on lower urinary tract symptoms and erectile dysfunction related to prostatic hyperplasia, as well as the effect of this therapeutics on PSA values and prostate volume.

General ethical research considerations

The study was reviewed and approved by an Ethics Committee, which complied with the Declaration of Helsinki, corresponding to the General Assembly of Edinburgh, Scotland, in October 2000. To carry out the study patients were asked to consent informed in writing and oral on the part of the researcher according to the norms of Good Clinical Practices, after having been informed about what would be done during the investigation, it was guaranteed not to divulge the personal data of the patients when informing or publishing the results of this. The medical staff who participated in the study had clinical experience in the management of magnetotherapy and was trained in the management and evaluation of the patients and the application of the treatment. The information related to the identity of the study subjects was treated confidentially, using codes to identify them, this was handled only by the specialized personnel who participated in the investigation.

Material and methods

The study universe consisted of patients with clinical and radiological diagnosis of benign prostatic hyperplasia, with the objective of evaluating the effect of treatment with pulsed electromagnetic fields on moderate benign prostatic hyperplasia according to the International Prostate Symptoms Scale (IPSS), which attended the Natural and Traditional Medicine consultation at the Rampa Polyclinic University in Havana, Cuba, from September 2016 to February 2017. A randomized, prospective, longitudinal study was conducted in a sample of 120 patients with this diagnosis according to the ranges of International Scale Values of Prostatic Symptoms.

Inclusion criteria were: patients 60 years of age or older with clinical and radiological diagnosis of moderate benign prostatic hyperplasia according to the International Scale of Prostatic Symptoms (IPSS) who gave their consent to be included in the study.

The exclusion criteria considered were that patients were below 60 years of age, those who did not consent to be included in the study, or those who had mental or neurological deficit, as well as patients with a diagnosis of cancer of prostate and patients in whom PSA values have doubled in the last 4 years, patients with complications secondary to urinary flow obstruction (renal failure, acute urinary retention or recurrent infections) were also excluded. The exit criteria were defined as voluntary departure from the study, absence in more than 2 consecutive treatment sessions and those who presented irregularity in the treatment. In the interrogation and the physical examination data of interest were obtained as age, predisposing factors, time of evolution, previous treatment and adverse reactions. The patient was correctly informed about his illness.

The sample was divided into two groups of 60 patients each: Group 1 or Control: It did not receive specific treatment only expectant management with hygienic dietary indications, which consisted in guiding avoidance of excessive fluid especially at dinner, regulate the intestinal rhythm, urinate before leaving home and at bedtime, avoid as much as possible the use of drugs that may aggravate BPH such as diuretics, calcium antagonist, anticholinergics, tricyclic antidepressants, and 1st generation antihistamines, a low fat diet and rich in vegetables. Group 2 in addition to giving the same orientations as the previous group was applied 30 sessions of electromagnetic fields pulsed in the perineal area with the patient in a sitting position, with a daily frequency, was stimulated for 9 minutes in three three-minute repetitions with a 5 minute interval between each stimulation at 30 kHz and 1000 Gauss, a US PEMF-100 equipment was used.

In the two groups, the following variables were evaluated before and after three months of treatment: IPSS Scale classified as Light: 0 to 7; Moderate: 8 to 19; Severe: 20 or more, a reduction of 3-4 points on this scale is considered a clinically relevant improvement.¹⁷ In addition, the quality of life item of this scale was assessed by urinary symptoms, assessed according to the responses of the participants grouping them in: Good: 0 to 2 points (includes answers Lucky, Satisfied and Somewhat satisfied), Regular: 3 or 4 points (includes Mixed and Somewhat unsatisfied answers) and Poor: 5 or 6 points (including Unhappy and Terrible responses), the "quality of life" question score is not added to the IPSS total score. The prostate volume determined by a conventional ultrasound with a 3.5 to 5.0 MHz multifrequency transducer was also evaluated; was classified as follows: I: 20-30 cc, II: 30-50 cc, III: 50-80 cc and IV: > 80 cc. Other parameters evaluated were prostate specific antigen: 2.5-4 normal, 4-10 ng / ml slightly elevated, 10-19.9 ng / ml moderately elevated, > 20 ng / ml highly elevated, as well as the score obtained at IIEF which characterizes the severity of Erectile Dysfunction (ED) as follows: 22-25 No ED, 17-21 mild, 12-16 mild to moderate, 8-11 moderate, 5-7 severe ED.

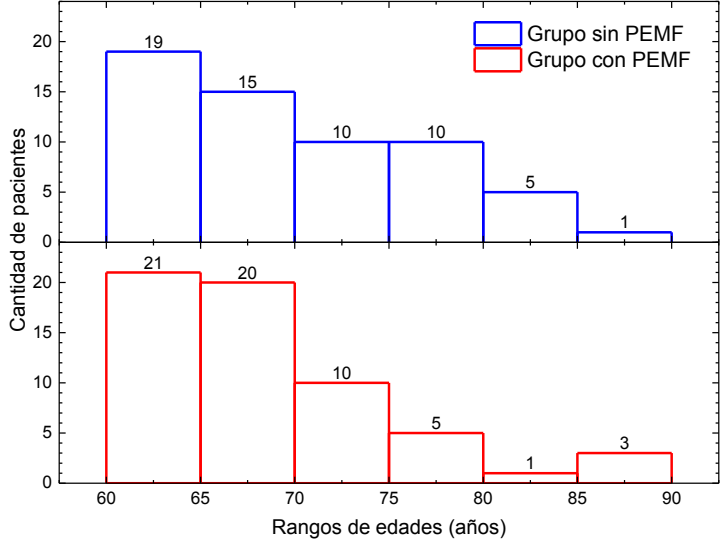
Statistical processing.

The different groups were compared before treatment using the analysis of covariance ANOVA and it was verified if there was improvement in the values of the studies realized after three months of having begun the treatment, for which the statistical test of Student's t was used and the associated probabilistic test. The significance level in all cases was 0.05, ie a value of $p \leq 0.05$ was considered significant and a value of $p \leq 0.01$ was considered highly significant. A comparison was made on all parameters evaluated in each group before and after three months of treatment, and both treatments were compared to each other before and after three months of treatment. We also correlated the results of the evaluation of each parameter with the age of the patients.

Results

We performed a variance analysis (ANOVA) for comparison of ages of both groups were obtained that were significantly similar ($p = 5.9 \cdot 10^{-8} = 0.00$). They were also considered to be within the same age range (60-89 years), so it was possible to make a comparison between both groups.

Graph 1. Distribution of the number of patients in the different age ranges considered for the two groups studied.



Red with PEMF and Blue without PEMF above.

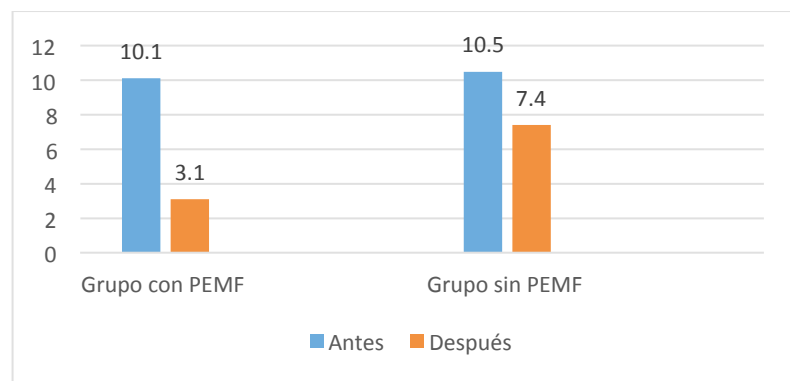
Age	Cases with PEMF		Cases without PEMF		Total	
	No.	%	No.	%	No.	%
60 – 64	21	35.0	19	31.7	40	33.3
65 – 69	20	33.3	15	25.0	35	29.2
70 – 74	10	16.7	10	16.7	20	16.7
75 – 79	5	8.3	10	16.7	15	12.5
80 – 84	1	1.7	5	8.3	6	5.0
85 – 90	3	5.0	1	1.7	4	3.3
Total	60	100	60	100	120	100
Average age	68.35		69.53		68.94	

Source: Clinical history N = 120 distributed in two groups of 60 patients.

Evaluation of the results of the International Scale of Prostatic Symptoms (IPSS)

- The two groups evaluated improved after three months of treatment (comparison of before and after independent groups) $p = 0.00$.
- The PEMF group improved significantly more than the non-PEMF group (comparison between groups after three months of starting treatment) $p = 0.00$.
- The two groups were the same before treatment so the comparison is valid.
- In the two groups the older patients were more affected
- After treatment, all patients were unrelated to age, that is, age did not influence the effect of treatment

Mean values of IPSS symptoms

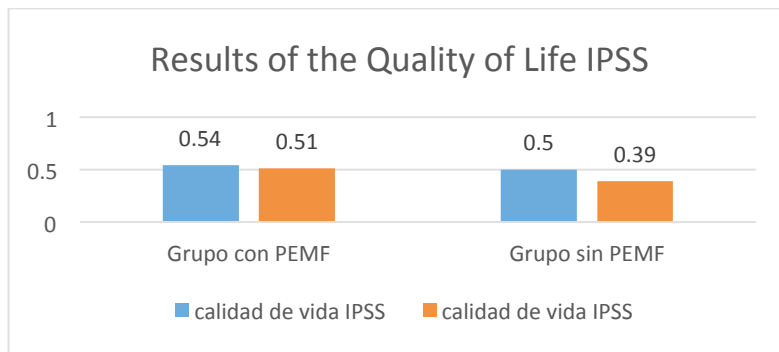


Blue before and rust color after Group on the left with PEMF and right without PEMF.

Statistically very significant improvement ($p = 0.00$) in favor of the group treated with PEMF

Evaluation of IPSS quality of life outcomes

- The PEMF group improved their quality of life significantly after treatment ($p = 0.00$)
- The group without PEMF improved after treatment but was not significant ($p = 0.10$).
- The group with PEMF before treatment had a lower quality of life than the group without PEMF
- The PEMF group had a highly significant improvement over the group without PEMF $p = 0.00$)
- In both groups (with PEMF and without PEMF) prior to treatment the older patients had less quality of life.
- The improvement obtained was not related to age, or it improved the same in all ages evaluated. Age did not influence treatment outcomes



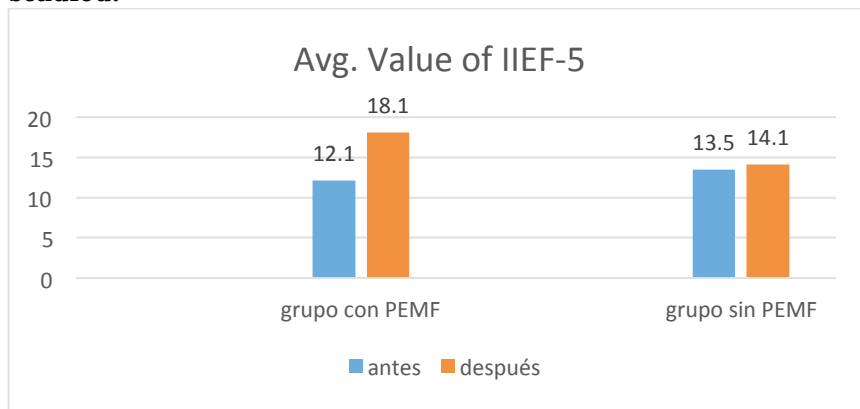
Blue before and rust color after Group on the left with PEMF and right without PEMF.

Graph 3. IPSS quality of life values before and after three months of treatment in the two groups studied.

Evaluation of the results of the erectile dysfunction questionnaire IIEF-5

- The PEMF group improved significantly after ($p = 0.00$).
- In the non-PEMF group did not improve significantly after treatment ($p = 0.22$).
- Before treatment, the IIEF-5 values in the PEMF group were worse than the non-PEMF group.
- After IIEF-5 the PEMF group showed a greater improvement than the non-PEMF group, ($p = 0.00$).
- In the PEMF group an improvement was observed, but this was smaller the older the patients were. Age influenced treatment outcome

Graph 4. IIEF-5 values before and after three months of treatment in the two groups studied.



Blue before and rust color after Group on the left with PEMF and right without PEMF.

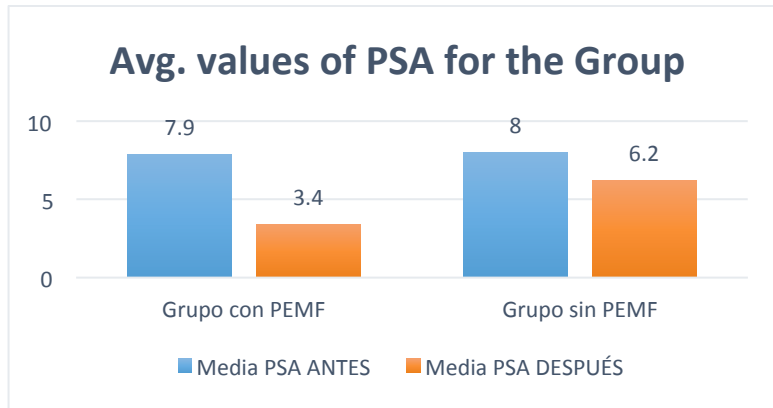
Highly significant difference between groups in favor of PEMF after treatment between ($p = 0.00$).

Table V. Analysis of the values of the erectile dysfunction questionnaire IIEF-5.

Rango de IIEF-5		Group with PEMF				Group without PEMF			
Numéric	Qualitative	Before		After		Before		After	
		No.	%	No.	%	No.	%	No.	%
22 – 25	No ED	0	0	16	26.7	0	0	0	0
17 – 21	Light ED	5	8.3	25	41.7	21	35	23	38.3
12 – 16	Mild to Moderate	29	48.3	12	20	19	31.7	17	28.3
8 – 11	Moderate ED	20	33.3	4	6.7	13	21.7	14	23.3
5 – 7	Severe ED	6	10	3	5	7	11.7	6	10
Total		60	100	60	100	60	100	60	100
Correlation of Pearson (Edad – IIEF-5)		-0.78		-0.89		-0.86		-0.85	

Evaluation of prostate specific antigen (PSA)

- The PEMF Group had a highly significant improvement in PSA three months after starting treatment ($p = 0.00$). of a mean PSA of 7.9 ng / ml dropped to an average of 3.4 ng / ml
- In the non-PEMF group it went from a mean PSA of 8.0 ng / ml to 6.2 ng / ml, ie improved, but less than the PEMF group.
- The PEMF group had a significantly higher improvement than the non-PEMF group, ($p = 0.00$)
- In the two study groups the older the age of the older patients were the PSA values.
- Age did not influence the effects of treatment.



Blue before and rust color after Group on the left with PEMF and right without PEMF.

According to Pearson's correlation there is a statistically significant difference ($p = 0.00$) in favor of the PEMF group

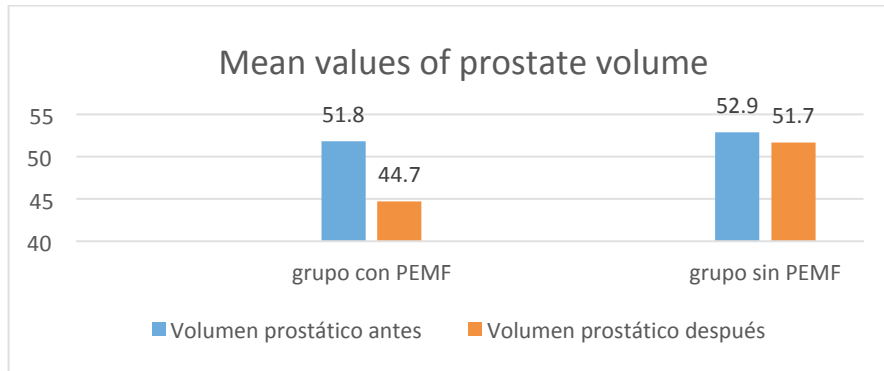
Graph 5. PSA values before and after three months of treatment started in the two groups studied.

Table II. Analysis of PSA values.

Range of PSA		Group with PEMF				Group without PEMF			
Numéric	Qualitative	Before		After		Before		After	
		No.	%	No.	%	No.	%	No.	%
2.5 – 4	Normal	0	0	55	91.7	0	0	1	1.7
4 – 10	Slightly high	53	88.3	5	8.3	53	88.3	58	96.7
10 – 19.9	Moderately high	7	11.7	0	0	7	11.7	1	1.7
> 20	Extremely High	0	0	0	0	0	0	0	0
Total		60	100	60	100	60	100	60	100

Evaluation of prostate volume (PS) results by US

- The PEMF group had a very significant improvement after treatment $p = 0.00$.
- In the group without PEMF did not improve significantly after treatment $p = 0.29$.
- The PEMF group had a highly significant improvement over the group without PEMF $p = 0.00$;
- is
- In the two groups before treatment, the greater the age of the elderly patients were the values of the prostate volume
- The prostate volume improved more in patients less aged. Age influenced treatment outcome



Blue before and rust color after Group on the left with PEMF and right without PEMF.

Highly significant difference between groups in favor of PEMF after treatment between ($p = 0.00$).

Graph 6. PV values by Ultrasound before and after three months of treatment in the two groups studied.

Table VI. Analysis of VP values by US.

Range of VP by US		Group with PEMF				Group without PEMF			
Numéric	Qualitative	Before		After		Before		After	
		No.	%	No.	%	No.	%	No.	%
0 – 20	HP 0 (normal)	0	0	0	0	0	0	0	0
20 – 30	HP I	0	0	12	20	0	0	0	0
30 – 50	HP II	16	26.7	34	56.7	27	45	27	45
50 – 80	HP III	44	73.3	14	23.3	33	55	33	55
> 80	HP IV	0	0	0	0	0	0	0	0
Total		60	100	60	100	60	100	60	100
Correlation of Pearson (Edad – VP por US)		0.79		0.79		0.83		0.83	

Discussion

The prevalence of benign prostatic hyperplasia increases linearly with age, generally affecting men over 45 years, but the presentation of symptoms usually occurs at 60 or 65 years of age, which is why in this study only patients aged 60 years and older were included.

Benign prostatic hyperplasia (BPH) is a result of urogenital aging. Studies suggest that an age-related impairment of blood supply in the lower urinary tract plays a role in the development of BPH, therefore, it may be a contributing factor to the pathogenesis of BPH.¹⁸ The primary goals of therapy for BPH are to improve symptoms, improve quality of life, halt the disease process and prevent some of the adverse effects associated with BPH, treatment goals may differ, however, depending on the of the different sectors involved: patients focus on the issue of symptom relief, quality of life and prefer a natural product with minimal side effects, particularly effects that alter sexual function or alter ejaculation; doctors are concerned about the safety of the treatment used; insurers, and funders of national health systems, seek to minimize and delay treatment costs.¹⁹

It should also be taken into account that HPB is a disease with multiple etiologies, including hormone signaling, altered apoptosis proliferation (programmed cell death) and chronic dynamics and inflammation, with changes in morphology and the stromal phenotype of the prostate. Both chronic and acute inflammation represent a mechanism for prostate hyperplasia, as well as oxidative stress, with resulting compensatory hyperplastic growth.²⁰

In patients with mild or moderate symptoms, expectant management is recommended and in many cases it is also valid for patients with moderate to severe symptoms, since the medications are not exempt of complications and the surgery is only justified in the presence of complications or that they have a very severe affection of the quality of life for this cause, reason why many patients with Benign Prostatic Hyperplasia live with symptomatology, that does not always improve with a change in the way of life.

The US National Institutes of Health (NIH) accept treatment with electromagnetic fields for the following indications: bone repair and chronic tendon injuries, nerve stimulation, wound healing and varicose ulcers, osteoarthritis, electropuncture, tissue regeneration, system stimulation immunological and neuroendocrine modulations.²² Other authors have expanded this list by adding: pain control, trauma and injury, reduction of inflammation and improvement of blood circulation, fibromyalgia, infectious processes (antimicrobial effects), specific malaria treatment, stress reduction, correction of neurological disorders, increased physical energy and athletic performance, among others.^{23,24}

Studies have been carried out where benign prostatic hyperplasia has been linked to erectile dysfunction.²⁵ Erection to a hormonally controlled neurovascular phenomenon, which consists of dilatation of the arteries, smooth muscle relaxation and stimulation of the veno-occlusive mechanism of the corpora cavernosa, Erectile dysfunction is the persistent inability to achieve and maintain a sufficient erection which allows for a satisfactory sexual performance. In spite of being considered a benign disorder, it causes an affectation to the physical and especially psychosocial health of the individual, besides that it has important repercussions on their quality of life and their partners.²⁶

PEMF has been reported to stimulate blood flow in the prostate adenoma²⁷

It has been shown that there is a positive correlation between PSA levels and prostate volume with BPH and STUI, as well as a high prevalence of erectile dysfunction that increases consistently according to age and PSA levels, ²⁸ which coincides with the However, it is interesting that in this study it was observed that PSA values and urinary symptoms improved equally in all patients who received PEMF therapy without this improvement having a correlation with age, which makes us think that this therapy acts on some aspects that can raise PSA and produce prostatic symptoms such as inflammation, and although age and prostate volume may have some influence on the symptomatology, they are not determinant, it

was also verified in these patients that although there was a marked improvement with PEMF in terms of prostate volume and erectile dysfunction as you age In patients, the improvement was lower, suggesting that the causes of prostatic growth and erectile dysfunction include in their pathophysiology more complex aspects related to age than those that produce urinary symptoms and elevate PSA levels in the adenoma prostatic, which were more sensitive to this therapy in all ages evaluated, it could be appreciated that perhaps with the application of new cycles of treatment of PEMF therapy would have been possible to obtain better results in terms of erectile dysfunction and prostate volume in patients more years.

It has been suggested that the physiological impacts of the low frequency electromagnetic field have the ability to induce different cellular changes including cell reproduction and differentiation, programmed cell death, new DNA formation, RNA synthesis, protein formulation, protein phosphorylation, redox signaling and inflammatory mediators, which leads to an increase in ATP production, hormonal secretion, increased antioxidant activity of enzymes and an improved cellular metabolic action³⁰ through cascades of molecular signaling³¹ which gives it numerous PEMF therapy biological effects including anti-inflammatory³² and suppression of pain. The mechanisms of action of PEMF therapy can explain the results obtained in this study, which not only improved symptomatology and quality of life, but also influenced the decrease in PSA values, decreased prostate volume and improved the erectile function of these patients. In other studies³³, a significant decrease in IPSS, U / S prostate size, residual urine, and urine flow rate in patients treated with PEMF compared to treatment with medication and there was also a significant improvement in clinical symptoms in the electromagnetic treatment group, monitoring patients treated for one year revealed that the results obtained by the PEMF treatment were maintained. As for the incidence of adverse reactions, they were not present in any of the treated patients, coinciding with other studies where PEMF therapy has been shown to be noninvasive, safe and easy to use.^{34, 9}

CONCLUSIONS

Therapy with pulsed electromagnetic fields in the treatment of benign prostatic hyperplasia with moderate symptomatology according to the International Scale of Prostatic Symptoms proved to be a safe and effective method that improves prostatic symptoms, quality of life, PSA values, volume prostatic and the erectile function of these patients, in the last two parameters the results were smaller the older the patients were.

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