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Long-term efficacy and safety of extracorporeal shock wave therapy (Li-ESWT) protocols in the treatment of chronic prostatitis/chronic pelvic pain syndrome (CP/CPPS) patients

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ABSTRACT

Aim: This study aims to evaluate the long-term effectiveness of Li-ESWT in chronic prostatitis/-chronic pelvic pain syndrome (CP/CPPS) patients and to compare the effect of treatment protocol differences on success.

Method: Between December 2019 and January 2021, the data of male patients over the age of 18 who applied to the urology outpatient clinic with CP/CPPS symptoms were retrospectively analyzed. International Prostate Symptom Index (IPSS) and International Index of Erectile Function—Erectile Function (IIEF-EF) questionnaires were filled in for the evaluation of erectile function. All patients received treatment with the Medispect Bold Li-ESWT. The treatment responses of the patients who received a total of 6 sessions from one session per week and 12 sessions from two sessions per week were compared.

Results: A total of 129 patients were included in the study. Significant improvements were observed in the NIH-CPSI, IPSS, and IIEF-EF scores at the third month follow-ups of the patients after EWST ($p < 0.001$ for each). Improvements in scores were also found to be significant in NIH-CPSI, IPSS, and IIEF-EF at the 12th month evaluation. When the patients were evaluated according to the number of Li-ESWT sessions they received, the IPSS score average of the patient group who received 12 sessions of Li-ESWT was found to be lower than the patients who received 6 sessions of Li-ESWT (5.67 ± 2, 30 vs 4.51 ± 2.21; $p = 0.005$). There was no significant difference in the IIEF-EF and IPSS scores in the 12th month evaluations of the patients, but the mean NIH-CPSI score was found to be higher in the group that received 12 sessions of Li-ESWT ($p = 0.003$).

Conclusion: Li-ESWT in the treatment of CP/CPPS patients shows positive improvements in urinary symptoms, erectile function, and quality of life in patients unresponsive to other medical treatments. The increase in the number of sessions does not seem to influence the symptoms of the patients.

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Introduction

Chronic prostatitis (CP) is a disease that is frequently seen in middle-aged men and can severely affect the quality of life [1]. Category III chronic pelvic pain syndrome (CPPS) is a condition characterized by disturbing pelvic discomfort and tenderness, persisting for three of the last 6 months by the National Institute of Health (NIH). All infections and other pathologies must be excluded for this diagnosis [2]. In the pathogenesis of CP/CPPS, it is held responsible that arterioles terminate between the acini, not in the glandular tissue, and the inflammation that will take place here leads to edema and ischemic [3].

CP/CPPS symptoms include prostatic inflammation, penile, pelvic, perineal pain, voiding dysfunction such as frequent urination and/or residual urine sensation, erectile dysfunction (ED), and acquired premature ejaculation [4,5]. Since the etiology has not been clearly revealed, there is no standard in treatment. Antibiotics, analgesics, anti-inflammatories, alpha blockers, 5-alpha reductase inhibitors, and phospho-

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diesterase type-5 inhibitors that can pass to the prostate tissue as medical treatment have been tried both alone and in combination, and some studies have found improvement in symptoms [6]. In addition, treatments such as electromagnetic therapy, acupuncture, thermal therapy, transcutaneous nerve stimulations, and intraprostatic Botox are among the second-line treatments [7,8]. However, the full success of all these treatment methods has not been demonstrated.

Extracorporeal shock wave therapy (Li-ESWT) has been used since 1980 in many areas and diseases for the reduction of soft tissue pain and increased blood supply [9]. Since Li-ESWT decreases muscle tone and increases local perfusion, it has been used recently in diseases such as ED, Peyronie's disease, and CP/CPPS [10]. Li-ESWT, which was first applied in CP/CPPS in 2009, provides ease of use and emerges as an effective and reliable method [11]. This effect of Li-ESWT has been shown to be decreased passive muscle tone, overstimulation of nociceptors, interruption of the flow of nerve impulses, or reduction of pain [9].

Although many studies have shown the effect of Li-ESWT on CP/CPPS, no consensus has been reached in terms of device differences, treatment protocol, and application sites [12,13]. In addition, the evaluation of the short-term effects of treatments is another problem. The aim of this study is to evaluate the long-term effectiveness of Li-ESWT in CP/CPPS patients and to compare the effect of treatment protocol differences on success.

Method

The files of male patients over the age of 18 who applied to the urology outpatient clinic between December 2019 and January 2021 with CP/CPPS symptoms and did not respond to previous treatments (antibiotic, anti-inflammatory, alpha-blocker) were retrospectively reviewed. The study was performed in accordance with the Declaration of Helsinki and written informed consent was obtained from each patient.

Patients with previous benign prostate hyperplasia (BPH) surgery, symptoms persisting for less than 3 months, patients with proven urinary tract infection, patients with previous pelvic surgery or radiotherapy, and patients with bladder stones, urethral stenosis, and neurogenic bladder were excluded from the study. Patients with a PSA >4 ng/ml were included in the study after a detailed screening for prostate cancer (biopsy, multiparametric MRI) showed benign pathology. Patients with symptoms of CP/CPPS underwent a two-cup test. Patients with negative urine analysis before and after prostate massage were included in the study as type IIIB.

Demographic data of the patients were recorded, and the degree of their symptoms was evaluated with the NIH-CPSI. In addition, International Prostate Symptom Index (IPSS) and International Index of Erectile Function—Erectile Function (IIEF-EF) questionnaires were filled in for the evaluation of erectile function.

All patients received treatment with the Medispect Bold Li-ESWT device without using any anesthesia method. In each session, using ultrasound transmission gel, 500 shock waves were applied to each point (a total of 3000 shock waves) to six points in the perineum (four points of perineal prostate projection, and to the right and left areas from the root of the penis to the prostate). The energy setting was 3 Hz frequency, and the maximum total energy flow density was 0.25 mJ/mm^2.

The treatment responses of the patients who received a total of 6 sessions from one session per week and 12 sessions from 2 sessions per week were compared. Initially, 51 patients received six sessions of ESWL. Twelve sessions of ESWL were applied to the patients after.

The NIH-CPSI, IPSS, and IIEF-EF scores of the patients at the 3rd and 12th months after Li-ESWT were compared. Side effects and complications during Li-ESWT were recorded.

The NIH-CPSI is a questionnaire that can assess the severity of CP symptoms and response to treatment [14,15]. The high score obtained from the questionnaire indicates the severity of the symptoms.

IPSS is a questionnaire consisting of seven questions and evaluating lower urinary system functions (LUTS) [16]. The score range in the questionnaire prepared with a five-point Likert scale is between 0 and 35. A high score is associated with LUTS severity.

IIEF is an inquiry form consisting of 15 questions and evaluating male sexual functions [17]. IIEF-EF is a questionnaire that includes questions 1–5 and 15 of IIEF and evaluates erectile function. The score obtained from the questionnaire is between 0 and 30. A low score is associated with ED. Turkish validation of the questionnaire was done by Turunc et al. [18].

Statistical analysis

Data analysis was done with SPSS 25.0 (IBM, NY, USA) program. Kolmogorov–Smirnov test was used for distribution. Dependent sample *t*-test and Wilcoxon test were used to evaluate symptoms before and after

Li-ESWT. Independent sample *t*-test and chi-square test were used to evaluate treatment efficacy according to the number of sessions. Significant *p* value was determined as <0.05.

Results

A total of 129 patients were included in the study. The mean age of the patients was 45.54 ± 8.32, and the mean BMI was $28.72 \pm 6.64\ kg/m^2$. The total PSA value of the patients was 1.34 ± 1.33 ng/ml, and the mean prostate volume was 31.02 ± 14.53 ml. 46.5% (60/129) were type IIIa CP, and 69 patients (53.5%) were type IIIb. There was a diagnosis of IIIb CP (Table 1).

The mean NIH-CPSI score of the patients before Li-ESWT was 19.88 ± 5.62; IPSS mean score was 12.08 ± 5.38; the mean IIEF-EF score was 18.19 ± 3.92.

Table 1. Demographic characteristics.

	Mean	SD	Min	Max	*N*	%
Age	45.54	8.32	22	58		
BMI	28.72	6.64	19.98	38.52		
CP type						
IIIa					60	46.5
IIIb					69	53.5
Total PSA	1.34	1.53	0.1	7.33		
Prostate volume	31.02	14.53	16	80		
Session number						
6					51	39.5
12					78	60.5
Baseline						
IIEF-EF	18.19	3.92	8	24		
IPSS	12.08	5.38	4	31		
NIH-CPSI	19.88	5.62	6	28		
Posttreatment 3rd month						
IIEF-EF	20.41	3.59	10	25		
IPSS	4.97	2.31	1	8		
NIH-CPSI	4.00	1.39	2	6		
Posttreatment 12th month						
IIEF-EF	20.92	2.86	12	25		
IPSS	5.81	2.96	1	16		
NIH-CPSI	5.23	2.16	2	10		

When the patients were divided into two groups according to the number of sessions (6 or 12 sessions), the number of patients who received 6 sessions of Li-ESWT was 51, while the number of patients who received 12 sessions of Li-ESWT was 78.

Significant improvements were observed in the NIH-CPSI, IPSS, and IIEF-EF scores at the third month follow-ups of the patients after Li-ESWT ($p < 0.001$ for each). Improvements in symptoms were also found to be significant in NIH-CPSI, IPSS, and IIEF-EF at the 12th month evaluation. The improvement achieved by the patients at the 3rd month after Li-ESWT continues to increase at the 12th month controls ($p < 0.001$ for NIH-CPSI and IPSS; $p = 0.032$ for IIEF-EF; Table 2). No side effects or complications were observed in the patients.

When the patients were evaluated according to the number of Li-ESWT sessions they received, no significant difference was observed in the NIH-CPSI and IIEF-EF scores at the third month after the treatment, while the IPSS score average of the patient group who received 12 sessions of Li-ESWT was found to be lower than the patients who received 6 sessions of Li-ESWT (5.67 ± 2, 30 vs 4.51 ± 2.21; $p = 0.005$). There was no significant difference in the IIEF-EF and IPSS scores in the 12th month evaluations of the patients, but the mean NIH-CPSI score was found to be higher in the group that received 12 sessions of Li-ESWT ($p = 0.003$; Table 3).

Discussion

At the end of the study, it was observed that Li-ESWT treatment applied in CP/CPPS patients provided progressive improvement in CP symptoms, LUTS, and erectile functions up to 12 months. In addition, there is no significant difference between 6 sessions of Li-ESWT and 12 sessions of Li-ESWT in terms of symptoms.

Table 2. Comparison between pretreatment and posttreatment scores.

	0–3 Difference	*p*	0–12 Difference	*p*	3–12 Difference	*p*
IIEF-EF	2.22 ± 3.31	<0.001	2.74 ± 2.37	<0.001	0.51 ± 2.67	0.032
IPSS	-7.11 ± 4.39	<0.001	-6.27 ± 3.77	<0.001	0.84 ± 1.91	<0.001
NIH-CPSI	-15.88 ± 5.26	<0.001	-14.64 ± 4.93	<0.001	1.23 ± 2.36	<0.001

Wilcoxon test.

Table 3. Comparison between 6 sessions and 12 sessions of ESWT.

	Posttreatment 3rd month			Posttreatment 12th month		
	6 Sessions	12 Sessions	*p* Value	6 Sessions	12 Sessions	*p* Value
IIEF-EF	20.02 ± 3.42	20.67 ± 3.70	0.319	21.20 ± 2.48	20.74 ± 3.08	0.381
IPSS	5.67 ± 2.30	4.51 ± 2.21	0.005	6.27 ± 3.04	5.50 ± 2.89	0.147
NIH-CPSI	4.10 ± 1.43	3.94 ± 1.36	0.518	4.55 ± 1.85	5.68 ± 2.24	0.003

Independent sample *t*-test.

In our study, a significant decrease was found in the NIH-CPPS scores of the patients. The positive improvements of symptoms obtained from the questionnaire, in which pain, QoL, and urinary symptoms were evaluated, can be explained by the short and long-term pain-relieving effect of Li-ESWT.

Li-ESWT, which provides mechanotransduction, microcavitation, and thermodynamic energy transfer, applies mechanical force to and inside the cell membrane [19,20]. With the overstimulation of nociceptors, it inhibits the stimulation of pain nerves in the old memory and can alleviate pain.

CP can sometimes be detected histologically by tissue diagnosis and may produce LUTS similar to BPH [21–23]. In CP typing, tests such as urine culture and sperm culture may be requested. In the treatment of CP/CPPS, although there is no definite consensus, new treatments are being sought [24,25]. One cause of the symptoms of CPPS is the increase of immunological inflammation with the activation of prostate afferent nerves and the induction of prostate pain and referred pain [26]. Li-ESWT plays a significant role in pain relief by triggering mechanotherapy and immunomodulatory mechanism [13,27]. In our study, significant improvements were observed in both CPSI and IPSS scores at both the 3rd month and 12th month controls of the patients. This condition is characterized by the effects of Li-ESWT on both pain mechanisms and prostatic blood flow. In our previous study, we showed that Li-ESWT treatment applied to patients with CP/CPPS symptoms also improved the symptoms of acquired PE [28]. In this study, we included all type IIIa and type IIIb patients regardless of PE symptom. Our study differs in this respect.

Treatment of CP patients is one of the most demanding and challenging issues in urology. Most current treatment options are limited to symptomatic treatments and do not treat the underlying cause. Although the precise mechanisms of shockwave therapy are currently under investigation, shockwave therapy can improve CPPS symptoms through several mechanisms, including nociceptor hyperstimulation, nitric oxide synthesis induction, passive muscle tone reduction, interruption of nerve impulses, and increased arteriolar blood flow [29]. The efficacy of Li-ESWT in CP/CPPS patients has been studied before and its efficacy has been demonstrated [30,31]. Li-ESWT, which is also used for ED, increases the synthesis of many growth factors and stem cell proliferation occurs [32]. In our study, Li-ESWT applied to the perineal region, although not to the penile region, also improves erectile functions. This agrees with other studies conducted [12,33,34].

Although studies on Li-ESWT show its effectiveness in many diseases, the lack of a standard treatment protocol and the variety of devices make it difficult for the treatment to be included in the guidelines. A recent meta-analysis stated that there are insufficient data on long-term outcomes for Li-ESWT in the treatment of ED [35]. In the same study, it was observed that the effectiveness of the treatment increased as the pulse rate increased. In a study conducted in 2018, it was observed that the increase in the number of Li-ESWT sessions did not lead to an extra improvement in treatment effectiveness. There was no difference in Erection Hardness Score changes between the groups ($p = 0.82$). In our study, however, the IPSS score of the patients showed a greater improvement in the group that received 12 sessions of therapy, only in the third month follow-up. In the 12th month follow-up of these patients, the NIH-CPSI score showed greater decrease in the group that received six sessions of Li-ESWT. This shows the long-term effects of Li-ESWT.

The study has some limitations. The first of these is the absence of a control group in the study. The Li-ESWT received by the patients was performed with a single device and no comparison was made with other devices. The lack of follow-up of the patients after 12 months is another limitation.

Conclusion

In conclusion, Li-ESWT in the treatment of CP/CPPS patients shows positive improvements in urinary symptoms, erectile function, and quality of life in patients unresponsive to other medical treatments. The increase in the number of sessions does not seem to influence the symptoms of the patients. Studies with larger numbers of patients are needed to evaluate the effect of Li-ESWT in CP/CPPS patients.

Disclosure statement

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