

P023. Efficacy of Extracorporeal Shockwave Treatment for male chronic pelvic pain syndrome: a phase III, randomized, double-blind placebo controlled study. Preliminary results.

Romero Vargas LM¹ MD; Ramón Rona S² MD, PhD; Lorente Garín JA¹ MD, PhD; Romero Tabares LD² MD; Hernández L² MD; Bielsa Galí O¹ MD, PhD.



1. Urology Service Hospital Quirónsalud Barcelona (Spain)
2. Rehabilitation Service Hospital Quirónsalud Barcelona (Spain)



INTRODUCTION

Chronic Prostatitis / Chronic Pelvic Pain Syndrome (CP/CPPS) is defined as chronic genitourinary pain or discomfort lasting at least 3 months according to the National Institute of Health (NIH). CPPS causes high morbidity and an important impact on patients' quality of life (QoL). ESWT have achieved significant improvement of CPPS-related symptoms, particularly with regard to pain. The aim of our study was to study ESWT efficacy in 40 patients suffering from CPPS.

MATERIAL AND METHODS

Randomized, double-blind, placebo-controlled study has been conducted in 40 male patients diagnosed of CPPS. One month uro-drug washout period was required. Patients were randomly assigned to receive either ESWT or ESWT placebo using a perineal approach without anaesthesia. The equipment used was the Urogold 100 (MTS) op 155 soft-wide unfocused applicator. Treatment group received 1500 impulses, 0.14 mJ/mm², 4 Hz. Control group received 1500 pulses, 0.01 mJ/mm², 4 Hz with gel membrane on the insulation head. Both groups were treated once a week during 4 weeks. The primary endpoint was pain according to the visual analogue scale (VAS). Secondary endpoints were National Institutes of Health chronic prostatitis symptom (NIH-CPSI), International Prostate Symptom Score (IPSS), International Index of Erectile Function-5 (IIEF-5), treatment satisfaction in a Likert scale and Roles and Maudsley. Ultrasound, flowmetry and cultures were performed in all study periods. Follow-up was performed 4 and 12 weeks after ESWT.

RESULTS

From 40 CPSS patients completed outpatient treatment and follow-up, only 2 patients were lost during the follow up period so 38 patients were evaluated. Mean age was 41.9 years (25-65). ESWT Group showed statistically significant improvement of pain compared to the placebo group measured by NIH-CPSI pain (6 vs. 11). These beneficial results were maintained until 12th week (5.9 vs. 9.75). QoL measured by the NIH-CPSI improved in ESWT group compared to placebo group significantly at 4th weeks (3.35 vs. 5.81) (Table 1) and 12th weeks (3 vs. 5.69) (Table 2). ESWT patients did not show erectile dysfunction according to the IIEF-5 at any time. No significant adverse events were observed throughout the study.

Table 1. Questionnaires' results at 4 weeks after the intervention

	ESWT -placebo	ESWT	p
CPSI-P	11 +/- 5.14	6 +/- 5.7	0.028
CPSI-U	4.88 +/- 3.48	3.29 +/- 2.68	0.156
CPSI-LF	5.81 +/- 3.62	3.35 +/- 2.12	0.035
IPSS	10.3 +/- 9.7	6.5 +/- 6.6	0.18
IIEF-5	22.8 +/- 4	22.5 +/- 3.8	0.83

Table 2. Questionnaires' results at 12 weeks after the intervention

	ESWT -placebo	ESWT	p
CPSI-P	9.75 +/- 5.3	5.9 +/- 5.7	0.04
CPSI-U	4.19 +/- 3.64	2.41 +/- 2.42	0.198
CPSI-LF	5.69 +/- 3.64	3 +/- 2.45	0.02
IPSS	9.44 +/- 8.8	6.41 +/- 6.5	0.31
IIEF-5	24.06 +/- 18	23 +/- 3.8	0.83

Fig 1. Treatment satisfaction (Likert Scale)

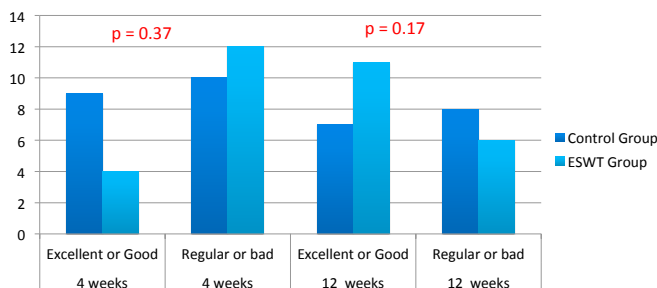
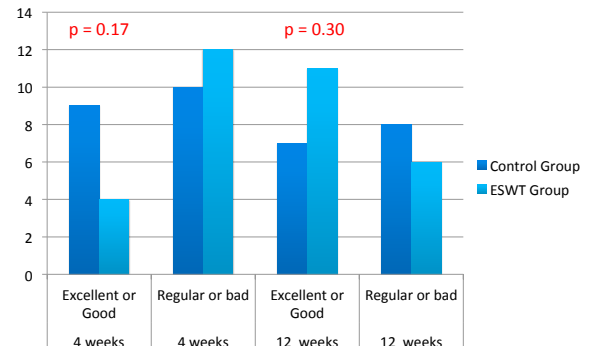


Fig 2. Roles and Maudsley Scale



CONCLUSIONS

- ESWT is a safe and effective treatment for patients suffering from CPSS.
- Further research is needed to confirm its effectiveness as first line treatment in CPSS and long-term effects.