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

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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/mm^2, 4 Hz. Control group received 1500 pulses, 0.01 mJ/mm^2, 4 Hz with gel membrane on the insulation head. Both groups where treated once a week during 4 weeks.

The primary endpoint was pain according to the visual analogue scale (VAS). Secondary endopoints were National Institutes of Health chronic prostatis 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´s 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´s 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)

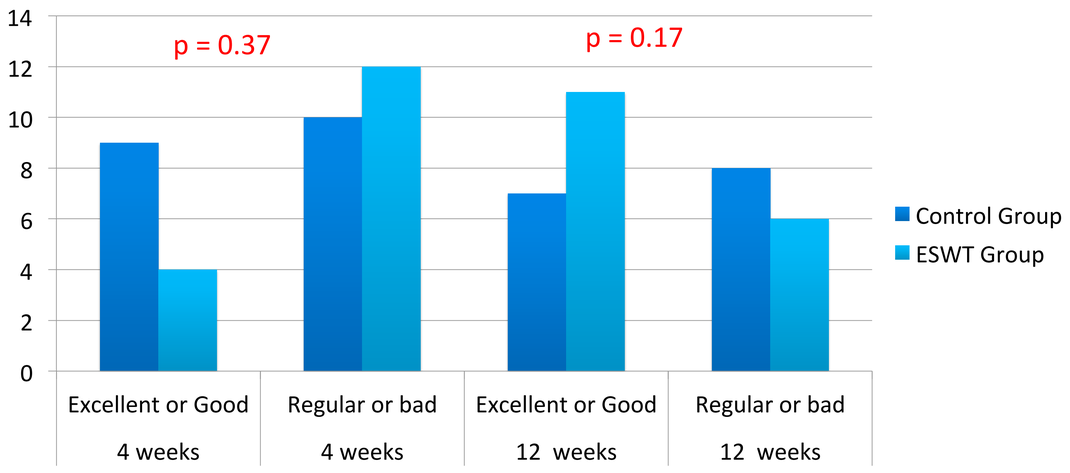
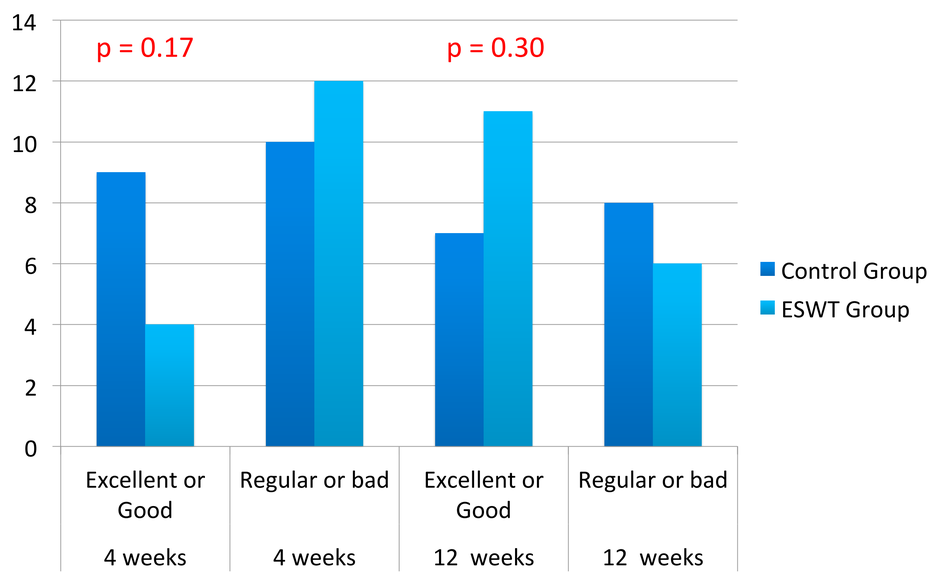


Fig 2. Roles and Maudsley Scale



CONCLUSIONS

- ESWT is a safe an 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.