Pilot Study of Low Intensity Shock Wave Lithotripsy for the Treatment of Chronic Pelvic Pain Syndrome

Introduction

Chronic Pelvic Pain Syndrome (CPPS) is a common condition in men and women and therapy can be challenging\(^1\). A majority of these patients have pelvic floor spasm as a component of their symptoms\(^2\). Successful therapy often relies on specialized physical therapy which is not widely available\(^3\). Low intensity shock wave therapy (SWT) has been available for many years outside the USA and is used to treat a number of conditions including chronic pain due to tendinitis, muscle spasm and neuropathy\(^4\). Several sham controlled studies have shown improvement in men with CPPS treated in the perineum once a week for 4 weeks\(^5\)\(^-\)\(^8\) with no adverse events reported. With long term follow up, one study reported persisted improvement at 12 weeks\(^9\) while another showed return of symptoms to baseline\(^10\). Of note, none of these studies used clinical phenotyping to stratify their patients and in particular, none commented on the presence of pelvic floor spasm or trigger points prior to therapy. There are no large scale studies in women but one positive case report\(^11\).

The DermaGold device by TRT (Woodstock, GA) delivers SWT and is covered under an IDE in the USA to treat chronic pain and improve blood flow. We wish to test the efficacy of this device in men with CPPS to see whether their symptoms improve following 4 weeks of therapy and whether that improvement persists to 12 weeks. Furthermore we plan to clinically phenotype these patients and stratify the outcomes according to the phenotype. We hypothesize that patients with clinical evidence for pelvic floor spasm will be those most likely to show a clinically meaningful response.

Aim 1: To assess the clinical utility of SWT using the DermaGold device in men with CPPS

Aim 2: To see whether men with pelvic floor spasm have a different response to SWT than those without

Protocol

Patient population: Men diagnosed with CPPS based on the NIDDK criteria\(^12\) will be offered therapy. They will be phenotyped according to the UPOINT system\(^13\) and symptom severity assessed with the NIH Chronic Prostatitis Symptom Index (CPSI)\(^14\). Clinical improvement will be defined as a 6 or greater point reduction in total CPSI\(^15\).

Primary endpoint: Change in CPSI at 12 weeks
Secondary endpoints: Change in CPSI and GRA during therapy
Proportion of patients reaching a 6 point or greater improvement in CPSI
Change in CPSI between those with and without pelvic floor spasm

Inclusion
Age > 18
CPSI pain score > 4 and total score > 21
Ability to comprehend and sign informed consent

Exclusion
History of prostate surgery (other than prostate biopsy)
History of prostate cancer
Documented urinary tract infection within the prior 3 months
Current antibiotic therapy
Inability to tolerate sitting in lithotomy position for at least 15 minutes
Patient started a new therapy for CPPS within the past 4 weeks.

Treatments
DermaGold focused probe will be applied to the perineum bilaterally. Initial energy setting 6 and increase to 7 as tolerated. Frequency 4 Hz. Total of 3000 shocks with repositioning of the probe every 500 shocks ensuring that left and right treated with 1500 total each. This gives a treatment time of 12 minutes.

Treatments weeks 1, 2, 3 and 4. Patient will fill out a CPSI at weeks 2, 3 and 4.

Phone contact at 5 and 8 weeks for adverse events and question of improvement on a 5 point GRA (significantly worse, somewhat worse, the same, somewhat better, significantly better).

Clinic visit 12 weeks with CPSI and GRA (primary endpoint)

Power calculation
We expect based on prior studies to have a mean CPSI of 25 and SD of 6. With a 6 point CPSI improvement as clinically relevant, 16 patients would give a power of 80% with alpha 0.05. Assuming a 20% dropout and that gives 20 patients.

Data Analysis
Pre and post CPSI will be compared with the paired T test. Responder/non responder based on GRA or CPSI with be assessed with the chi squared test.

Treatments and 12 week visit will be provided at no charge. Initial visit will be standard of care.
References
