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Original experimental

Evaluation of external vibratory stimulation as a treatment for chronic scrotal pain in adult men: A single center open label pilot study

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HIGHLIGHTS

- The efficacy of vibratory stimulation for treatment of scrotal pain was evaluated.
- Vibration for 20 min daily improved scrotal pain intensity and frequency.
- Vibratory stimulation appears to be a safe alternative to current treatment options.

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ABSTRACT

Background and aims: Chronic scrotal pain is a common yet poorly understood urologic disease. Current treatment paradigms are sub-optimal and include anti-inflammatory drugs and opioids as well as invasive surgical management such as microdenervation of the spermatic cord. In this study, the efficacy of external vibratory stimulation (EVS) was evaluated as an alternative treatment option for idiopathic scrotal pain.

Materials and methods: Ten consecutive patients presenting to an academic urology clinic between December 2016 and April 2017 with scrotal pain were prospectively enrolled. After a comprehensive history and physical exam, patients were presented with and oriented to a spherical vibratory device that they were instructed to use topically each day for four weeks. Average and maximum pain severity, frequency, and bother scores were tracked at 2-week intervals using a visual analog scale (0–10) via survey. Descriptive statistics facilitated interpretation of individual changes in pain.

Results: Nine men, with a median age of 46 years, completed at least 2 weeks of the study intervention. 78% (7/9) of men achieved some improvement in daily scrotal pain levels. Overall, average pain decreased from 4.9 to 2.7 ($p = 0.009$) while maximum pain severity decreased from 6.3 to 4.0 ($p = 0.013$). The frequency of pain also decreased for 55.6% (5/9) of men. No severe side effects were noted by any of the participants though several patients reported mild paresthesia only during application of the device. The majority of men expressed interest in continuing treatment after conclusion of the study.

Conclusion: External vibratory stimulation has been suggested as a promising non-invasive tool to alleviate chronic pain. As a proof-of-concept, we implemented EVS to treat men with idiopathic orchialgia. The majority of patients noted benefit in both severity and frequency of pain. Given its low risk profile, EVS deserves further evaluation and inclusion in treatment guidelines as a promising experimental therapy for a disease with few conservative treatment options available to providers.

Implications: In this longitudinal study, external vibratory stimulation was found to decrease chronic scrotal pain without any adverse effects. The use of this non-invasive, non-pharmaceutical therapy to treat chronic scrotal pain has the potential to decrease physician and patient dependence on surgical procedures and opioid prescriptions. Future randomized, double blind clinical trials with a placebo arm are required to corroborate these findings and establish the true efficacy of EVS.

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1. Introduction

Scrotal pain (SP), or orchialgia, is a common urologic condition that contributes to significant morbidity among adult men. Symptoms are often debilitating and interfere with employment, relationships, and overall quality of life [1]. Furthermore, recent findings have suggested that the prevalence of scrotal pain is on the rise along with its associated financial burden [2]. Unfortunately, current diagnostic and treatment paradigms are insufficient to adequately address this growing epidemic. Men with scrotal pain will seek on average 4.5 different opinions for their pain as physical examination and ultrasonography rarely uncover an underlying source, often leaving patients without validation of their symptoms [3,4]. Diabetic neuropathy, intracanalicular deposits, testicular trauma, and infection have all been posited as possible etiologies, though referred pain and psychogenic etiologies may also contribute [5].

While a variety of treatment modalities (i.e. medical and surgical) have been utilized to alleviate scrotal pain, their efficacy remains mostly equivocal. Conservative therapies such as nonsteroidal anti-inflammatory drugs (NSAIDs) and opiates offer temporary symptom relief for some patients, though frequently have undesirable side effect profiles and introduce risk of dependency. Surgical interventions including microdenervation of the spermatic cord (MDSC), epididymectomy, and orchiectomy have also been studied [4,5]. Yet, success rates of these invasive procedures are as inconsistent ranging from 32% to 70% [1,6,7]. In addition, surgical risks including testis loss can rarely occur. There are few treatment options currently available for men with scrotal pain that are both efficacious, noninvasive, and nonpharmacologic.

Vibratory treatment has recently been explored as a form of conservative therapy for non-urologic pain syndromes such as fibromyalgia, lower back pain, and diabetic neuropathy [8–10]. Forced mechanical oscillation, a form of non-painful vibration, activates mechanoreceptors and competitively inhibits central and peripheral nociceptors. Initially coined in 1965 as "the Gate Control Theory of Pain" by Melzack and Wall, this mechanism of pain relief has shown promise for various chronic pain conditions though has yet to be tested in the urologic setting. We thus sought to evaluate the utility of external vibratory stimulation (EVS) as a non-invasive intervention to alleviate idiopathic scrotal pain in a consecutive series of adult men presenting for care at a urology clinic in an academic medical center.

2. Methods

2.1. Patients

A longitudinal, prospective study was conducted between December 2016 and April 2017 and included 10 adult men who presented to a single academic medical center with the chief complaint of chronic scrotal pain persisting for at least 3 months. Upon physical examination, patients were excluded if they presented with an identifiable or correctable cause of pain, a condition necessitating surgical treatment (e.g. mass suspicious for malignancy or acute scrotum), or history of vasectomy. The presence of varicocele, hydrocele, or benign pathology alone did not meet grounds for exclusion. Patients were approached and consented at the initial visit and had subsequent follow-up via telephone and electronic correspondence. Institutional Review Board approval and standard ethical principles in human subject research were met and included in the consent form.

2.2. Intervention

Each patient was provided with an 8 cm NOV 506C Vibration Accue-Node Massager by HoMedics (300 N. Pontiac Trail, Commerce Township, MI), a battery-operated massage ball that produces mild vibratory stimuli. Patients were instructed to apply stimulation to the location of external ring for 20 min per day for 4 weeks. Somatic stimulation at this rate, even when self-administered at home, has previously been found to provide increasing pain relief over the course of weeks to months [11]. Mid- and post-study surveys captured the true frequency and duration of device use as well its overall comfort and ease-of-use. Patients were instructed to limit their use of pain medications to over-the-counter NSAIDs during the study period.

2.3. Data acquisition

Demographic data were obtained during the initial patient interview and supplemented by the electronic medical record. All participants completed a survey at baseline, 2 weeks, and 4 weeks which established their average and maximum pain levels over the prior 2 weeks and also the frequency and location at which they experience pain. Frequency was described by the number of pain episodes experienced per day or week. Daily pain scores were assessed at each interval using an analog visual pain scale (range 0–10). Changes in pain quality were assessed using a 5-point qualitative scale from severe worsening (−2) to drastic improvement (+2). Two-sided paired *t*-tests were utilized to describe the significance in improvement. All surveys were created and distributed using Qualtrics (Provo, UT).

3. Results

A total of 10 patients aged 28–69 years (median 46 years) were enrolled in the study with a mean duration of pain of 10.3 months. One patient was lost to follow-up immediately after enrollment while two declined follow-up after completion of the second survey (2 weeks). The majority of men presented with normal physical exams, though 2 patients had ipsilateral, epididymal head cysts which were felt to be noncontributory, and another 2 had contralateral, non-tender varicoceles. Ultrasonography (usually obtained prior to office evaluation) did not identify any correctable etiologies of scrotal pain. All but 1 patient were previously prescribed non-steroidal anti-inflammatory drugs or antibiotics as first line therapy, though no patients had undergone prior physical therapy or utilized topical heat/ice. Baseline characteristics of the study participants and their respective scrotal pain were presented in detail in Table 1.

Reduction in average and maximum daily pain severity was noted in 78% (7/9) patients. Overall, the average daily pain score decreased from a mean of 4.9–2.7 ($p = 0.009$) while the maximum daily pain score decreased from a mean of 6.3–4.0 ($p = 0.013$) over the four-week study period (Fig. 1). 5 patients also reported a decrease in the frequency of their pain. 22% (2/9) patients reported a drastic reduction of pain from more than once a day to less than once a week. Another 2 patients described their pain as being constant and unaltered by use of the device (Table 2).

All 5 men who utilized the device as instructed for 20 min per day, reported some improvement in severity and frequency of their scrotal pain over the course of the study. The 2 men who denied improvement of symptoms reported inconsistent use of the vibratory device and did not meet the recommended 20 min per session. No significant or permanent side effects were experienced.