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Incorporation of Mindfulness Exercises to Reduce Anxiety during Urodynamic Testing: A Randomized, Single-blind, Controlled Pilot Trial

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Running head: Mindfulness Based Exercises Before Urodynamics

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Introduction

Urodynamics (UDS) involves a study of the bladder in which the patient is accompanied by a healthcare team and involves placement of catheters in the bladder and/or other body cavities along with needles or probes; making the study quite invasive. Given such a setting, it is not surprising that patients experience physical and emotional distress [1,4-8]. Mindfulness based stress reduction exercises (MBSR) have shown a reduction in emotional and physical discomfort; therefore, we investigated the emotional and physical impact of short-term (MBSR-BE) breathing exercises prior to undergoing UDS [2,3].

Methods

This a single-center, investigator-blinded, randomized, parallel-group randomized control pilot trial is registered with ISRCTN registry – Trial # NCT03625843 which adhered to consort criteria and was performed between August 2016 and December 2017. Eligibility criteria were age 18 and were excluded if they were pregnant or had neurogenic bladder. Subjects randomization using permuted blocks and assignments were concealed in consecutively numbered opaque envelopes. Those in the MBSR-BE group participated in psychologist led mindfulness practice, all with the same psychologist who read the same script, which took 10 minutes to complete, while the control arm was seated into a quiet, empty room where they waited for 10 minutes.

Control and MBSR-BE groups then underwent UDS by a single blinded provider who conducted the testing. Baseline, upon undergoing control or MBSR-BE, and after UDS; anxiety and pain levels were obtained. Anxiety was assessed with the state-trait anxiety inventory (STAI-6), pain measured with a visual analog scale for pain (VAS), and after completion of UDS patients also

completed a clinically validated UDS questionnaire that measured emotional and physical discomfort [1].

Statistical analysis was performed using JMP version 12.3. Students' t-test was used to compare the continuous variables and visual analog scale scores between groups. Ordinal data was compared with the Kruskal-Wallis test, and categorical data was assessed with chi-squared test. Paired t-test along with a repeated measures ANOVA was used to compare the mindfulness versus control groups' STAI-6 and VAS over time. P-values less than 0.05 were considered significant. A sample size calculation was performed to detect a clinically significant difference of the STAI-6 with accrual of 51 equally allocated in each arm with power of 80%, alpha 5%, and to allow for a 5% dropout. This is a pilot study that is underpowered, but designed to estimate effect and feasibility.

Results

A total of 27 patients enrolled, 13 patients were randomized to the MBSR-BE arm and 14 to the control arm. Demographics, percentage of patients that had prior UDS testing, presenting symptoms, and anxiety and pain scores were similar between groups.

After UDS, anxiety was similar between groups (Figure 1), as was pain scores. Fear was statistically lower in the mindfulness group, $p=0.04$. Patient perceived physical discomfort after UDS was similar between groups. Emotional discomfort was ranked as worse than physical discomfort, by 15% of participants in the control group, this did not reach significance. Equal numbers of subjects in both groups reported the test as being as expected.

Discussion

In this study mindfulness breathing exercises did not reduce anxiety or pain; however, there are some suggestions that it has an impact on the emotional experience during UDS. The MBSR-BE group reported significantly less fear when compared to the control group. Additionally, none of the patients in the MBSR-BE group reported their worst discomfort as emotional while emotional discomfort was “the worst” as perceived by 15% in the control group which is similar to the findings reported by Suskind et al. to patients undergoing standard clinic urodynamics [1].

This study is limited by confounding effect with several patients in the control arm providing unsolicited feedback stating that they engaged in short naps or prayer while waiting in the quiet, empty room that is not typically experienced in the busy clinic waiting area. These behaviors may have created a “mindfulness effect” which might reduce anxiety or pain. As a pilot-study, it is limited in number, thus, not powered, to obtain significant differences.

Author Disclosure Statement

Pansy Uberoi, MD, MPH- No competing financial interests exist.

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