Original Article

Comparison of Two Different Distraction Methods Affecting the Level of Pain and Anxiety during Extracorporeal Shock Wave Lithotripsy: A Randomized Controlled Trial

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Abstract:

Extracorporeal shock wave lithotripsy can cause pain and anxiety for patients. Despite the use of many distraction methods to reduce pain and anxiety, there is no study on the use of stress balls during lithotripsy. The aim of the study was to investigate the efficacy of use of stress balls and music therapy to reduce pain and anxiety during lithotripsy. This was a single-center, parallel randomized controlled trial. The study involved the lithotripsy unit in a training and research hospital in Turkey. The study included 120 patients who had kidney or ureter stones. The patients were randomly divided into three groups. The control group (group 1) received no interference, whereas experimental groups received stress ball (group 2) and music (group 3) interventions during lithotripsy, respectively. Data were collected using the Patient Information Form, visual analog scale, and State-Trait Anxiety Inventory. There was no statistically significant difference among the three groups in regard to anxiety and pain mean scores ($p > .05$). No statistically significant difference was found between anxiety scores before and after lithotripsy in each group ($p > .05$), whereas there was a statistically significant difference between pain scores during and after lithotripsy ($p < .05$).Based on the present study, no statistically significant difference was found between the use of stress balls and music in reducing pain and anxiety during lithotripsy. Further studies are needed to evaluate the effectiveness of stress balls used during lithotripsy.

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Received January 6, 2016; Revised June 10, 2017; Accepted September 26, 2017.

1524-9042/$36.00

https://doi.org/10.1016/j.pmn.2017.09.005

Urinary stones are an important health problem affecting approximately 12% of the world population (Diana & George, 2013). Several factors, including gender, race/ethnicity, age, climate, vocational factors, body mass index, water consumption, socioeconomic status, genetic predisposition, and metabolic diseases, play an effective role in the formation of these stones (Aboumarzouk, Kata, Keeley, McClinton, & Nabi, 2012; Pearle & Lotan, 2012). Extracorporeal shock wave lithotripsy (ESWL) has been effectively used in the treatment of urinary stones since the early 1980s. Lithotripsy is often preferred in the treatment of urinary stones because it is a simple, successful, and noninvasive treatment method with a low risk of morbidity (Akin & Yucel, 2014; Joshi et al. 2013; Ozsaker & Diramali, 2014; Perera & Perera, 2013).

Lithotripsy procedure may cause pain in patients (Bosio et al., 2013; Ozsaker & Diramali, 2014; Yilmaz et al., 2003). The pain may result from trauma caused by shock waves passing through skin and muscles, stretching of the renal capsule around the affected area, or an increase in the internal pressure of the kidney (Ozsaker & Diramali, 2014; Salinas et al., 1999). The presence of pain affects patients' tolerance of the ESWL procedure and the effectiveness of treatment (Ozsaker & Diramali, 2014; Yilmaz et al., 2003). Furthermore, patients may experience anxiety related to the procedure before treatment. Pain during ESWL is more common in patients with anxiety (Yilmaz et al., 2003).

Various pharmacologic options, such as analgesics, opioids, and sedative agents, are used to reduce pain and anxiety (Ozsaker & Diramali, 2014; Yilmaz et al., 2003). Nonpharmacologic methods include patient education, music, hypnosis, relaxation training, distraction, biofeedback, humor, massage, aromatherapy, reflexology, acupuncture, therapeutic touch, and transcutaneous electrical nerve stimulation (Demir, 2012). In addition, the stress ball is regarded in the literature as one distraction method that may decrease the pain and anxiety of ESWL (Hudson, Ogden, & Whiteley, 2015; Pellino et al., 2005).

The nurse has a role in the successful implementation of these pharmacologic and nonpharmacologic interventions for effective pain and anxiety management (Karabulut, Gürçayır, & Aktaş, 2016). Very few studies have investigated the effects of music (Bosio et al., 2013; Cepeda, Diaz, Hernandez, Daza, & Carr, 1998; Yilmaz et al., 2003), and no studies investigating the effects of stress balls to decrease pain and anxiety during ESWL were found in the literature. Thus, we aimed to investigate the effectiveness of stress balls and music for reducing pain and anxiety in patients during ESWL in the current study.

METHODS

Trial Design

This study was a single-center, parallel randomized controlled trial. Patients (n = 120) were equally divided into three groups of 40 patients with block randomization method generated by computer (Fig. 1).

The study was conducted under the approval of the Ethics Committee of Gulhane Military Medical Academy in Ankara, Turkey (No: 50687469-1491-85-14/1648.4-464). Before data were collected, the patients were informed about the study and their approval was obtained. It was explained that they could withdraw from the study whenever they liked. The study was reported in accordance with the Consolidated Standards of Reporting Trials (CONSORT) statement. The trial is registered at clinicaltrials.gov (NCT02725281).

Participants

The inclusion criteria of the study were kidney or ureter stones eligible for the ESWL procedure based on the European Association of Urology Guideline (Turk et al., 2014), the first ESWL treatment, older than 18 years, a body mass index of 30 kilograms per square meter or less, given no analgesics before the procedure, no renal colic just before ESWL procedure, no contraindication in terms of ESWL, and no ureteral stent. The study was conducted on 120 patients who were admitted to the ESWL unit of a urology clinic in a training and research hospital in Ankara, Turkey, between April and September 2014.

The sample size of the study was calculated using the Power and Sample Size Programme (http://biostat.mc.vanderbilt.edu/wiki/Main/PowerSampleSize). Based on the literature (Yilmaz et al., 2003), a calculated sample size of at least 39 patients per group could allow for detection of a difference in visual analog scale (VAS) score of 27 millimeters between the intervention and control group, given a standard deviation (SD) of 42 millimeters with accompanying $\alpha = .05$, power $(1 - \beta) = .80$. All patients (n = 120) were randomly assigned to three groups of 40 patients per group with computer-based block randomization generated by an advisory biostatistician. Blinding of the patients was not possible because of the design of the present study.

Interventions

All patients who were admitted to the ESWL unit received the standard care protocol. This protocol was used as specific to ESWL unit of Gulhane Military Medical Academy. Standard care protocol was as follows: