The Effect of Video-Guided information on Anxiety and Pain in Extracorporeal Shock Wave Therapy: A control group study

Serkan Özcan¹, Enis Mert Yorulmaz¹*, Yuksel Yılmaz¹, Mustafa Bilal Hamarat¹, Arif Demirbaş³

¹ Department of Urology, Izmir Katip Celebi University, Izmir, TR
² Department of Urology, Health Sciences University, Konya, TR
³ Department of Urology, Afyonkarahisar Health Sciences University, Afyonkarahisar, TR

* Corresponding Author: Enis Mert Yorulmaz E-mail: enismertyorulmaz@yahoo.com

ABSTRACT

Objective: In the present study, after adapting the Extracorporeal Shock Wave Lithotripsy (ESWL) video produced by the European Association of Urology (EAU) into the Turkish language and showing it to the participating patients, we evaluated the effect on their anxiety and pain levels using the State-Trait Anxiety Inventory (STAI-I) anxiety form and the Visual Analogue Scale (VAS).

Methods: A total of 59 patients, who were assessed at three centers between July 1st and October 1st, 2020, were involved in the study. The patients were divided into two groups, the first of which was asked to fill out a consent form and was shown the video and provided with verbal and written information; On the other hand, the second group was given a consent form and received verbal and written information exclusively. Each group completed the STAI-I Anxiety form after being given preoperative information, while the VAS was applied after the procedure.

Results: The STAI-I anxiety form score was higher in Group 1 than in Group 2, and the difference was statistically significant (p=0.004), and the recorded fluoroscopy time and VAS scores were lower in favor of Group 1 (p=0.045 and p=0.021).

Conclusion: While the provision of video-guided information prior to ESWL resulted in heightened anxiety among the patients, it led to improved compliance during the procedure, as well as reduced total fluoroscopy time and pain scores for the patients.

Keywords: Kidney Stone, Extracorporeal Shockwave Therapy, Anxiety

INTRODUCTION

Kidney stones are the most common urological health issue worldwide, the incidence, prevalence and stone composition of which varies according to the geographical location (1). Kidney stones affect 9% of the population in Europe, 7–13% in North America and 1–5% in Asia (2), and the prevalence in Turkey was 14.8% in 1991, but 11.1% in more recent studies (3, 4).

The treatment options for stones include extracorporeal shock wave lithotripsy (ESWL), rigid or flexible ureteroscopy, percutaneous nephrolithotomy, open surgery, laparoscopy, medical therapy or combined therapy (5). In general, ESWL, as a minimally invasive procedure, is considered the best option for managing urolithiasis in most patients, particularly when the stone size is <2 cm (6). The ESWL method was first introduced by Chaussy et al. (7) in 1980 as an alternative to the conventional open-surgical approach to the treatment of kidney stones.

ESWL can be considered a highly advantageous treatment option, involving shorter hospital stays, more rapid recovery and lower complication rates when compared to other treatment modes. The success of ESWL depends on the quality of the machine used, the user’s experience, the stone's localisation, the anatomy of the urinary system, and more importantly, patient compliance (7).
The most current American Urological Association (AUA) and EAU guidelines identify ESWL as a valid option for the treatment of ureteral and renal stones in children (8, 9), and there have been studies recording a success rate of 93% associated with ESWL (10). ESWL, however, is not an innocuous procedure, and its adverse effects have been well documented, the most significant of which is the pain experienced during the procedure (11). The success of the technique, particularly for stones exceeding 2 cm in size, is highly dependent on the pain tolerance of the patient, as well as patient compliance. During ESWL, the cooperation of the patient while breaking up the stone and relieving their pain is important in increasing the effectiveness of ESWL. Various methods have been employed for pain management during ESWL, including general anesthesia, spinal or epidural anesthesia, local anesthesia/analgesic agents, acupuncture, opioid analgesics, analgesic anti-inflammatory agents, and sedatives (12, 13). However, the impact of patient anxiety on patient tolerance, compliance, and pain control has not been adequately explored in existing literature. This study aims to fill this gap by investigating the aforementioned relationship.

Although ESWL is a minimally invasive approach, the patient may experience considerable pain that can lead them to ask for the procedure to be interrupted, and that can cause them to feel so anxious about the procedure that they may decline or discontinue the treatment. The success of ESWL treatment is thus dependent on patient tolerance. Several medical approaches have been put forward to prevent pain, as the main contributor to anxiety and tolerance (14). Furthermore, studies have shown that anxiety can contribute to heightened levels of perceived pain (15), and that the extent of anxiety experienced can be mitigated by providing information prior to ESWL procedures (14).

Anxiety is an emotion that is manifested when there is an indeterminate sense of danger, and this can drive a person to take steps to deal with the said danger, which is usually accompanied by autonomic symptoms. When experienced at a mild level, anxiety can enhance the individual’s spontaneous attention, courage, and assertiveness. However, at high levels, it can impair perception, comprehension, and decision-making abilities (16). The State-Trait Anxiety Inventory (STAI-I), developed by Spielberger et al. (17) in 1970, is a widely utilized tool for measuring anxiety levels. As for assessing pain, the Visual Analogue Scale (VAS) is commonly employed due to its practicality and ease of converting immeasurable values into numerical values (18). This makes it particularly suitable for measuring pain experienced during ESWL procedures.

In the present study, we aimed to evaluate the effect of video-guided information prior to ESWL, as opposed to only written and verbal information, on the anxiety and pain levels experienced by patients, by using the STAI-I anxiety form and Visual Analogue Scale (VAS).

**MATERIAL and METHODS**

After gaining ethics committee approval (18.06.2020/727) for the study, and after permission for the study was also obtained from the European Association of Urology (EAU), an assessment was made of 59 patients who underwent treatment in three centers between July and October 2020. Excluded from the study were patients with whom communication was limited due to language or disorders, noncompliance, those with neurological or psychiatric disorders, or with psychiatric disorders requiring chronic sedative use, and those with acute renal colic (VAS score >0), those who had received analgesics within the previous 48 hours, those with kidney stones <5 mm or >2 cm, those with a history of operations for stones and those with a history of ESWL (Table 1).

### Table 1. Exclusion Criteria

<table>
<thead>
<tr>
<th>Criterion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lack of language communication or disorders</td>
</tr>
<tr>
<td>Patient Noncompliance</td>
</tr>
<tr>
<td>Neurological or psychiatric disorders</td>
</tr>
<tr>
<td>Psychiatric patients using chronic sedatives</td>
</tr>
<tr>
<td>Acute renal colic (VAS score &gt;0)</td>
</tr>
<tr>
<td>Use of analgesics within the previous 48 hours</td>
</tr>
<tr>
<td>Patients with kidney stones measuring &lt;5 mm or &gt;2 cm</td>
</tr>
<tr>
<td>Patients with a history of operations for stones</td>
</tr>
<tr>
<td>Patients with a history of ESWL</td>
</tr>
</tbody>
</table>

Neither group received any form of analgesia or anesthesia (topical, infiltration, sedoanalgesia, etc.) during the procedure. To prevent the potential influence of one patient on another, the study was conducted across multiple centers. The study patients were divided into two groups, and the first session of each group was evaluated. The first group was provided with a consent form and was given verbal and written information and video information about the procedure, for which the EAU ESWL video was adapted into the Turkish language (https://youtu.be/ryUelnRPOVs) before the study. The second group, in turn, was provided only with a consent form, and verbal and written information about the procedure. After being provided with preoperative information, each group filled out the STAI-I Anxiety form, and the VAS was applied after the procedure. When the planned number of patients had been reached, the results from the three centers were collected, and the age, sex, Body Mass Index (BMI), stone size, stone surface area, stone side, stone localization, stone-to-skin distance, the mean number of shock waves, and fluoroscopy time were compared statistically with the VAS scores and the STAI-I anxiety form scores. The stone surface area was calculated using the formula: stone surface area (mm²) = Width x Length x π x 0.25.

### Anxiety and Pain Scoring Systems

A psychological evaluation was made using the STAI-S form (19), and the anxiety scores were calculated as follows: among the 20 items on the form, items 1, 2, 5, 8, 10, 11, 15, 16, 19 and 20 were reverse-coded, and the total points scored from these reverse-coded items were subtracted from the total points of the remaining direct items. A fixed value of 50 points was added to the result to calculate the anxiety score. The range of possible scores was 20 to 80, with higher scores indicating greater anxiety.

Pain was assessed by the patients using the Visual Analog Scale for Pain (VAS Pain = 0–10), in which a value of zero refers to “no pain” and a value of 10 refers to “unbearable pain”.

Medical Science and Discovery, 2023; 10(7):449-454
Ethical Approval

The study protocol was approved by the clinical research ethics committee of university (approval number: 18.06.2020/727). The study conformed to the most recent guidelines of the Declaration of Helsinki and was conducted in accordance with the STROBE checklist guidelines. Prior to participation, all patients or their parents/legal guardians were provided with oral and written information about the study and signed a written consent form.

Statistical Analysis

Statistical analysis was performed with the Statistical Package for the Social Sciences (SPSS) version 21.0 for Windows (SPSS Inc., Chicago, IL). Normal distribution of continuous variables was tested with the Kolmogorov–Smirnov test. To identify the scale points that exhibited changes between the first and second tests for variables with a normal distribution, a paired samples t-test was employed. For variables with a normal distribution, the t-test was used to assess differences between the two groups. On the other hand, the Mann–Whitney U test was utilized for variables that did not follow a normal distribution. A significance level of p<0.05 was considered statistically significant.

RESULTS

The mean age of the 59 study patients was 40.1±13.1 (16–68); the male-to-female ratio was 3:2; the mean stone size was 12.4±4.5 mm, and the mean stone surface area was 99.8±77.4 (15–320). The mean number of shock waves was 2075.42±386 for all groups, and there was no difference in the number of shock waves between the two sessions (p = 0.191). No patient was observed to develop hematuria requiring transfusion. Most of the identified stones were located at the ureteropelvic junction (UPJ) [pelvic stones (37.3%)], while the second and third most common were lower pole stones and upper ureteral stones, respectively. All groups were in the overweight BMI category. The mean stone-to-skin distance was 90.17±27 mm. There was no statistical difference in sex, age, BMI, stone size, stone surface area, stone side, stone localization, and stone-to-skin distance between the groups (Table 2).

In Group 1, where members were provided with verbal, written, and video information about the procedure, the STAI-I anxiety form score was 44.1±10.5. On the other hand, in Group 2, who were only provided with written and verbal information, the score was 34.8±10.5. The difference was statistically significant, with the anxiety value higher in Group 1 (p = 0.004). The fluoroscopy time was 25.4±14.6 and 35.1±19.5 seconds in Groups 1 and 2, respectively (p = 0.045), distinctly shorter in Group 1. In the pain assessment, Group 1 recorded a mean VAS score of 6.03±2.14, compared to 7.27±2.22 in Group 2, with a lower rate seen in favor of Group 1 (p = 0.021) (Table 2), indicating that Group 1 experienced less pain.

Table 2. Characteristics and Comparative results between groups

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gender (%)</td>
<td></td>
<td></td>
<td>0.110</td>
</tr>
<tr>
<td>Male (%)</td>
<td>15 (51.7)</td>
<td>22 (73.3)</td>
<td></td>
</tr>
<tr>
<td>Female (%)</td>
<td>14 (48.3)</td>
<td>8 (26.7)</td>
<td></td>
</tr>
<tr>
<td>Age (Year) (Mean±SD)</td>
<td>41.8±12.3</td>
<td>38.5±13.9</td>
<td>0.306</td>
</tr>
<tr>
<td>BMI (Mean±SD)</td>
<td>24.5±3.3</td>
<td>26.2±4.6</td>
<td>0.074</td>
</tr>
<tr>
<td>Stone Size (Mean±SD)</td>
<td>12.3±5.4</td>
<td>12.5±3.7</td>
<td>0.643</td>
</tr>
<tr>
<td>Stone Surface Area (mm²)</td>
<td>108.4±84.4</td>
<td>91.5±70.5</td>
<td>0.773</td>
</tr>
<tr>
<td>Side (%)</td>
<td></td>
<td></td>
<td>0.795</td>
</tr>
<tr>
<td>Right, N (%)</td>
<td>13 (44.8)</td>
<td>12 (40)</td>
<td></td>
</tr>
<tr>
<td>Left, N (%)</td>
<td>16 (55.2)</td>
<td>18 (60)</td>
<td></td>
</tr>
<tr>
<td>Stone Location (%)</td>
<td></td>
<td></td>
<td>0.379</td>
</tr>
<tr>
<td>Upper Calix</td>
<td>1 (3.4)</td>
<td>2 (6.7)</td>
<td></td>
</tr>
<tr>
<td>Middle Calix</td>
<td>1 (3.4)</td>
<td>2 (6.7)</td>
<td></td>
</tr>
<tr>
<td>Lower Calix</td>
<td>8 (27.6)</td>
<td>5 (16.7)</td>
<td></td>
</tr>
<tr>
<td>Renal Pelvis-UPJ</td>
<td>11 (37.9)</td>
<td>11 (36.7)</td>
<td></td>
</tr>
<tr>
<td>Upper Ureter</td>
<td>5 (17.2)</td>
<td>6 (20)</td>
<td></td>
</tr>
<tr>
<td>Multiple</td>
<td>3 (10.3)</td>
<td>4 (13.3)</td>
<td></td>
</tr>
<tr>
<td>Stone Skin Distance (mm)</td>
<td>89.4±24.7</td>
<td>90.9±30.5</td>
<td>0.467</td>
</tr>
<tr>
<td>Mean shock waves number</td>
<td>2010.3±413.4</td>
<td>2138.3±353.7</td>
<td>0.191</td>
</tr>
<tr>
<td>Mean Fluoroscopy Time (sec)</td>
<td>25.4±14.6</td>
<td>35.1±19.5</td>
<td>0.045</td>
</tr>
<tr>
<td>VAS (0 = no pain to 10 = unbearable pain)</td>
<td>6.03±2.14</td>
<td>7.27±2.22</td>
<td>0.021</td>
</tr>
<tr>
<td>STAI-State Anxiety Score (min=20 to max=80)</td>
<td>44.1±10.5</td>
<td>34.8±10.5</td>
<td>0.004</td>
</tr>
</tbody>
</table>
DISCUSSION

ESWL is one of the standard approaches to treating ureteral and renal stones (20).

Pain is an unpleasant sensation with a somatic, emotional component that is usually associated with tissue damage (21). It is known that two different factors cause pain during ESWL. The first factor is the pain activated by the pain receptors in the skin due to the effect of shock waves on the skin and muscle tissues, and the other is the visceral organ pain experienced due to the stretching of the renal capsule (22). These two factors can be controlled partially pharmacologically, although there are also non-pharmacological approaches to pain management that not only address the physical sensations of pain, but also try to prevent pain by improving the psycho-emotional and spiritual components of care (23). In the present study, our aim was to explore non-pharmacological methods of pain control by providing video-based information to the patients. The VAS score was found to be lower in the patients who were provided with video information.

There have been studies reporting the sex of the patient to be a factor affecting pain behavior, with pain tolerance being higher in males, and reporting that this difference between females and males is a reflection of cultural attitudes towards pain (8). Stone size also influences the success of ESWL procedures, being low in stones 2 cm or larger (24). A previous study reported that small stones caused more pain during break-ups (25). In the present study, multifactorial effects were reduced by the homogeneity of the gender distribution across the groups, and the lack of statistical difference in age, BMI, stone size, stone surface area, stone side, stone localization and stone-to-skin distance, thus enhancing the reliability of our findings.

Anxiety is a physiological reaction that includes fear, restlessness and nervousness in the presence of an unidentified danger or an unknown threat and occurs when one feels unsafe. Patient anxiety levels are affected by several factors, including previous experience, reason for hospital admission, gender, age and type of surgery, or the procedure scheduled. Studies have demonstrated that 60–80% of patients feel anxious before interventional procedures or surgery (26), and this increased anxiety during procedures or surgery may lead to psychological and physiological outcomes with an adverse effect on the quality of life, work motivation, postoperative pain, analgesic consumption, long-term recovery and length of hospital stay (27–29). It was observed in the present study observed that anxiety levels increased in the group who were presented with video information, and this increase in anxiety had a positive effect on some parameters, contrary to expectations, in those with high levels. In this sense, the total fluoroscopy time, which also indicates the time to adjust the stone shocking position, and is affected by breathing and patient compliance during the procedure, was decreased, which supports the finding that anxiety increases spontaneous attention, courage and assertiveness of a person when experienced at a mild level (10).

Additionally, a decrease was observed in the pain scores of the patients in Group 1, and the theory put forward by Haber and Krainovich explains the cause of anxiety in conjunction with the behavioral theory as being the fear of the unknown, since they have never experienced this procedure before. In subsequent procedures, anxiety can be heightened as a learned behavior due to the patient's increased sensitivity to endogenous and environmental stimuli (30). In the present study, the level of anxiety increased as a learned behavior in patients who were provided with video information, but this increase was not high enough to cause the patient to lose control. Instead, it enabled patients to cooperate and prepare themselves for the experience.

The present prospective study was conducted in three centers. While this contributed to the strength of the findings, the low number of patients could be considered a limitation of the study, although this was due to the strict exclusion criteria applied; for example, a VAS score of >0 before ESWL was a direct exclusion criterion. The ongoing COVID-19 pandemic further affected the number of patients. Disorders affecting communication were a further exclusion criterion, and another limitation of our study was that the patients’ education levels, which could have affected patient compliance, were not evaluated, and it was only assessed using the fluoroscopy time. Since our objective in the study was to evaluate only patients undergoing ESWL for the first time, only the first sessions were assessed, and so the achieved success rate of breaking up the stones was not mentioned in the study.

CONCLUSION

It was concluded that although ESWL continues to be a successfully used minimally invasive approach, the addition of video information to patient information to the information provided in verbal and written forms, improved ESWL compliance, thus decreasing the total fluoroscopy time, and reducing the pain without the inclusion of pharmacological therapy. Studies involving more extensive patient series are required, and further studies could look into the benefit of providing the patient with video information ahead of other interventions.

Key Messages

1. The primary objective of this study is to assess the impact of providing patients with a video information film about the procedure on their levels of anxiety and pain. These variables will be measured using the state-trait anxiety inventory (STAI-I anxiety form) and the Visual Analogue Scale (VAS).

2. Another goal is to enhance compliance with ESWL, reducing the overall fluoroscopy time and alleviating pain without relying on pharmacological interventions. Additionally, we aim to prevent pain by focusing on enhancing the psycho-emotional and spiritual aspects of care provided to the patients.
Acknowledgements: none

Conflict of interest: The authors declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Author Contributions: SO determined the hypothesis of the study. In addition, as the main author, he analyzed and interpreted the data of patients who underwent ESWL for stones. EMY contributed to the evaluation of the resulting data. MBH made the statistics of the study and interpreted the results. AD compared the results found in the study with the literature data. SO and EMY significantly revised the study.

Ethical approval: All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and/or with the Helsinki Declaration of 1964 and later versions. This study was carried out in the urology clinic of University Hospital with the approval of the Local Ethics Committee (18.06.2020/727).

REFERENCES

