

Prospective Randomized Controlled Trial to Evaluate the Effectiveness of Watching Movies to Decrease Anxiety During Extracorporeal Shock Wave Lithotripsy

This article was published in the following Dove Press journal:
Research and Reports in Urology

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Background: Extracorporeal shock wave lithotripsy (ESWL) is the only non-invasive treatment for urolithiasis; however, it can cause anxiety and pain for patients. Several new nonpharmacological adjuvant approaches have been developed to reduce adverse events.

Objective: To analyze the efficacy of watching movies during ESWL to relieve anxiety and pain.

Methods: A total of 84 patients were randomly divided into two groups. The experimental group consisted of 42 patients who watched their own selected movies during the ESWL session, while the control group included 42 patients who did not watch movies. Basic characteristics, hemodynamic parameters, State-Trait Anxiety Inventory, Visual Analog Scale for pain, willingness to repeat the procedure, and patient satisfaction rates were collected and analyzed.

Results: After watching movies during ESWL, patients had a significantly lower anxiety level ($p = 0.001$) and a higher satisfaction rate ($p = 0.021$). No statistically significant differences were found in terms of demographic data, hemodynamic parameters, pain scores, or willingness to repeat the procedure.

Conclusion: Watching self-selected movies during an ESWL can effectively reduce anxiety and improve satisfaction.

Keywords: extracorporeal shock wave lithotripsy, movie, anxiety

Introduction

Multiple urological procedures are performed as daycare surgery without using general anesthesia. Extracorporeal shock wave lithotripsy (ESWL) has been performed as a non-invasive procedure to remove urolithiasis from kidneys and ureters since the early 1980s.¹ ESWL could be considered as the initial treatment for patients with a stone burden < 20 mm in general or < 10 mm for lower renal caliceal stones with favorable composition and anatomy.^{2,3} The anxiety and pain associated with this procedure may affect the treatment's efficacy and tolerance.⁴ Various modalities, including medicine and distraction methods, were given during the procedure to control pain and reduce anxiety.^{5,6} However, these analgesics, opioids, and sedative agents are not highly recommended because of some avoidable adverse events, including gastrointestinal and renal toxicity, respiratory distress, hypotension, and hypersensitivity reactions.^{7,8} Therefore, non-pharmacological interventions, such as

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watching movies, are commonly well-accepted by patients and may alleviate pain, fear, distress, and anxiety as well as improve mood, satisfaction and physical function.

Thus, the present study aimed to evaluate the impact of movies on pain, anxiety, and overall satisfaction in patients undergoing ESWL.

Methods

Trial Design

This study was conducted according to the Good Clinical Practice guidelines and the principles of the Declaration of Helsinki after obtaining approval from the Institutional Review Board of the Faculty of Medicine at Ramathibodi Hospital (COA. MURA2020/1). This study was also registered at clinicaltrials.in.th (TCTR20200316002). Written informed consent was received from all individual participants, who were instructed that they could withdraw their consent at any time during the study. The proposed study was a single-center, two-arm superiority trial with randomized and controlled parallel groups. Patients ($n = 84$) were equally divided into two groups ($n = 42$) by using computer-generated block randomization. Allocation concealment was performed using opaque envelopes.

Participants

The sample size of the study was calculated using STATA software version 14.1 (STATA Corp., TX, USA). Based on the literature,⁵ the required sample size is at least 38 patients per group based on a difference in means between the experimental and control groups using the visual analog scale (VAS) of 27 mm with a standard deviation of 4.2 mm ($\alpha = 0.05$ and a power $(1-\beta) = 0.80$). Thus, at an estimated dropout rate of 10%, 84 patients were required for enrollment. Patient blinding was impossible due to the methodology of the study. The primary outcome was anxiety, as measured by The State-Trait Anxiety Inventory—State Anxiety (STAI-SA). Secondary outcomes were pain, willingness to repeat the procedure, and patient satisfaction rates, as measured by the VAS.

The inclusion criteria included patients who were undergoing ESWL for renal or ureteral stones with a diameter up to 20 mm and who were over 18 years of age. The exclusion criteria included patients who exhibited absolute contraindications for ESWL, possessed a congenital renal anomaly, were receiving ongoing anticoagulant medication, had received an analgesic before the

procedure, had suffered renal colic just prior to ESWL, had hearing or vision problems, or who failed to comply with experimental methods.

Settings, Protocol, and Interventions

The study took place at the ESWL unit at the Faculty of Medicine Ramathibodi Hospital from March 2020 to August 2020. All patients were managed on an outpatient basis, undergoing a lithotripter system (Storz Modulith® SLK, Storz Medical, Switzerland). Ultrasound and fluoroscopy localization were utilized in the supine position to detect both renal and ureteric stones. A highly experienced technician performed all sessions under the supervision of a urologist. Patients with calyx and renal pelvis stones received 4000 impulses, with energy levels between 70 and 90 at a rate of 60 impulses per minute. Ureteral stones received 6000 impulses with energy levels between 70 and 90 at a rate of 90 impulses per minute.

For each patient, a midstream-voided urine specimen was collected preoperatively, and a standard urine culture test was performed only on those who were suspected of having a urinary tract infection. Intravenous fluid and analgesic drugs were not given during the procedure. Fluoroscopy and ultrasound imaging were used to localize and focus the stone. ESWL treatment was terminated if satisfactory fragmentation was noted before delivering the maximum number of impulses as stated in the protocol. All patients were placed on bed rest and closely monitored in the recovery room for their vital signs for one hour after finishing ESWL. Patients were followed up after a period of 4 weeks with X-Ray or ultrasound KUB.

A registered nurse (P.T.) provided information to all patients regarding the study protocol. The patients who met the inclusion criteria were divided equally into two groups: Group 1 consisted of patients who did not receive an intervention during ESWL, and Group 2 consisted of patients who watched the movie of their choice using an iPad. All available films present on Netflix in Thailand in 2020 were available for the patient to watch, and the genres included musicals, romances, and children/family movies. The intervention started five minutes before the procedure and continued through the process. This study was performed with Apple iPad 6 Wi-Fi + Cellular (9.7", 128GB).

Measures

The State-Trait Anxiety Inventory is a self-assessment inventory initiated by Spielberger, translated into the

Thai language, and evaluated for reliability by T. Nonthasak.⁹ The Cronbach's alpha of this questionnaire was 0.78. The STAI-SA consists of 20 items measuring different emotional scenarios on a 4-point Likert rating scale, with a total score ranging from 20 to 80, where higher scores corresponding to higher anxiety levels. STAI scores are generally classified as "no or low anxiety" (20–37), "moderate anxiety" (38–44), and "high anxiety" (45–80).¹⁰ State anxiety measures were taken five minutes after the ESWL procedure.

The Visual Analogue Scale for pain, satisfaction, and willingness to repeat the procedure is a horizontal line 10 cm long. At the beginning and at the end, there are two descriptors to illustrate the extremes of perception (specifically, no pain and extreme pain). The patient makes a vertical mark on the 10 cm line to indicate their feelings. The measurement in centimeters is converted to the same number of points, ranging from 0 to 10 points.

Stone free status was determined as complete stone clearance or clinically insignificant residual fragments of ≤ 4 mm on radiological imaging at the time of the first follow-up appointment.

Statistical Analysis

Statistical analysis was performed with STATA version 14.1 (STATA Corp., TX, USA). Descriptive statistics for continuous variables were expressed as mean $\pm$ SD or median (min–max), where applicable. The number of cases and percentages were used as categorical data. A Pearson chi-square test was used for statistical comparison of the categorical variables. Normal distribution of continuous variables was tested with the Kolmogorov–Smirnov test. To determine differences between the two groups, a two-sample *t*-test was used for variables with normal distribution, while a two-sample Wilcoxon rank-sum (Mann–Whitney) test was used for non-normal variables. A *p*-value < 0.05 was accepted as significant.

Results

There were 104 total eligible patients, and 20 (19.2%) patients were excluded from the study before assignment to each arm. Eight of these excluded patients refused to engage in the trials, and the other 12 excluded patients failed to meet the inclusion criteria. The remaining 84 subjects, consisting of 54 males and 30 females, were enrolled in this study. Thus, the experimental and control groups consisted of 42 subjects each. The average kidney stone size was 7.29 ± 2.65 mm (range: 3–15 mm) and the

average ureteric stone size was 7.00 ± 2.16 mm (range: 5–13 mm). Most of the patients (52.3%) did not have any chronic diseases, but 44.0% and 20.2% of the patients exhibited hypertension and diabetes mellitus, respectively. Overall stone clearance rate was 83.3%. Figure 1 illustrates the flow diagram of the present study according to the CONSORT statement. No statistically significant difference was found among the groups regarding baseline characteristics, stone factors, and operative variables, as shown in Table 1.

Peri-operative hemodynamic responses, including systolic and diastolic blood pressure, pulse rate, and respiratory rate, are shown in Table 2. A comparison of these parameters between the control and experimental groups revealed that the experimental group was better; however, the differences did not reach statistical significance. Table 2 also illustrates STAI-SA scores and the VAS scores of pain, willingness to repeat the procedure, and satisfaction of the two groups. The patients in the experimental group had significantly lower mean postoperative STAI-SA scores and higher satisfaction scores compared to the control group (47.90 ± 2.64 vs 52.04 ± 7.50 , *p* = 0.001 and 8.90 ± 2.12 vs 7.69 ± 2.58 , *p* = 0.021, respectively). However, there were no significant differences in terms of willingness to repeat the procedure and VAS-pain. Hematuria requiring transfusion was not seen in either group. No patient was discontinued earlier than planned.

Discussion

The present study was conducted to assess the effectiveness of a complementary practice of watching self-selected movies during an ESWL period. The experimental group presented significant reductions in anxiety scores as well as improvements in satisfaction score. Findings also indicated that there was a decreased perceived intensity of pain and increased willingness to repeat the procedure, albeit non-significant, in the experimental group.

Individuals with renal or pelvic calculi experience a period of intense pain and poor physical function when compared to the general population.¹¹ Furthermore, a high recurrence rate increases the chance of patients experiencing major depression, which negatively impacts their quality of life as it develops into a chronic problem. Lien et al¹² demonstrated that patients with kidney stones who were followed over a 10-year period were found to have a 50% increased risk for anxiety and a 26% increased risk for depression compared with those individuals without urolithiasis. Furthermore, patients undergoing ESWL had

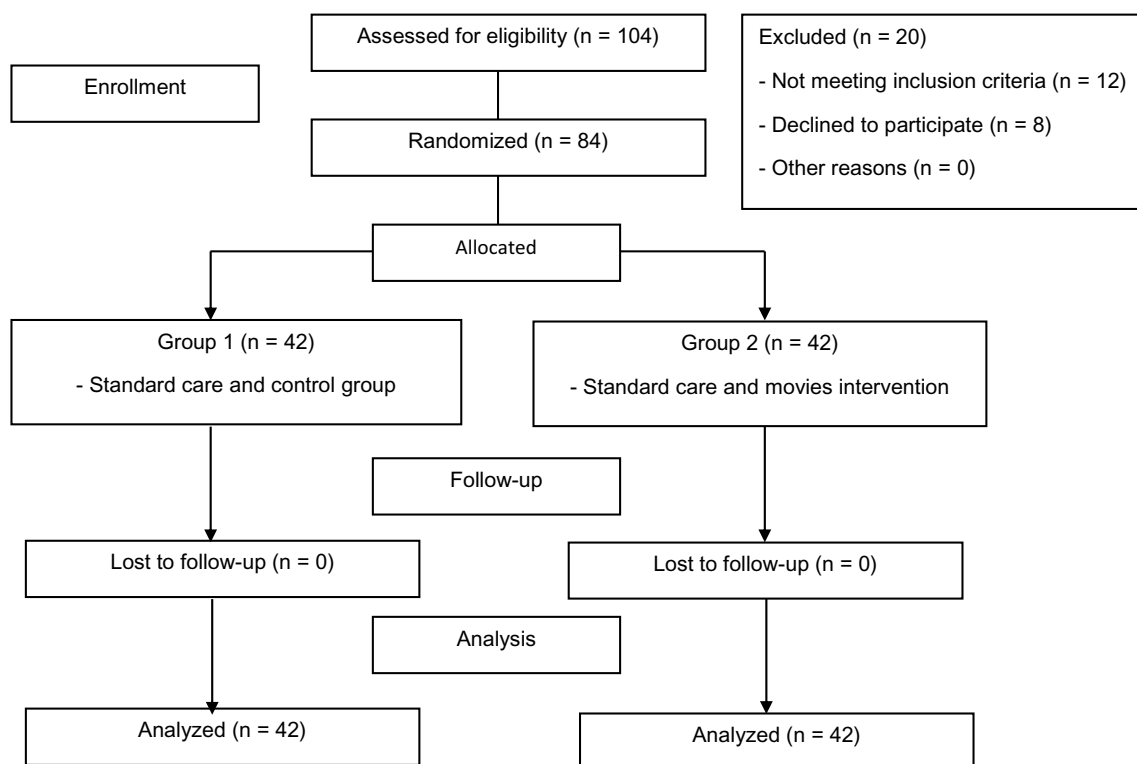


Figure 1 Flowchart of the randomized controlled trial.

significantly higher anxiety than those undergoing ureteroscopic lithotripsy and PCNL. The reason for this anxiety may be that an ESWL session requires the patient to be awake and constantly lying in the supine position without moving the body for a period of time. In addition, the annoying sounds from the large ESWL machine may lead patients to feel uncomfortable and stressed, causing them to move.¹³

Movies are one of the new modalities of non-pharmacological interventions used for reducing the level of pain and anxiety during the procedure. This intervention is without side-effects and costs little compared to other pharmacological options. The mechanism for this distraction is caused by stimulating sensory components, activation brain-related pleasure centers faster than nociceptor centers, increasing pain tolerance, and relieving distress. Furthermore, having self-selected movies is an essential part of the process since personal media preference increases autonomic reactivity.^{14,15} In the present study, we provided multiple different genres of films that the patients could choose, and we found that the patients were appreciative of this fact and enjoyed the films. The possible choices included romantic movies, kid/family movies, and musicals. Comedies and horror films were

not selected for our study because of the necessity for constant patient positioning, and laughing or frightened reactions can lead to body movements that affect the precision of ESWL. Some procedures, such as dialysis and venipuncture, have integrated this distraction method into their processes and found it effective in reducing anxiety and depression. Morais et al¹⁶ evaluated the effect of watching comedy movies as a complementary practice during dialysis and found significant improvements regarding anxiety and depression scores (5.0 vs 3.0 ($p = 0.016$) and 7.0 vs 4.0 ($p = 0.017$), respectively). Inan et al¹⁷ reported that children watching cartoon movies during the procedure of achieving vascular access felt less anxiety score ($p < 0.01$). However, at the present time, there have been no clinical trials on the use of movies for relieving pain and anxiety during ESWL.

The present study found a lower anxiety score in the experimental group compared to the control group, with a statistically significant difference ($p < 0.001$). Regarding this outcome, the hypothesis that post-ESWL anxiety levels decrease in patients with urolithiasis who watch movies on demand has been confirmed. Furthermore, we also noticed a significant increase in satisfaction by incorporating movies into the therapeutic

Table I Demographic Data

	Group 1 (No Movies) (n = 42)	Group 2 (Movies) (n = 42)	Total (n = 84)	p-value
Age (year) (mean $\pm$ SD)	54.42 $\pm$ 10.62	57.04 $\pm$ 11.25	55.73 $\pm$ 10.95	0.276
Gender: n (%)				
Male	28 (66.7)	26 (61.9)	54 (64.3)	0.649
Female	14 (33.4)	16 (38.1)	30 (35.7)	
BMI (kg/m ²): (mean $\pm$ SD)	25.71 $\pm$ 4.81	26.60 $\pm$ 4.48	26.16 $\pm$ 4.64	0.286
Economic Situation: n (%)				
Low	7 (16.7)	4 (9.5)	11 (13.1)	0.457
Middle	26 (61.9)	25 (59.5)	51 (60.7)	
High	9 (21.4)	13 (31.0)	22 (26.2)	
Place of residence: n (%)				
City	28 (66.7)	31 (73.8)	59 (70.2)	0.655
Town	6 (14.3)	6 (14.2)	12 (14.3)	
Village	8 (19.0)	5 (12.0)	13 (15.5)	
Education: n (%)				
Illiterate	1 (2.4)	2 (4.8)	3 (3.6)	0.657
Primary school	9 (21.4)	5 (11.9)	14 (16.7)	
High school	10 (23.8)	11 (26.2)	21 (25)	
University	22 (52.4)	24 (57.1)	46 (54.8)	
Marital status: n (%)				
Unmarried	7 (16.7)	6 (14.2)	13 (15.5)	0.743
Married	32 (76.2)	31 (73.8)	63 (75)	
Divorce	3 (7.1)	5 (12.0)	8 (9.5)	
Stone size (mm ²) (mean $\pm$ SD)	7.33 $\pm$ 2.13	7.04 $\pm$ 2.80	7.19 $\pm$ 2.48	0.601
Stone laterality: n (%)				
Right	16 (31.8)	20 (47.6)	36 (42.9)	0.378
Left	26 (61.9)	22 (52.4)	48 (57.1)	
Stone location: n (%)				
Pelvis	7 (16.7)	4 (9.5)	11 (13.1)	0.663
Calices	20 (47.6)	23 (54.8)	43 (51.2)	
Upper ureter	7 (16.7)	5 (11.9)	12 (14.3)	
Lower ureter	8 (19.0)	10 (23.8)	18 (21.4)	
Duration of the procedure, (min) (mean $\pm$ SD)	72.26 $\pm$ 14.36	71.30 $\pm$ 12.92	71.78 $\pm$ 13.59	0.750
Number of shockwave (impulses) (mean $\pm$ SD)	4690.47 $\pm$ 896.82	4619.04 $\pm$ 961.51	4654.76 $\pm$ 924.00	0.726

(Continued)

Table 1 (Continued).

	Group 1 (No Movies) (n = 42)	Group 2 (Movies) (n = 42)	Total (n = 84)	p-value
Type of movie: n (%)				
Music Movies	11 (26.2)	10 (23.8)	21 (25)	0.799
Romantic movies	19 (45.2)	22 (52.4)	41 (48.8)	
Children & family movies	12 (28.6)	10 (23.8)	22 (26.2)	

Abbreviations: BMI, body mass index; ESWL, extracorporeal shock wave lithotripsy; SD, standard deviation.

Table 2 Hemodynamic Parameter, Anxiety, Pain, Satisfaction, and Willingness to Undergo ESWL

	Group 1 (No Movie) (n = 42)	Group 2 (Movie) (n = 42)	Total (n = 84)	p-value
Pre-ESWL SBP (mm Hg) (mean $\pm$ SD)	134.26 $\pm$ 11.64	135.11 $\pm$ 11.82	134.69 $\pm$ 11.66	0.739
Pre-ESWL DBP (mm Hg) (mean $\pm$ SD)	81.19 $\pm$ 8.16	82.59 $\pm$ 10.34	81.89 $\pm$ 9.29	0.492
Pre-ESWL PR (beats/min) (mean $\pm$ SD)	78.85 $\pm$ 12.79	79.52 $\pm$ 10.87	79.19 $\pm$ 11.80	0.798
Pre-ESWL RR (breaths/min) (mean $\pm$ SD)	18.61 $\pm$ 1.49	19.02 $\pm$ 1.10	18.81 $\pm$ 1.32	0.161
Post-ESWL SBP (mm Hg) (mean $\pm$ SD)	133.02 $\pm$ 9.64	128.52 $\pm$ 17.83	130.77 $\pm$ 14.43	0.154
Post-ESWL DBP (mm Hg) (mean $\pm$ SD)	78.54 $\pm$ 9.82	76.47 $\pm$ 9.46	77.51 $\pm$ 9.64	0.328
Post-ESWL PR (beats/min) (mean $\pm$ SD)	72.21 $\pm$ 9.11	71.61 $\pm$ 8.05	71.91 $\pm$ 8.55	0.752
Post-ESWL RR (breaths/min) (mean $\pm$ SD)	18.76 $\pm$ 1.16	18.64 $\pm$ 1.55	18.70 $\pm$ 1.36	0.693
Post-ESWL STAI-S (20–80) (mean $\pm$ SD)	52.04 $\pm$ 7.50	47.90 $\pm$ 2.64	49.97 $\pm$ 5.96	0.001*
VAS-Pain (0–10) (mean $\pm$ SD)	2.47 $\pm$ 2.02	2.33 $\pm$ 2.23	2.40 $\pm$ 2.12	0.760
VAS-Satisfaction (0–10) (mean $\pm$ SD)	7.69 $\pm$ 2.58	8.90 $\pm$ 2.12	8.29 $\pm$ 2.43	0.021*
VAS-Willingness to repeat (0–10) (mean $\pm$ SD)	2.11 $\pm$ 2.09	2.35 $\pm$ 2.41	2.23 $\pm$ 2.25	0.631

Note: *Statistically significant.

Abbreviations: DBP, diastolic blood pressure; ESWL, extracorporeal shock wave lithotripsy; PR, pulse rate; RR, respiratory rate; SBP, systolic blood pressure; SD, standard deviation; STAI-S, State-Trait Anxiety Inventory-State; VAS, visual analog scale.

strategy (7.69 vs 8.29, $p = 0.021$). The other benefit that was found in this study was that VAS-pain scores were lower and the willingness to repeat the procedure was higher in the experimental group. Thus, it can be postulated that watching movies during an ESWL period enhances patient contentment and compliance. The multiple distraction method demonstrated the ability to decrease anxiety and pain and improve satisfaction in our study. Marsdin et al,¹⁸ in their prospective analysis, demonstrated that audiovisual distraction during shock wave lithotripsy can reduce pain perception score (6.1 vs 2.4, $p < 0.001$) and the distress score (4.4 vs 1.0, $p = 0.0001$). Akbas et al¹⁹ investigated the effects of preferred music listening on anxiety, overall satisfaction, and pain perception in 400 patients undergoing an

ESWL session. They found that music not only had a beneficial effect on the patient's pain and anxiety but also provided greater treatment satisfaction. Listening to music during stone crushing decreased the STAI-SA and VAS pain scores ($p < 0.001$) and increased the satisfaction rate ($p < 0.001$). Kararmaz et al²⁰ revealed the superior effect of using conventional transcutaneous electrical nerve stimulation therapy modality (impulse pattern: continuous at 80 Hz; intensity: 10–30 mA) during ESWL in order to decrease the analgesic requirements and for providing more satisfaction ($p < 0.0001$ and $p < 0.05$, respectively). For the acupuncture method, Hodzic et al²¹ found that the analgesic effectiveness of acupuncture during ESWL at the following points: colon 4 bilateral, liver 3 bilateral, urinary bladder 23 bilateral, gall bladder

25 contralateral to the stone, circulation 6 bilateral, and RenMai was significantly superior to drugs, including pethidine and diazepam.

A previous study found that a distraction method can also have a positive effect on hemodynamic parameters. Cakmak et al²² revealed that systolic blood pressure, diastolic blood pressure, and pulse rate were significantly lower in patients who listened to music during ESWL compared to patients who did not ($p = 0.002$, $p = 0.024$, and $p = 0.001$, respectively). This outcome is comparable to the Yilmaz et al⁵ study in 2003. The present study indicates that after finishing an ESWL session, all hemodynamic variables were lower in the experimental group; however, the difference was not statistically significant. This is in line with both positive and negative physiological responses to using or not using nonpharmacological therapy, respectively, during stressful situations.

This is a pioneering study illustrating the application of movies as a complementary therapeutic intervention during ESWL. The strength of our study lies in its prospective nature. However, our study had several limitations. First, stone analysis and stone-free status were not investigated, although the present study did focus on anxiety, pain, and satisfaction during ESWL. Thus, stone compositions or stone-free rates were not essential outcomes. Second, the Trait Anxiety Scale was not used to evaluate patients in terms of the stable aspects of anxiety proneness. Finally, the results of the present study may not be applied to all lithotripsy centers because of the specific model of ESWL machine used at this single site.

Conclusion

Supplementation with movies during ESWL is a safe, inexpensive, and efficient method of lowering patient anxiety and improving patient satisfaction. Additional studies involving larger samples are necessary to validate the beneficial effects of movies during ESWL.

Data Sharing Statement

The authors intend to share individual data. Deidentified data regarding patients' characteristics, hemodynamic parameters, State-Trait Anxiety Inventory, Visual Analog Scale for pain, willingness to repeat the procedure, and patient satisfaction rates will be made available upon request to Ms. Timjapoe (Division of Urology, Department of Surgery, Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand, phanida.timj@gmail.com) right after the publication and for a period of six months, until September 2021. No other study documents will be available.

Acknowledgments

The authors would like to express our appreciation for all the health personnel and patients who agreed to participate in the study, as well as the support of the Clinical Epidemiology and Biostatistics, Faculty of Medicine, Ramathibodi Hospital.

Disclosure

The authors have no conflicts of interest to declare.

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