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Comparing Anxiety Levels and Pain Scores for Video-assisted and Traditional Informed Consent in Extracorporeal Shockwave Lithotripsy: A Prospective, Randomised, Controlled Study

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Authors' contributions

This work was carried out in collaboration among all authors. Author NZSH wrote the manuscript and contributed to the research design, analysis, and interpretation of data. Other authors supervised the study and wrote the manuscript. All the authors have read and approved the final version of the manuscript

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ABSTRACT

Aims: Traditionally, informed consent involves verbal and/or written material provided to the patient by a treating clinician. Multimedia interventions improve patients' knowledge and understanding during the informed consent process. This study aimed to compare pre-procedural anxiety levels

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and pain scores between educational video-assisted informed consent and traditional informed consent for extracorporeal shockwave lithotripsy (ESWL) at our centre.
Study Design: This was a prospective, randomised, controlled study conducted at two centres.
Place and Duration of Study: The study was conducted in two Urology centre Department of Urology, Penang General Hospital and Department of Urology, Hospital Kuala Lumpur between 15th May 2022 till 15th October 2022.
Methodology: The study group consisted of all adult patients undergoing ESWL in. both centres. A video presentation explaining the ESWL procedure was developed in two languages, and group allocation was randomised using a computer-based random number generator. Anxiety levels were assessed using the Amsterdam Preoperative Anxiety and Information Scale (APAIS) questionnaire, visual analogue scale, and numerical rating scale used to collect data on pain scores.
Results: A total of 54 respondents, with a predominance of male patients (57.4%) and the majority of patients having completed secondary school education (53.7%). In comparing the two groups, the video-assisted respondents exhibited significantly lower anxiety scores regarding the procedure than those in the traditional group ($p < 0.05$). However, there were no statistically significant differences between the groups in terms of pain scores, both pre- and post-procedural.
Conclusion: Video-assisted informed consent can reduce procedure-related patient anxiety levels before ESWL; however, there was no difference in pain scores between the two consent methods. patients.

Keywords: Informed consent; video-assisted; ESWL; anxiety; pain score; randomized controlled trial.

1. INTRODUCTION

Informed consent is essential for clinicians to provide comprehensive information regarding intended medical procedures. Informed consent describes the indications, risks, benefits, and alternatives of the procedure. It is important that patients have sufficient information about the procedure to allow them to make appropriate decisions regarding their treatment options. Informed consent is a way to respect patient's autonomy, dignity and rights. [1].

Traditionally, the informed consent process involves verbal and/or written material provided to the patient by a treating clinician. However, this traditional approach can be time-consuming, increasing the likelihood of patient misunderstanding and inadequate comprehension of the procedure. Effectively communicating complex medical information to individuals who may not possess a deep understanding of the subject matter presents a significant challenge. Thus, there is a need to explore alternative methods to improve patient understanding of the informed consent process. Several methods have been explored to increase patient knowledge, including multimedia interventions, feedback modules, and extended discussions [2]. In a review by Nishimura et al. [2], it was found that five of the sixteen total multimedia interventions (31%) resulted in a significant improvement in understanding of the informed consent process [2]. Chill, Dior, and Shveiky [3] expressed a favourable clinical opinion regarding the use of multimedia during the informed consent process [3]. Tait and Voepel-Lewis [4] also reported increasing effectiveness and acceptance of multimedia tools for research and healthcare consent [4]. There is potential drawbacks of using digital tools for informed consent, such as technical issues, accessibility, cost and privacy [5].

Extracorporeal shockwave lithotripsy (ESWL) is a common procedure performed in our urology unit for the management of urolithiasis. ESWL is a procedure where shockwave delivered externally to fragment stone. Traditionally, oral and written informed consent is obtained prior to the procedure. However, elucidating how ESWL functions and its role in the management of urolithiasis can sometimes pose challenges. Patients are often unable to visualize how the procedure will be performed, potentially leading to incomplete information delivery to patients, which may further confuse them. Multimedia tools could help patients to visualize the procedure such as videos, animations or interactive simulations.

1.1 Anxiety

Pre-procedural anxiety is common and important issue in pre operative setting. A study conducted by Paton et al. [6] demonstrated that the use of multimedia teaching tools significantly decreases anxiety levels [6]. Limitation of the study by

Paton et al. [6] is small sample size, lack of control group and use of a single surgical procedure. Moerman et al. developed the Amsterdam Preoperative Anxiety and Information Scale (APAIS) in 1996, which comprises self-report questionnaires [7]. It includes six self-reported items that gauge anxiety and the need for information, rated on a five-point Likert scale. It was originally a Dutch version and has been validated in the Malay version by Mohd Fahmi et al. [6]. It is a simple and reliable instrument for assessing anxiety, widely utilised across the globe.

1.2 Pain Score

Cognitive impairment caused either by pain or opioids can interfere with the informed consent process [7]. In a study by Elke et al. (2018), the median pain score during ESWL was 5, despite the administration of analgesia [8]. Patients with anxiety also experienced different levels of pain perception during the procedure. A study by Felice et al. (2020) suggested that effective anxiety management can reduce the need for analgesia during office procedures [9]. However, no study has compared the differences in pain scores between patients who underwent traditional informed consent and those who received educational video-assisted consent.

Currently, no studies have compared the use of educational video-assisted informed consent with traditional informed consent for ESWL for urolithiasis. Our study aimed to investigate the impact of educational video-assisted informed consent on pre-procedural anxiety levels and pain scores. We hypothesized that educational video-assisted informed consent would reduce anxiety and result in lower pain scores in the intervention group. This could lead to more robust use of educational video during consent process in urological procedure.

2. MATERIALS AND METHODS

2.1 Aim

This study aimed to assess pre-procedural anxiety levels between educational video-assisted informed consent and traditional informed consent for ESWL. Our secondary objective was to compare the pain scores between educational video-assisted informed consent and traditional informed consent for ESWL. We hypothesized educational video-assisted informed consent reduces anxiety and pain compared to traditional informed consent group.

2.2 Study Type and Design

This was a prospective, randomised, controlled study conducted in two tertiary healthcare centres. The study group included all adult patients undergoing ESWL between 15 May 2022 and 15 October 2022 in both centres.

A video presentation of the ESWL procedure was developed by the research team members using online software. The content of the video was adapted based on The British Association of Urological Surgeons (BAUS) guideline on ESWL for stones and is available in both Malay and English languages. The video content included how ESWL was performed and what patients could expect during and after the procedure. The video lasted about two minutes in both languages. In both centres, the video was played in the waiting area after registration. I-Pad and TV was used to play the video once patient is consented for the study. The video is played once based on preferred language and ample time given to ask for questions. All patients had no further questions after the video was played.

Group allocation was achieved through simple randomisation based on odd and even numbers generated using a computer-based random number generator. The randomization was concealed and blinded.

2.2.1 Anxiety level

All participants provided informed consent and completed a validated questionnaire regarding their anxiety levels using the Amsterdam Preoperative Anxiety and Information Scale (APAIS). It includes six self-reported items assessing anxiety and the need for information, rated on a five-point Likert scale. Both the Amsterdam Preoperative Anxiety and Information Scale (APAIS) and validated Amsterdam Preoperative Anxiety and Information Scale (APAIS) in Malay were used to measure the anxiety levels. Cronbach's alpha coefficient for APAIS and the Malay version of the questionnaire was 0.93 and 0.90 for anxiety and need for information respectively. Reliability of the total questionnaires was reported as alpha value of 0.906. Validity of the questionnaire were reported as inter-items correlation ranging 0.40 to 0.88 and Kaiser-Meyer-Olkin measure of sampling adequacy reported it was at 0.755. The anxiety score of > 11 were reported as anxious group of patients. The information seeking were categorized as low (2-4), intermediate (5-7) and high (8-10).

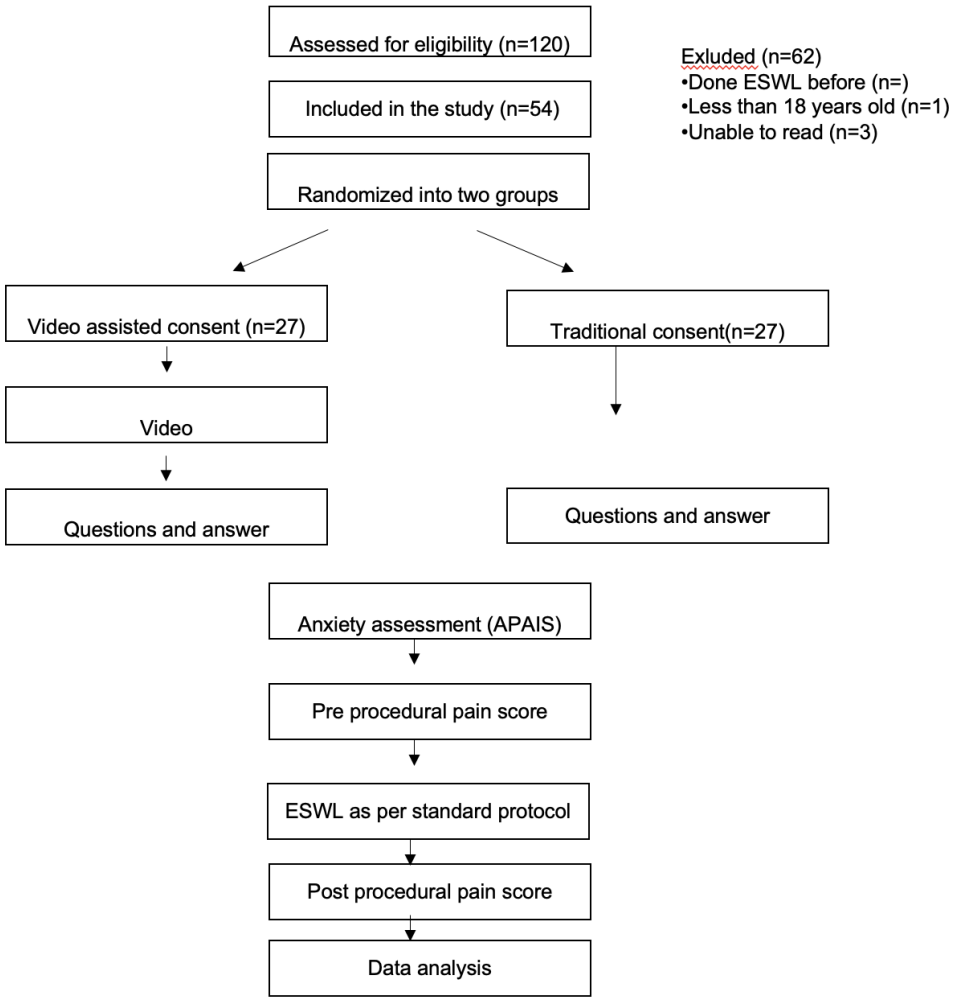

Diagram 1. Consort diagram of the study

2.2.2 Pain score

The visual analogue scale (VAS) and numeric rating scale (NRS) were used to assess the pain scores before and after the procedure. The pain score was measured before starting ESWL procedure and after ESWL was completed. Participants self-reported their pain score on data collection form before and after the procedure. All participants used numeric rating scale for pain score in our study.

2.3 Study Population

All adult patients were scheduled for ESWL in the ESWL Suite at both centres during the study period screened. Total of 120 patients was screened during the study period in both centres. Both study centres were tertiary centres and have similar number of patients undergoing ESWL procedures as outpatient in the ESWL suite.

2.4 Inclusion Criteria

Inclusion criteria included male and female individuals aged 18 and above undergoing ESWL in ESWL suite as daycare, capable of reading and hearing either in the English language or Bahasa Malaysia and no previous personal history of ESWL procedure. Total of 54 of patients were included in the study.

2.5 Exclusion Criteria

Exclusion criteria includes participants with hearing impairments, participants with impaired vision, participants who refuse to provide consent to the study and participants below 18 years of age. Total of 66 patient were excluded from the study.

2.6 Withdrawal Criteria

The participants had the option to withdraw from the study at any time. Withdrawn participants was not replaced. There was no patient withdrawn from the study.

2.7 Sample Size

Based on the Miao et al. study, to achieve our objective of comparing the mean scores of the two groups, a sample size of 27 (n1) was required for the baseline/control group and a sample size of 27 (n2) for the other group in order to detect a mean difference of 2.00 with a power of 0.80 (80%) and a significance level (alpha) of 0.05 [6]. The mean difference was 2.00, which was considered the smallest important difference to detect. The standard deviation (SD) of the knowledge difference was estimated as 2.61 (Miao et al. study). This calculation was performed using ScalexMean version 1.0.2 (Naing, 2016).

2.8 Study Visits and Procedures

During the study period, all patients who underwent ESWL pre-screening were randomised into two groups. All patients were seen on the same day of the procedure in the ESWL suite. After obtaining their consent to participate in the study, they were recruited into the study by a trained research team. A trained research team member explained the ESWL procedure in the traditional consent group. Patients in the intervention group watched an educational video after providing verbal and written consent. The video was available in either of the following languages, according to patient's preference: Malay or English. Both groups were given ample time to ask questions. Patients were provided with a form to self-report their anxiety levels after signing their written procedural consent. Pre procedure pain score was recorded and patients underwent ESWL as per the standard protocol with a standard dose of pain medication. Pain scores post-procedural was recorded using the same data collection form.

2.9 Statistical Analysis

Data analysis was performed using IBM SPSS Statistics for Windows version 22. Descriptive statistics were employed for selected variables. Chi-square, Fisher's exact, and paired t-tests were used for statistical analysis. A value of $P < 0.05$ is considered significant.

3. RESULTS AND DISCUSSION

A total of 54 respondents were included in the study. Demographic data indicated that 31 participants ,57.4%, were male, with a mean age of 51.2 years in the traditional consent and 52.2 years in the video-assisted consent group (Table 1). Most participants had an educational background in secondary school (53.7%) or a diploma (22.2%). Most of the common stone location that underwent ESWL in the traditional group were renal stones with 15 participants, 55.6% followed by 6 participants, 22.2% having stone in the distal ureteric stone and the remaining patients were in the mid-ureteric and proximal ureteric stone.In the video group , the most common location of the stone were renal stones (37%), mid-ureteric stone (33.3%), proximal ureteric stone (25.9%) and distal ureteric stone (3.7%).

Table 1. Descriptive data of the respondents

Demographic data		Traditional		Video	
		Count (%)		Count	%
Gender	Female	8	29.6%	15	55.6%
	Male	19	70.4%	12	44.4%
Education level	Primary	5	18.5%	0	0.0%
	Secondary	12	44.4%	17	63.0%
	Diploma	7	25.9%	5	18.5%
	Degree	3	11.1%	4	14.8%
	Master	0	0.0%	1	3.7%
Location of the stone	Distal ureteric stone	6	22.2%	1	3.7%
	Mid ureteric stone	3	11.1%	9	33.3%
	Proximal ureteric stone	3	11.1%	7	25.9%
	Renal stone	15	55.6%	10	37.0%

Table 2. Statistical analyses of anxiety level scores between two study groups.

APAIS		Traditional		Video		P value
Question 1	Not at all	4	14.8%	8	30.8%	0.093
	Somewhat anxious	7	25.9%	12	46.2%	
	Moderately anxious	10	37.0%	5	19.2%	
	Highly anxious	5	18.5%	1	3.8%	
	Extremely anxious	1	3.7%	0	0.0%	
Question 2	Not at all	3	11.5%	8	29.6%	0.055
	Somewhat anxious	7	26.9%	13	48.1%	
	Moderately anxious	12	46.2%	4	14.8%	
	Highly anxious	3	11.5%	2	7.4%	
	Extremely anxious	1	3.8%	0	0.0%	
Question 3	Not at all	1	3.7%	9	33.3%	0.026
	Somewhat anxious	8	29.6%	10	37.0%	
	Moderately anxious	11	40.7%	6	22.2%	
	Highly anxious	6	22.2%	2	7.4%	
	Extremely anxious	1	3.7%	0	0.0%	
Question 4	Not at all	4	14.8%	11	40.7%	0.012
	Somewhat anxious	3	11.1%	9	33.3%	
	Moderately anxious	13	48.1%	5	18.5%	
	Highly anxious	6	22.2%	2	7.4%	
	Extremely anxious	1	3.7%	0	0.0%	
Question 5	Not at all	2	7.4%	12	46.2%	0.001
	Somewhat anxious	5	18.5%	9	34.6%	
	Moderately anxious	11	40.7%	5	19.2%	
	Highly anxious	8	29.6%	0	0.0%	
	Extremely anxious	1	3.7%	0	0.0%	
Question 6	Not at all	1	3.7%	12	44.4%	0.000
	Somewhat anxious	4	14.8%	9	33.3%	
	Moderately anxious	9	33.3%	5	18.5%	
	Highly anxious	10	37.0%	1	3.7%	
	Extremely anxious	3	11.1%	0	0.0%	

Refer to appendix. P< 0.05 is significant.

The video-assisted consent group reported significantly lower anxiety scores for the procedure-based questions than the traditional consent group (see Table 2 for details).

Majority of the patient in the video group were anxious respondents (59.3%) compared to respondents in the traditional group who were non anxious respondents (81.5%). There were 21 respondents ,77.8%, in the traditional group whom were low in seeking information as compared to respondents in the video group (51.9%) who were intermediate group of seeking information. There was significant difference in the anxiety score and information seeking in both groups with p value < 0.05.

Table 3. Statistical analyses of between anxious respondents vs non anxious respondents and information seeking respondents

Category	Anxiety	Video	Traditional	P value
Anxiety	Anxious	16 (59.3%)	5 (18.5%)	0.002
	Non-anxious	11(40.7%)	22 (81.5%)	
Information seeking	Low	5 (18.5%)	21 (77.8%)	0.000
	Intermediate	14 (51.9%)	6 (22.2%)	
	High	8 (29.6%)	0 (0.0%)	

P value <0.05 is significant

Table 4. Pre- and post-procedural pain score between both study groups.

	Traditional		Video		
Pain score	**Mean score**	**Standard deviation**	**Mean score**	**Standard deviation**	**P value**
Pre procedure	2.3	1.2	1.2	0.4	0.026
Post procedural	3.7	2.2	3.2	2.2	0.458

P value < 0.05 is significant.

Higher pre and post procedural pain score noted traditional group compared to video group. However, there was no statistical difference between the pre-and post-procedural pain scores in both groups (see Table 4 for details).

Informed consent is an important aspect of urological procedures, ensuring that patients possess a thorough understanding of the procedures, associated risks, benefits, and available alternatives before consenting to undergo urological procedures. Traditional consent relies on both verbal and written information. However, the integration of assisted technologies, such as videos, has been shown to reduce anxiety levels during various medical procedures. A study conducted by Gouda et al. [10] among women undergoing colposcopy showed that video-assisted teaching reduced anxiety levels and alleviated pain experiences among these patients [11]. Similarly, research conducted by Shome et al. [12] using video consent for blepharoplasty showed a decrease in preoperative anxiety levels [13]. Nevertheless, only a few studies have focused on video-assisted consent for urological procedures.

In our study, we used the Amsterdam Preoperative Anxiety and Information Scale, which is subdivided into two major components. Items 1 and 2 assessed anaesthesia-related anxiety, and items 4 and 5 evaluated surgery-related anxiety. The need for information was assessed using items 3 and 6. In our study, the video-assisted group exhibited lower anxiety scores than the traditional consent group in terms of surgery-related and need-for-information components. However, there was no significant difference in anaesthesia-related anxiety between the two groups. This could be because the patient perceived the procedure as potentially painful, thus anticipating the need for anaesthesia or analgesia during the procedure, leading to a lower anaesthesia-related anxiety level.

Notably, our study did not reveal a significant difference in the pre-and post-procedural pain scores between the groups. We postulate that most of our patients were on analgesia prior to the procedure, as pain is one of the indications for active stone treatment at our centre. Various analgesic options were available for pre-procedural use at both centres. Additionally, it is conceivable that probably fewer shocks or energy were delivered during the procedure, and no data were collected if ESWL was completed with the intended delivered shockwave.

A limitation of the study is the absence of an assessment of participants' comprehension of the video content. In the era of internet and web browser access, patients may have conducted their own research on their medical condition and management options before the ESWL procedure. In the future, this study can be extended to explore the utilisation of internet resources, such as Google and social media, to evaluate patient comprehension, anxiety levels, and pain scores in ESWL or other urological-related procedures.

4. CONCLUSION

Video-assisted informed consent has been shown to reduce procedure-related anxiety in patients undergoing ESWL for stone management. Furthermore, integrating video-assisted consent into the process of prior urological procedures is a promising avenue for enhancing patient understanding and reducing anxiety.

CONSENT

All authors declare that 'written informed consent was obtained from the patient to participate in this study.

ETHICAL APPROVAL

This is study is registered with Malaysian National Medical Research Registry, Research ID NMRR-21-1677-60782. Medical research and Ethics committee approval has been obtained.

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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APPENDIX

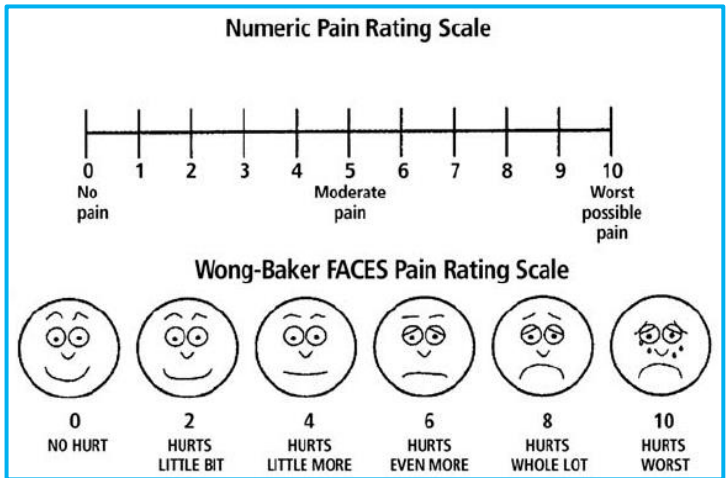
1. Anxiety level / Tahap kegelisahan

Please circle the most appropriate feeling for each questions/ Sila bulat perasaan anda untuk setiap soalan.

1 – Not at all / Tiada rasa gelisah
2 - Somewhat / Sedikit rasa gelisah
3 – Moderate / Sederhana rasa gelisah
4 – Moderately high / Sederhana tinggi rasa gelisah
5 – Extremely / Sangat gelisah

Questions / Soalan	1	2	3	4	5
I am worried about the anesthetic *Saya bimbang tentang pembiusan saya*	1	2	3	4	5
The anesthetic is on my mind continually *Saya bimbang tentang pembiusan saya*	1	2	3	4	5
I would like to know as much as possible about the anesthetic *Saya ingin tahu sebanyak yang mungkin tentang pembiusan saya*	1	2	3	4	5
I am worried about the procedure Saya bimbang tentang prosedur pembedahan saya *Saya bimbang tentang prosedur pembedahan saya*	1	2	3	4	5
The procedure is on my mind continually *Prosedur pembedahan sentiasa berada di fikiran saya*	1	2	3	4	5
I would like to know as much as possible about the procedure *Saya ingin tahu sebanyak yang mungkin tentang pembedahan saya*	1	2	3	4	5

PAIN SCORE



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