

EDUCATIONAL VIDEO-ASSISTED CONSENT VERSUS TRADITIONAL INFORMED CONSENT FOR EXTRACORPOREAL SHOCKWAVE LITHOTRIPSY: A RANDOMISED CONTROLLED STUDY

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 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.

Comment [M1]: Comparing Anxiety Levels and Pain Scores for Video-Assisted and Traditional Informed Consent in Extracorporeal Shockwave Lithotripsy: A Prospective, Randomised, Controlled Study.

Comparing Pre-Procedural Anxiety and Pain Scores between Educational Video-Assisted Informed Consent and Traditional Informed Consent for Extracorporeal Shockwave Lithotripsy - A Prospective, Randomized, Controlled Study.

Comparing Pre-Procedural Anxiety and Pain Scores between Educational Video-Assisted Informed Consent and Traditional Informed Consent for Extracorporeal Shockwave Lithotripsy (ESWL): A Prospective, Randomised, Controlled Study.

Comment [M2]: .

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.

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 [1]. In a review by Nishimura et al. (2013), it was found that five of the sixteen total multimedia interventions (31%) resulted in a significant improvement in understanding of the informed consent process [1]. Chill, Dior, and Shveiky (2019) expressed a favourable clinical opinion regarding the use of multimedia during the informed consent process [2]. Tait and Voepel-Lewis (2015) also reported increasing effectiveness and acceptance of multimedia tools for research and healthcare consent [3]. Extracorporeal shockwave lithotripsy (ESWL) is a common procedure performed in our urology unit for the management of urolithiasis. 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 visualise how the procedure will be performed, potentially leading to incomplete information delivery to patients, which may further confuse them.

1.1 Anxiety

A study conducted by Paton et al. (2018) demonstrated that the use of multimedia teaching tools significantly decreases anxiety levels [4]. Moerman et al. developed the Amsterdam Preoperative Anxiety and Information Scale (APAIS) in 1996, which comprises self-report questionnaires [5]. 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

Comment [M3]: The first paragraph is accurate and provides a clear definition of informed consent and its importance for patients and clinicians. However, you could also mention the ethical and legal aspects of informed consent, such as respecting the patient's autonomy, dignity, and rights.
<https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-021-05493-1>

The second paragraph is also accurate and highlights the challenges and limitations of the traditional approach to informed consent. You have cited some relevant sources that support the use of alternative methods, such as multimedia interventions, to improve patient understanding and satisfaction. However, you could also acknowledge the potential drawbacks or barriers of using digital tools for informed consent, such as technical issues, accessibility, cost, and privacy.
<https://bmcmedethics.biomedcentral.com/articles/10.1186/s12910-021-00585-8>

The third paragraph is accurate and describes a specific procedure that requires informed consent. However, you could also explain what urolithiasis is and how ESWL works to break down the kidney stones. You could also provide some examples of multimedia tools that could help patients visualise the procedure, such as videos, animations, or interactive simulations.
<https://research-compliance.umich.edu/informed-consent-guidelines>

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. Our study aimed to investigate the impact of educational video-assisted informed consent on pre-procedural anxiety levels and pain scores. We hypothesised that educational video-assisted informed consent would reduce anxiety and result in lower pain scores.

2. MATERIAL 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.

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 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.

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

2.2.2 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.

2.2.3 Pain score

The visual analogue scale (VAS) and numeric rating scale (NRS) were used to assess the pain scores before and after the procedure. Participants were required to choose one of these pain measurement tools and self-report their pain on a data collection form.

Comment [M4]: The first subsection (1.1) is accurate and cites a relevant source that supports the use of multimedia teaching tools to decrease anxiety levels.

https://www.researchgate.net/publication/362176685_The_effect_of_teaching_using_multimedia_on_mahematical_anxiety_and_motivation

However, you could also mention the limitations of the study by Paton et al. (2018), such as the small sample size, the lack of a control group, and the use of a single surgical procedure.

<https://link.springer.com/article/10.1007/s00383-018-4352-z>

You could also provide some background information on why anxiety is a common and important issue in the preoperative setting, and how it can affect the patient's outcome and satisfaction.

<https://www.researchsquare.com/article/rs-2717856/v1>

<https://link.springer.com/article/10.1007/s00383-018-4352-z>

The second subsection (1.2) is accurate and cites some relevant sources that show the association between pain, anxiety, and informed consent.

<https://karger.com/cur/article/12/2/81/102827/The-Influence-of-Pain-on-the-Outcome-of>

<https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-020-04296-0>

Comment [M5]: I have checked the scientific accuracy of your sentences and here is my feedback:

The aim of your study is clear and relevant, as pre-procedural anxiety and pain are important outcomes for patients undergoing ESWL.

<https://bmcanaesthesiol.biomedcentral.com/articles/10.1186/s12871-021-01361-2>

However, you could also state the research question or hypothesis that you are testing in your study, such as whether educational video-assisted informed consent reduces anxiety and pain compared to traditional informed consent.

The study type and design are appropriate for your aim, as a prospective, randomised, controlled stud...

Comment [M6]: Please include the consort diagram for the study implementation process as it will give readers a better understanding of how your study was implemented. This visual representation will provide detailed insights into the different stages and processes involved in carrying out the research, enhancing transparency and clarity for readers.

Comment [M7]: The validity and reliability of the questionnaires have not been reported at all, which is crucial for establishing the credibility of the research findings. It is essential to provide detailed information about the methods used to assess their validity and reliability in order to give a clear understanding of their accuracy and consistency. This should be elaborated on in the method section under the subtitle "Data Collection Tool," including specific references that indicate the percentage of validity and reliability established in previous studies.

2.3 Study Population

All adult patients were scheduled for ESWL in the ESWL Suite at both centres during the study period.

2.4 Inclusion Criteria

- a) Male and female individuals aged 18 and above undergoing ESWL
- b) Capable of reading and hearing either in the English language or Bahasa Malaysia
- c) No previous personal history of ESWL procedure

2.5 Exclusion Criteria

- a) Participants with hearing impairments
- b) Participants with impaired vision
- c) Participants who refuse to provide consent to the study
- d) Participants below 18 years of age.

2.6 Withdrawal Criteria

The participants had the option to withdraw from the study at any time. Subjects may be withdrawn if the investigator deems it detrimental or risky to continue their participation. Withdrawn participants will not be replaced.

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. Following an explanation of the study, the patients were randomised into two groups. 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 Malay or English, according to the patient's preference. After obtaining consent, both groups were given ample time to ask questions. Patients were provided with a form to self-

Comment [M8]: It is important to indicate whether there is a history of taking psychoactive drugs or depression medication. Additionally, the number of excluded participants based on the inclusion and exclusion criteria should be clearly stated.

Comment [M9]: In previous instances, the past should be acknowledged. Instead of stating that it will be withdrawn, it must be explained that it was withdrawn due to...

report their anxiety levels after signing their written consent. Patients underwent ESWL as per the standard hospital protocol with a standard dose of pain medication according to the hospital protocol. Pain scores post-procedural were recorded using the same data collection form.

3. RESULTS AND DISCUSSION

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

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). The majority of participants had an educational background in secondary school (53.7%) or a diploma (22.2%). Based on each anxiety question score, procedure-based questions were significant in the video-assisted consent group compared to the traditional consent group (Table 2). However, there was no significant difference in the anaesthesia-related questions between the two groups. Additionally, there was no statistical difference between the pre-and post-procedural pain scores in both groups. (Table 3).

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%

Comment [M10]:

- You should avoid repeating the same information in different sentences. For example, you mentioned that the patients were randomised into two groups twice, and that they provided consent twice. You can combine these sentences or delete the redundant information to make your writing more concise and clear.
- You should use the past tense for describing what happened in the study, not the present tense. For example, you should say "all patients who underwent ESWL pre-screening were randomized into two groups", not "are randomized".
- You should use a colon (:) to introduce a list of items, such as the languages of the video. For example, you should say "the video was available in either of the following languages, according to the patient's preference: Malay or English."
- You should use a comma (,) to separate independent clauses joined by a coordinating conjunction, such as and, but, or, nor, for, so, or yet. For example, you should say "patients underwent ESWL as per the standard hospital protocol, and pain scores post-procedural were recorded using the same data collection form."

Comment [M11]: • The first paragraph of the results and discussion section should provide a brief overview of the main findings and how they relate to the research question or hypothesis. You may also want to state the main implications or contributions of your study to the field of urology.

- You should avoid using parentheses to enclose numbers or percentages, as this may imply uncertainty or approximation. Instead, use commas or dashes to separate them from the text.

Comment [M12]: Your sentences are generally clear and precise, but they could be more concise and engaging. Avoid long flowery phrases and make sure your sentences contain a maximum of 15 to 20 words. Presenting information in short, manageable chunks also helps you to keep the reader with you, so stick to the principle of one idea per sentence.

Your first sentence should be indelible and leave your impression early. Many academics start with something more like a broader impacts statement

Comment [M13]: It should be emphasized that this information needs to be included before the presentation of the result and should form an integral part of the methodology section.

Comment [M14]: Since gender, age, and other potential confounding variables may have influenced the results, it is essential to conduct a comprehensive linear regression analysis to assess the impact of these factors on the outcomes.

Comment [M15]: Since you have conducted parametric tests, it is essential first to assess the normal distribution of your variables using appropriate statistical tests. Before presenting the main results, these tests should be reported in the method section under the analysis title (sub-heading).

	Renal stone	15	55.6%	10	37.0%
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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%	
Q6Possible	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.

Comment [M16]: What do you mean by this statement? Could you provide further context or explanation?

Table 3: Mean pre- and post-procedural pain score between both study groups.

Mean pain score	Traditional	Video	P value
Pre-procedural pain score	2.3	1.2	0.026
Post-procedural pain score	3.7	3.2	0.458

Comment [M17]: Descriptive statistics should be reported, including measures of central tendency such as the mean and variability represented by standard deviation.

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. (2022) among women undergoing colposcopy showed that video-assisted teaching reduced anxiety levels and alleviated pain experiences among these patients [10]. Similarly, research conducted by Shome et al. (2021) using video consent for blepharoplasty showed a decrease in preoperative anxiety levels [11]. 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 can 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 (WHEREEVER APPLICABLE)

All authors declare that written informed consent was obtained from the patient to participate in this study. A copy of the written consent is available for review by the Editorial office/Chief Editor/Editorial Board members of this journal.

ETHICAL APPROVAL (WHEREEVER APPLICABLE)

This 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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Comment [M18]: You should avoid using modal verbs such as can, could, may, might, should, or would in scientific writing, as they introduce uncertainty and vagueness. Instead, you should use more precise and confident language to convey the strength and validity of your claims. For example, you should say "video-assisted informed consent reduces procedure-related anxiety" or "video-assisted informed consent has been shown to reduce procedure-related anxiety", not "video-assisted informed consent can reduce procedure-related anxiety".

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APPENDIX

1. Anxiety level / Tahapkegelisahan

Please circle the most appropriate feeling for each questions/
Silabulatperasaanandauntuksetiapsoalan.

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

Questions / Soalan	1	2	3	4	5	Comment [M19]:
I am worried about the anesthetic <i>Saya bimbangtentangpembiusansaya</i>	1	2	3	4	5	
The anesthetic is on my mind continually <i>Saya bimbangtentangpembiusansaya</i>	1	2	3	4	5	
I would like to know as much as possible about the anesthetic <i>Saya ingintahusebanyak yang mungkintentangpembiusansaya</i>	1	2	3	4	5	
I am worried about the procedure <i>Saya bimbangtentangprosedurpembedahansaya</i> <i>Saya bimbangtentangprosedurpembedahansaya</i>	1	2	3	4	5	
The procedure is on my mind continually <i>Prosedurpembedahansentiasaberada di fikiransaya</i>	1	2	3	4	5	
I would like to know as much as possible about the procedure <i>Saya ingintahusebanyak yang mungkintentangpembedahansaya</i>	1	2	3	4	5	

PAIN SCORE

