Research Article

Efficacy of informed consent process using educational videos for skin biopsy procedures

Dichitchai Mettarikanon [1]
[iD] 0000-0002-0035-6205

Weeratian Tawanwongsri [2*]
[iD] 0000-0002-1949-7323

Pitchaya Jaruvijitrattana [3]
[iD] 0009-0001-4856-1160

Sasipaka Sindhusen [4]
[iD] 0009-0000-7498-9622

Surinnart Charoenchitt [4]
[iD] 0009-0000-5264-1369

Patsaraporn Manunyanon [5]
[iD] 0009-0004-5171-2558

[1] Division of Digital Content and Media, School of Informatics, Walailak University, Nakhon Si Thammarat, THAILAND
[2] Division of Dermatology, Department of Internal Medicine, School of Medicine, Walailak University, Nakhon Si Thammarat, THAILAND
[3] Chao Phraya Abhaibhubejhr Hospital, Prachin Buri, THAILAND
[4] Bhumibol Adulyadej Hospital, Bangkok, THAILAND
[5] School of Informatics, Walailak University, Nakhon Si Thammarat, THAILAND
* Corresponding author: weeratian.ta@wu.ac.th

ARTICLE INFO	ABSTRACT
	The informed consent process is integral to medical procedures, including skin biopsies, which are the definitive method for diagnosing challenging skin lesions. Educational videos are recognized for effective delivery of information for informed consent. This study aimed to evaluate the efficacy of an informed consent process using educational videos to improve patient understanding and reduce preprocedural anxiety. This multicenter, randomized controlled study was conducted during December 2021-June 2023. Participants were randomly assigned to either the video or verbal group in a 1:1 ratio. They completed knowledge and anxiety questionnaires before and after biopsy. The final analysis included 54 participants (verbal group: n=28; video group: n=26) with a mean age of 51.9 years (standard deviation [SD] 18.1), and a balanced gender distribution. Post-intervention knowledge scores (median 10.0; IQR 8.0-10.0) significantly increased compared to pre-intervention scores (median 6.0; IQR 4.0-9.0), p<0.001. Post-intervention Spielberger state-trait anxiety inventory (STAI) scores (median 5.0; interquartile range, IQR 5.0-6.0) significantly decreased compared to pre-intervention scores (median 7.0; IQR 5.0-10.0), p<0.001. Knowledge scores increased more in the video group (median, 2.5; IQR 1.0-5.0) than in the verbal group (median, 1.5; IQR 0.0-4.0), p=0.217. There was no significant difference in STAI score changes between the video group (median 1.0, IQR 0.0-4.0) and the verbal group (median 1.0, IQR 0.0-3.0), p=0.824. Despite statistical insignificance, educational videos exhibited greater effectiveness in enhancing comprehension and demonstrated comparable efficacy in reducing anxiety compared to conventional intervention. **Keywords:** educational videos, comprehension, anxiety, informed consent, skin biopsy

INTRODUCTION

Skin biopsy is used as a reference standard to establish the final diagnosis in difficult or doubtful lesions. Various techniques, like shave, punch, incisional and excisional biopsies, are employed depending on the clinical suspicion of the extent of skin involvement (Elston et al., 2016). Similar to any other surgical procedure, it is both an ethical and legal obligation for healthcare providers in Thailand to provide health information about the service to decide on the proper choice of service (Direksoonthorn, 2018). Despite their minimally invasive nature and low incidence of complications (Abhishek & Khunger, 2015), patients who undergo these procedures should receive sufficient information prior to the procedure to protect them from harm and respect their autonomy (Jefford & Moore, 2008).

Informed consent is a collaborative decision-making process that includes inputs from patients and healthcare providers. The decision is made based on patient preferences and available evidence-based medicine (Pietrzykowski & Smilowska, 2021). In usual practice, informed consent is obtained from each patient in both oral and written form. However, numerous challenges remain, including a document that is difficult to understand, limited recall of information, increased anxiety, and limited time for the consent process (Agozzino et al., 2019; Kadam, 2017; Rosique et al., 2006). There is a link between increased comprehension and better memorization along with reduced preoperative anxiety (Bounif et al., 2022; Convie et al., 2020). In dermatology clinics, the visit duration is approximately 15 minutes (Davis et al., 2014; Wong et al., 2017). This turns out to be shorter (less than three minutes) in the case of a larger number of patients per day (Wooldridge et al., 2010). Thus, physicians may find it difficult to convey adequate information to patients with uniform consistency in fast-paced clinical settings and receive informed consent (Betti et al., 2011). The consent based on incomplete information can result in negative legal and clinical outcomes as well as a low level of satisfaction (Arpey & Whitaker, 2001; Bailey & Bailey, 2007; Ivarsson et al., 2005).

The use of videos as educational tools has been deemed useful in conveying information for informed consent (Kadam, 2017). The creation of an educational video is initiated by establishing objectives for the video, followed by analysis, planning, modeling, implementation, and evaluation (Ab Hamid et al., 2021; Razera et al., 2019). To maximize patient learning from educational videos, several elements should be considered. These include keeping videos brief, highlighting important ideas to reduce cognitive load, using graphic elements to illustrate key points, and adopting a conversational style to enhance learner engagement (Brame, 2016). An appropriately designed educational video that undergoes content validation contributes to achieving patient comprehension levels, based on Bloom's taxonomy (Dettmer, 2005). Bloom's taxonomy is widely used in education and consists of three domains of learning: cognitive, affective, and psychomotor. The cognitive domain encompasses six levels: remembering, understanding, applying, analyzing, evaluating, and creating. This model assists educators in formulating learning goals, designing suitable activities, overseeing the learning process, and assessing the acquired knowledge. Educational videos not only enhance comprehension and recall with the consistency of information provided to patients but also alleviate patients' anxiety and gain compliance (Blake et al., 2015; Done & Lee, 1998; Farrell et al., 2014; Schooley et al., 2015; Zhang et al., 2017). These depictions of significant information can help avoid any misunderstanding, particularly regarding abstract terms and medical conditions that patients have never heard of. To the best of our knowledge, few studies have been conducted on digitally supported consent in dermatology. Armstrong et al. revealed a significant increase in knowledge scores with higher satisfaction following video education compared with traditional oral education (Armstrong et al., 2010). However, as it was a single-center study, the findings may not be generalizable to other populations in different cultural contexts. In non-Western countries, particularly China and Thailand, where the ways of life are deeply influenced by Confucianism and Buddhism, respectively, patients are usually not well informed about their medical conditions. Attending physicians and the patients' relatives play an important role in making final decisions (Raposo, 2019; Wongsawang et al., 2013). Therefore, patients may not be familiar with what they need to know about self-determination. Additionally, the previous study did not cover all common skin biopsy techniques or investigate their effectiveness in reducing preprocedural anxiety. We hence define the research questions (**RQ**s), as follows:

RQ1. Can educational videos serve as valuable tools to enhance patients' learning and comprehension of informed consent for skin biopsy procedures?

RQ2. Do educational videos mitigate participants' anxiety?

We conducted a multi-center randomized controlled trial to evaluate the effectiveness of educational videos in enhancing patient comprehension of informed consent for common skin biopsy procedures and alleviating preprocedural anxiety.

MATERIALS & METHODS

Patient & Public Involvement

PPI representatives were involved in multiple stages of the research process, including developing research questions and trial protocols, helping design the study, and facilitating its dissemination. We invited PPI participants via posters in the dermatology waiting room at Walailak University Hospital to join a closed social media group (Facebook). They were consulted about the research topics and priorities of their expected outcomes as service users of the health system. After discussing the proposed study design, they suggested conducting a multicenter study with a randomized allocation to interventions. They agreed that the methods and interventions proved the effectiveness of the educational media. They then helped distribute the results within the informal online groups.

Study Design & Population

This clinical trial has been registered in the Thai clinical trials registry (TCTR20220503002). We recruited participants from the dermatology clinics of three tertiary centers including Walailak University Hospital, Bhumibol Adulyadej Hospital, and Chao Phraya Abhaibhubejhr Hospital. The data were collected between December 2021 and June 2023. The eligibility criteria required that participants be aged 18 years or older and require a skin biopsy after assessment by an attending dermatologist. Biopsy techniques, depending on the characteristics of the skin lesions, include shave biopsy, punch biopsy, incisional biopsy, and excisional biopsy.

Study Procedures

Participants were randomized (1:1) with a simple randomization method using Microsoft Excel 2019 (Microsoft Corporation, Seattle, WA, USA) into either the video or verbal group. The code sequence was kept in opaque sealed envelopes by non-medical staff who were not involved in the intervention. In the video group, the participants were asked to watch a five-minute video, which consisted of details about indications, contraindications, procedure steps, pathology process, post-intervention self-care, and signs to see a doctor right away. Three video clips of shave biopsy, punch biopsy, and incisional/excisional biopsy were developed under the supervision of two board-certified dermatologists and one video creator (video 1 shave biopsy procedure, https://youtu.be/RipYvuDkEbY; video 2 punch biopsy procedure, https://youtu.be/AjWDRBwtlrg; video 3 incisional/excisional biopsy procedure, https://youtu.be/Q6rtMd0Jjrw). The videos were produced following the process of digital storytelling (Chaisriya et al., 2023). We collaboratively created films in actual operative rooms combined with the elements of motion graphics to explain and illustrate sophisticated medical information. The videos were displayed on a portable mp4 player with a 10.9-inch color screen (iPad Air 4, Apple Inc.). Three validated dermatologists, one person per study site, explained and answered the patients' questions. In the verbal group, the attending dermatologists were given a script containing the skin biopsy content to explain to the participants. The participants were informed of the details in four–five minutes. After passively receiving information, we allowed participants in both groups to ask questions and discuss issues regarding the procedure. This process took approximately two-three minutes. Written informed consent was obtained from all the participants after a full explanation of the study. A follow-up visit was scheduled two weeks after the intervention.

Assessment Measures

All participants completed a knowledge questionnaire before the skin biopsy procedure and again after two weeks. To date, there is no standardized assessment of the comprehensive level of skin biopsies. We collaboratively developed 10 questions–each with three possibilities of answer (true, false, and do not know), covering topics including indications, contraindications, procedure steps, pathology process, post-intervention self-care, and features of complications. One point was awarded for each question that was

answered correctly; the incorrect answers or the answers 'do not know' were given zero points. The short version of the Spielberger state-trait anxiety inventory (STAI) was used to measure the state and trait components of the participants' anxiety before and immediately after the informed video/verbal consent (Zsido et al., 2020). It is a five-item self-report measure of anxiety that uses a 4-point Likert-type scale (from one to four points) for each item. In the video group, the participants completed a satisfaction questionnaire two weeks after the skin biopsy procedure. All assessment measures in this study were comprehensively reviewed and validated by three board-certified dermatologists and one educational expert using an index of item objective congruence (IOC). An IOC index score higher than 0.5 confirmed the content validity of the questionnaire (Rovinelli & Hambleton, 1976). The initial questionnaires were pilot tested on 30 adult volunteers at dermatology clinics prior to the commencement of the study and revised for unclear wording. Internal consistency was assessed by calculating Cronbach's alpha coefficient; an alpha greater than or equal to 0.70 was considered acceptable (Nunnally, 1967).

Statistical Methods

The sample size, including an estimated 5% loss to follow-up based on a previous study, was 28 patients in each group (Armstrong et al., 2010). With a total of 52 participants (26 in each arm), the study had 90% power to detect an increase in mean scores of 1.55 points on the knowledge test after the VDO intervention, with a standard deviation (SD) of 1.71 and α of 0.05 in a two-tailed analysis. Continuous data were presented as means and SDs or medians and ranges. Categorical data were presented as frequencies and percentages. The paired t-test or Mann-Whitney Wilcoxon test was used to compare the knowledge and anxiety scores before and after skin biopsies. Pearson's Chi-square test was used to test for significant relationships between categorical variables. Two-tailed tests were considered statistically significant at $p<0.05$. Statistical analyses were performed using SPSS software version 18 (SPSS Inc., Chicago, IL, USA).

RESULTS

The effectiveness of the videos was analyzed by comparing two groups: a video group that consisted of participants who watched an educational video on the skin biopsy procedure, and a control group that received verbal instructions. The variables analyzed included understanding, anxiety, and patient satisfaction. A total of 56 participants were enrolled, with the verbal group completing the follow-up sessions and the video group exhibiting a 92.9% complete follow-up rate. Consequently, 54 participants (verbal group, n=28; video group, n=26) were included in the final analysis, as shown in **Figure 1**.

The mean age of the participants was 51.9 years, with a SD of 18.1. The age distribution of the patients ranged from 18 to 86 years. Sex distribution was balanced (50% each). The educational level of the participants was lower than that of high school graduates (n=17, 31.5%), high school graduates (n=6, 11.1%), undergraduates (n=2, 3.7%), and university graduates or higher (n=29, 53.7%). Most participants (n=52, 96.3%) had never undergone skin biopsy. The types of biopsies performed included punch biopsy (n=30, 55.6%), shave biopsy (n=13, 24.1%), and incisional or excisional biopsy (n=11, 20.4%). The biopsy sites included the lower extremities (n=18, 33.3%), head and neck (n=16, 29.6%), trunk (n=13, 24.1%), and upper extremities (n=7, 13.0%). Common pathological diagnoses were seborrheic keratosis (n=9; 16.7%), spongiotic dermatitis (n=7; 10.9%), and psoriasis (n=5; 9.3%). The baseline characteristics of the participants in each group are shown in **Table 1**.

Overall, post-intervention knowledge scores (median 10.0; interquartile range, IQR 8.0-10.0) were significantly higher than pre-intervention knowledge scores (median 6.0; IQR 4.0-9.0), p<0.001. 16 participants (29.6%) were clinically anxious (STAI score equal to or more than 10). Post-intervention STAI scores (median 5.0; IQR 5.0-6.0) were significantly lower than pre-intervention STAI scores (median 7.0; IQR 5.0-10.0), p<0.001. In the verbal group, post-intervention knowledge scores (median 10.0; IQR 7.0-10.0) were significantly higher than pre-intervention knowledge scores (median 6.0; IQR 4.0-9.5), p<0.001. Post-intervention STAI scores (median 5.0; IQR 5.0-6.5) were significantly lower than pre-intervention STAI scores (median 7.0; IQR 5.0-9.5), p=0.003. In the video group, post-intervention knowledge scores (median 10.0; IQR 9.0-10.0) were significantly higher than pre-intervention knowledge scores (median 6.0; IQR 3.0-9.0), p<0.001.
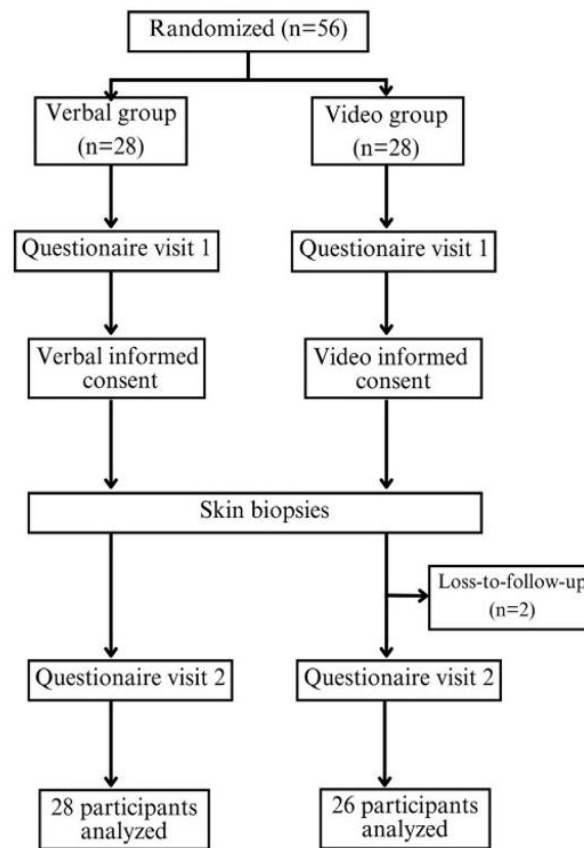
Figure 1. Flow chart of participants in the randomized controlled trial (Source: Authors)

Table 1. Baseline characteristics

	Verbal group (n=28)	Video group (n=26)
Gender, n (%)		
Male	14 (50.0)	13 (50.0)
Female	14 (50.0)	13 (50.0)
Age (years): mean (standard deviation)	53.9 (15.1)	49.7 (21.0)
Education levels, n (%)		
Lower than high school	10 (35.7)	7 (26.9)
High school graduate	2 (7.1)	4 (15.4)
Undergraduate	1 (3.6)	1 (3.9)
University graduate or above	15 (53.6)	14 (53.8)
Biopsy type		
Shave biopsy	5 (17.9)	8 (30.8)
Punch biopsy	18 (64.2)	12 (46.1)
Incisional/excisional biopsy	5 (17.9)	6 (23.1)
Biopsy site		
Head and neck	8 (28.5)	8 (30.7)
Upper extremity	5 (17.9)	2 (7.7)
Trunk	5 (17.9)	8 (30.8)
Lower extremities	10 (35.7)	8 (30.8)
Previous skin biopsy		
Yes	2 (7.1)	0 (0.0)
No	26 (92.9)	26 (100)

Post-intervention STAI scores (median 5.0; IQR 5.0-6.0) were significantly lower than pre-intervention STAI scores (median 7.5; IQR 5.0-10.0), $p < 0.001$. The changes in knowledge scores in video group (median 2.5; IQR 1.0-5.0) were higher than those in the verbal group (median 1.5; IQR 0.0-4.0), $p = 0.217$. The changes in STAI scores were not significantly different between the video group (median 1.0, IQR 0.0-4.0) and the verbal group (median 1.0, IQR 0.0-3.0), $p = 0.824$. No correlation was found between pre-intervention knowledge scores and pre-intervention STAI or between post-intervention knowledge scores and post-intervention STAI scores.
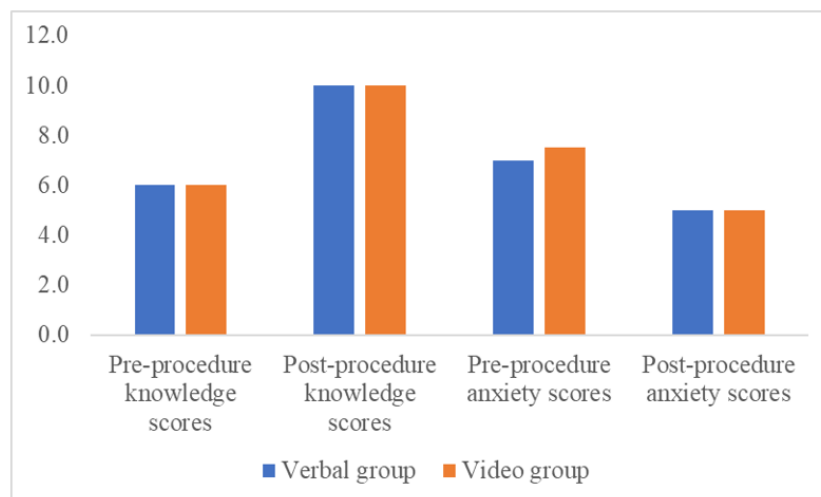
Figure 2. Median knowledge & anxiety scores in verbal & video groups before & after skin biopsies (Source: Authors)

Table 2. Participants' perspectives on educational videos of skin biopsies

	Satisfaction scores	
	Mean	Standard deviation
The educational videos were easily understood.	4.9	0.3
The narrative unfolded sequentially.	4.8	0.4
The appropriateness of the content.	4.7	0.4
The illustrations aligned with the content presented.	4.8	0.4
The illustrations were easily understandable and visually evident.	4.8	0.4
The background music corresponded to the content.	4.7	0.5
The narration was articulate & delivered with an appropriate volume & tone.	4.8	0.4
The video clips were of suitable duration.	4.9	0.3
The subtitles were clear & easily comprehensible, aiding in understanding content.	4.7	0.4

Figure 2 illustrates the median knowledge and anxiety scores in the verbal and video groups before and after the skin biopsies.

Perspectives on educational videos were collected and are presented in **Table 2**. The usefulness scores, assessed using a visual analog scale ranging from zero to 10, yielded a median rating of 10.0 (IQR 9.0-10.0).

DISCUSSION

Patient autonomy is a core element of medical ethics, and respect for it is considered the most important ethical principle in healthcare ethics (Beauchamp & Childress, 2019). Attending dermatologists must ensure that informed consent is obtained. Initial anxiety was then addressed through an effective consent process. To overcome the problem of incomplete informed consent in dermatology practice, we developed the comprehensive and concise educational videos to improve and maintain patient care standards. To the best of our knowledge, this is the first study in a non-Western country to address the efficiency of using educational videos to enhance patients' understanding of skin biopsies and reduce anxiety. Our findings demonstrated that knowledge scores significantly increased in both groups. Anxiety scores on STAI scale significantly decreased in both groups. The changes in scores were not statistically significant between the groups. These results agree with those of a previous study conducted in the USA (Armstrong et al., 2010). The knowledge scores of participants in the video group were significantly higher than those in the oral education group. However, this difference was not statistically significant in the between-group comparisons. In the video group, participants reported high satisfaction and usefulness scores.

Our findings support the notion that multimedia enhances learners' ability to comprehend given information deeply using words and pictures. Mayer and Mayer (2005) proposed how the learners processed the messages in a multimedia format effectively. Multimedia presentation consists of words and pictures that are then conveyed and processed in dual channels, including visual and auditory. Each channel has a limited

processing capacity. In working memory with a cognitive load, learners select relevant words and pictures into coherent mental representations before organizing them into two newly formed models: verbal and pictorial. New knowledge is constructed after integrating these two models with prior knowledge. Therefore, the development of medical multimedia has gained increasing attention in patient education to promote the understanding of various fields, including radiology, oncology, surgery, and dermatology (Armstrong et al., 2010; Dawdy et al., 2018; Grilo et al., 2022; Steves & Scafide, 2021). Not only did the patients gain the knowledge, Wang et al. (2022) demonstrated that they also improved their attitudes and behaviors after receiving multimedia-based education. However, our findings showed that participants in the video group achieved insignificantly higher scores compared to those in the verbal group. Several factors could potentially account for these findings. First, despite being provided with a script, doctor-patient communication in our study involves utilizing both verbal and non-verbal language to foster understanding. Second, communication skills vary among physicians, and training and practice are essential to develop effective communication skills (Nakagawa et al., 2019). The skills of our information providers, three experienced dermatologists, were validated prior to the commencement of the study. Third, most participants had completed university education or held a degree above the undergraduate level. Consequently, they may be able to achieve a high level of comprehension, even on complex topics, after providing informed consent.

The incidence of preoperative anxiety ranged from approximately 12% to 40% (Eberhart et al., 2020; Kuzminskaitė et al., 2019). Similarly, nearly one-third of participants in the study exhibited potential clinical anxiety. And both interventions were effective in reducing preprocedural anxiety. In relation to the impact on anxiety, previous studies indicate that informed consent can yield either positive, negative, or neutral effects on individuals' anxiety levels (Goldberger et al., 2011; Pramono & Raharjo, 2021; Seeliger et al., 2022; Tipotsch-Maca et al., 2016; Yucel et al., 2005; Zhang et al., 2019). However, Grilo et al. (2022) recently revealed through their meta-analysis that educational videos resulted in lower anxiety levels compared to the control groups. Providing detailed information, unfulfilled information needs, and non-paternalistic approaches are potential factors for higher anxiety scores (Fischbeck et al., 2021; Tipotsch-Maca et al., 2016; Yucel et al., 2005). The implementation of our approach involved a comprehensive set of strategies, including direct face-to-face communication, interactive question-and-answer sessions, and the active involvement of patients' relatives within the intervention environment, because the contributions of their relatives and attending physicians are vital in determining a final decision (Raposo, 2019; Wongsawang et al., 2013). This multifaceted approach holds promise for elucidating the underlying factors that contribute to the noticeable reduction in patients' anxiety levels following the intervention. Nevertheless, additional investigations are imperative to comprehensively assess the intricate contributing factors and devise an optimal approach for obtaining informed consent that can effectively mitigate anxiety.

Our study has several limitations. First, participants in the verbal group provided informed consent to three different dermatologists depending on the study site. Their levels of communication and interpersonal skills may vary. However, we provided them with a script to explain and answer their questions and ensure their validation before commencement. Second, the main objective of this study was to compare knowledge scores between the intervention and control groups. The increased scores directly implied better understanding, but not the skills needed for self-wound care. Further randomized controlled studies are required to ascertain the effectiveness of educational videos on patient performance and clinical outcomes, including wound infections after skin biopsies. Third, although the video intervention decreased the burden on physicians, our informed consent approach was complemented by a question-and-answer session, similar to the verbal group. It is crucial to acknowledge the inherent limitations in generalizing the findings of this study as it relied exclusively on video-based interventions. In addition, the acquisition and refinement of these communication skills require meticulous training and dedicated attention.

CONCLUSIONS

The use of educational videos in the informed consent process was an effective strategy with high satisfaction and usefulness scores for augmenting patient comprehension and mitigating preoperative anxiety, specifically for skin biopsy procedures. It is a valuable audio-visual tool for consistently conveying

essential information in fast-paced dermatology clinics. Further randomized controlled studies are required to assess the effectiveness of educational videos in improving patient performance and clinical outcomes.

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