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The Effect of Video-Assisted Informed Consent Before Thyroid Fine-Needle Aspiration Biopsy on Anxiety and Patient Experience in Patients with Suspected Malignancy: A Randomized Controlled Study

Malignite Şüphesi Olan Hastalarda Tiroid İnce İğne Aspirasyon Biyopsisi Öncesinde Video Destekli Aydınlatılmış Onamın Anksiyete ve Hasta Deneyimi Üzerine Etkisi: Randomize Kontrollü Bir Çalışma

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Abstract

Objective: This study aimed to compare video-assisted informed consent with standard informed consent regarding anxiety, recall of procedure-related risks, procedural experience, and patients' perceptions of the informed consent process among patients undergoing thyroid fine-needle aspiration biopsy.

Materials and Methods: This randomized controlled trial included 76 patients who underwent thyroid fine-needle aspiration biopsy. Patients were randomly assigned to video-assisted informed consent (n=38) and standard informed consent (n=38) groups. Data were collected using a demographic information form, the Beck Anxiety Inventory, and a structured questionnaire including recall of procedure-related risks, procedure experience, and patients' assessments of the informed consent process. Descriptive and comparative statistical methods appropriate to the variables' distributional characteristics and data type were used to evaluate the data.

Results: The groups were similar in terms of sociodemographic characteristics. The median Beck Anxiety Inventory score was 6.00 (1.00–15.00) in the standard informed consent group and 5.50 (1.25–11.75) in the video-assisted group, with no statistically significant difference between the groups (U=724.0; p=0.988). There was no statistically significant difference between the groups in terms of recalling individual risks associated with the procedure (p>0.05). Procedure experience also showed no significant difference between the groups (p=0.854), with 73 out of 76 participants (96.1%) reporting that the procedure was as expected or better than expected.

Conclusion: No statistically significant differences were found between the video-assisted and standard informed consent groups in anxiety scores, recall of procedure-related risks, procedural experience, or patient-reported assessments of the informed consent process.

Keywords: Audiovisual aids, informed consent, patient education, thyroid nodule

Öz

Amaç: Bu çalışmada, tiroid ince iğne aspirasyon biyopsisi geçiren hastalarda anksiyete, işlemle ilgili risklerin hatırlanması, işlem deneyimi ve hastaların bilgilendirilmiş onam sürecine ilişkin algıları açısından video destekli bilgilendirilmiş onamın standart bilgilendirilmiş onamla karşılaştırılması amaçlanmıştır.

Materyal ve Metot: Bu randomize kontrollü çalışmaya tiroid ince iğne aspirasyon biyopsisi uygulanan 76 hasta dâhil edildi. Hastalar video destekli aydınlatılmış onam (n=38) ve standart aydınlatılmış onam (n=38) gruplarına randomize olarak dağıtıldı. Veriler, tanıtıcı bilgi formu, Beck Anksiyete Envanteri ve işlemle ilişkili risklerin hatırlanması ile işlem deneyimi ve hastaların aydınlatılmış onam sürecine ilişkin değerlendirmelerini içeren yapılandırılmış bir soru formu kullanılarak toplandı. Verilerin değerlendirilmesinde, değişkenlerin dağılım özelliklerine ve veri türüne uygun tanımlayıcı ve karşılaştırmalı istatistiksel yöntemler kullanıldı.

Bulgular: Gruplar sosyodemografik özellikler açısından benzerdi. Medyan Beck Anksiyete Envanteri puanı standart aydınlatılmış onam grubunda 6,00 (1,00–15,00), video destekli grupta ise 5,50 (1,25–11,75) olup gruplar arasında istatistiksel olarak anlamlı bir fark bulunmadı (U=724,0; p=0,988). İşlemle ilişkili bireysel risklerin hatırlanması açısından gruplar arasında istatistiksel olarak anlamlı bir fark saptanmadı (tüm p>0,05). İşlem deneyimi de gruplar arasında anlamlı bir farklılık göstermedi (p=0,854) ve 76 katılımcının 73'ü (%96,1) işlemin beklediği gibi veya beklediğinden daha iyi olduğunu bildirdi.

Sonuç: Video destekli ve standart aydınlatılmış onam grupları arasında anksiyete puanları, işlemle ilişkili risklerin hatırlanması, işlem deneyimi veya hasta tarafından bildirilen aydınlatılmış onam süreci değerlendirmeleri açısından istatistiksel olarak anlamlı bir fark saptanmadı.

Anahtar Kelimeler: Aydınlatılmış onam, görsel-işitsel yardımcı araçlar, hasta eğitimi, tiroid nodülü

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INTRODUCTION

Thyroid nodules are commonly seen in the general population.[1] They can be frequently detected with the widespread use of high-resolution ultrasonography.[1,2] Accurate and timely assessment of the risk of malignancy in thyroid nodules is important for determining appropriate clinical and surgical management.[2] Fine-needle aspiration biopsy (FNAB) is an important method for the diagnostic evaluation of appropriately selected thyroid nodules in this context.[1,2] FNAB is a minimally invasive procedure.[2] While generally safe, it carries potential risks such as pain, bleeding/hematoma, infection, and, rarely, voice-related complications.[3] Therefore, it is important that patients are adequately informed about the possible risks before the procedure. Informed consent is a process that ensures respect for the patient's individuality and autonomy, granting them the right to make decisions.[4,5] This process has ethical and legal dimensions.[5] Informed consent requires patients to be adequately and understandably informed about the purpose, potential benefits, risks, and alternatives of the planned medical intervention, and to make a voluntary decision.[5,6] However, sufficient understanding of the information presented in the informed consent process by patients remains a significant problem in clinical practice.[7] In a study evaluating the informed consent process before interventional procedures in Türkiye, it was found that approximately 23% of patients reported not understanding what was explained to them at all or only partially understanding it, and 30.6% reported that there were statements on the consent form whose meaning they did not know.[4] Problems with comprehensibility were more pronounced in patients with lower levels of education.[4] Similarly, it has been reported that there can be differences in the quality and compliance with requirements of informed consent forms used in surgical and critical care settings.[8] These findings highlight the need for approaches that support the presentation of standard, clear, and understandable information to patients in the informed consent process.[5,6] The use of digital technologies in the informed consent process is a current and frequently discussed topic.[9] Visual, video-based, and other digital methods can support patients' understanding of the informed consent process by providing medical information in a more structured and understandable way.[9] A recent systematic review evaluating digital informed consent applications in surgical patients reported that digital interventions can have positive effects on patient understanding, especially in the early stages.[9] A randomized controlled trial comparing video-assisted informed consent with standard verbal consent also showed that a video-based approach can be an equivalent information method to standard consent.[10] A more recent randomized controlled trial reported that adding a short educational video to standard verbal information increased patients' understanding of the procedure, benefits, and risks, and that this benefit was also seen in patients with lower levels of education.[11]

Although thyroid fine-needle aspiration biopsy is a minimally invasive procedure, patients may experience anxiety associated with the procedure. Therefore, interventions to reduce anxiety during the procedure are being investigated.[12] The study aims to evaluate the effect of video-assisted informed consent on patients' anxiety levels during thyroid fine-needle aspiration biopsy, and to compare it with the standard written informed consent method. Recall of procedure-related risks, procedural experience, and patient perceptions of the informed consent process were evaluated as secondary outcomes.

MATERIALS AND METHODS

Ethics Committee Approval: Ethical approval for the study was obtained from the Clinical Research Ethics Committee of Sakarya Training and Research Hospital (Date: 31.11.2023, decision no: 335). All patients were informed in detail about the study before randomization. Written voluntary consent was obtained for participation, and participants were then included.

Study Design and Aim: This randomized controlled study aimed to compare the effects of video-assisted informed consent and standard informed consent in patients undergoing thyroid fine-needle aspiration biopsy. This study was conducted among 76 patients in a surgical oncology clinic in Türkiye between 2024 and 2025.

Participants and Eligibility Criteria: Patients who underwent fine-needle aspiration biopsy (FNA) for benign or malignant thyroid disease were included. Inclusion criteria: being over 18 years of age, having no prior history of thyroid FNAB, having no diagnosed psychiatric disorder, no visual or hearing impairment that would interfere with intervention, ability to read and understand Turkish, and agreeing to participate in the study.

Sample Size: A post hoc power analysis was conducted for the Beck Anxiety Scale, the study's primary endpoint. The sample size was 76 individuals (38 with standard consent, 38 with video-assisted consent). Based on a two-sided $\alpha=0.05$ and a Cohen's $d=0.68$ effect size accepted in the initial power analysis, the statistical power was calculated as 83.3%.

Randomization of the Study: Patients were randomly assigned to two groups, a video-assisted informed consent group and a standard written informed consent group. The closed-envelope method was used for randomization. Pre-prepared opaque envelopes were randomly mixed and sequentially distributed to participants by administrative personnel not part of the research team. This method divided participants into two groups. No withdrawals or protocol deviations were observed.

Intervention: An informed, video-assisted training video was recorded for the experimental groups and managed by the researchers. This video contained professionally narrated information regarding informed consent. The video was prepared to be about 5 minutes long and included subtitles to highlight key risks. Before the application, the video content was evaluated by local general surgeons and the hospital media unit for accuracy, scope, and suitability for standard informed consent forms. The video was shown in a hygienically cleaned area using a device belonging to the researchers. Patients were allowed to rewatch the video if they did not understand certain points. Following the video presentation, patients signed the standard hospital informed consent form, and the data collection forms were subsequently administered.

Control: Patients in the control group were given the routinely used written informed consent form. In addition, the attending physician provided approximately 5 minutes of routine glossary information. The verbal explanation covered the production method, the procedure, and possible risks and complications. Points that patients did not understand were explained verbally again. Following the routine verbal explanation, patients signed the standard hospital informed consent form, and data collection forms were completed.

Outcome Measures: Data were collected using a structured questionnaire comprising three sections: the Demographic Information Form, Structured Questionnaire Form, and Beck Anxiety Inventory (BAI).

Demographic Information Form: The sociodemographic information form, prepared by the researchers in line with the literature, includes information such as age, gender, and education level.

Structured Questionnaire Form: The Structured Questionnaire Form, developed by the researchers, included items assessing procedural experience, patient-reported evaluations of the informed consent process, and recall of procedure-related risks.

Beck Anxiety Inventory (BAI): Participants were assessed for anxiety using the BAI.[13] The scale consists of 21 items. Each item is scored from 0 to 3, yielding a total score ranging from 0 to 63. Higher scores indicate greater anxiety.[13,14] The validity and reliability of the Turkish form have been established, and the Turkish version was used.[14]

Data Collection: Participants were administered measures assessing their procedural experience, perceptions of the informed consent process, and recall of procedure-related risks. Risk recall was assessed using recall. Participants were asked an open-ended question about which procedure-related risks had been explained to them, without being provided with a list or prompted with specific risk options. The risks spontaneously recalled by each participant were recorded.

Statistical Analysis: Statistical analyses were performed using IBM SPSS Statistics 27.0. The normality of continuous variables was assessed using the Shapiro–Wilk test. Continuous variables with a normal distribution were summarized as mean ± standard deviation, and the independent-samples t-test was used to compare two independent groups. Continuous variables that did not exhibit a normal distribution were summarized as the median and interquartile range (IQR), and groups were compared using the Mann–Whitney U test. Categorical variables were presented as numbers and percentages. For intergroup comparisons of categorical variables, the Fisher exact test was used for 2 × 2 cross-tabulations with low expected cell frequencies, and the Fisher–Freeman–Halton exact test was used for tables containing more than two categories. Five-point Likert-type items assessing patients' perceptions of the informed consent process were analyzed while preserving their ordinal structure. Groups were compared using the Mann–Whitney U test. Results for these items were presented as the median. Because Beck Anxiety Inventory scores did not follow a normal distribution, they were summarized as the medians, and groups were compared using the Mann–Whitney U test. In analyses of recall of individual risks associated with the procedure, odds ratios (ORs) and 95% confidence intervals (CIs) were calculated with the video-assisted informed consent group as the index group and the standard informed consent group as the reference group. Accordingly, an OR > 1 indicated that the probability of recalling the relevant risk was higher in the video-assisted consent group. Two-way Fisher's exact tests were used to compare the recall rates of individual risks between groups. All statistical tests were performed in two-way analyses, and $p < 0.05$ was considered statistically significant.

RESULTS

Patients were assessed for eligibility, and eighteen patients declined participation and were excluded. The remaining 76 patients were randomized into the video-assisted informed consent group (n=38) or the standard informed consent group (n=38), as shown in Figure 1.

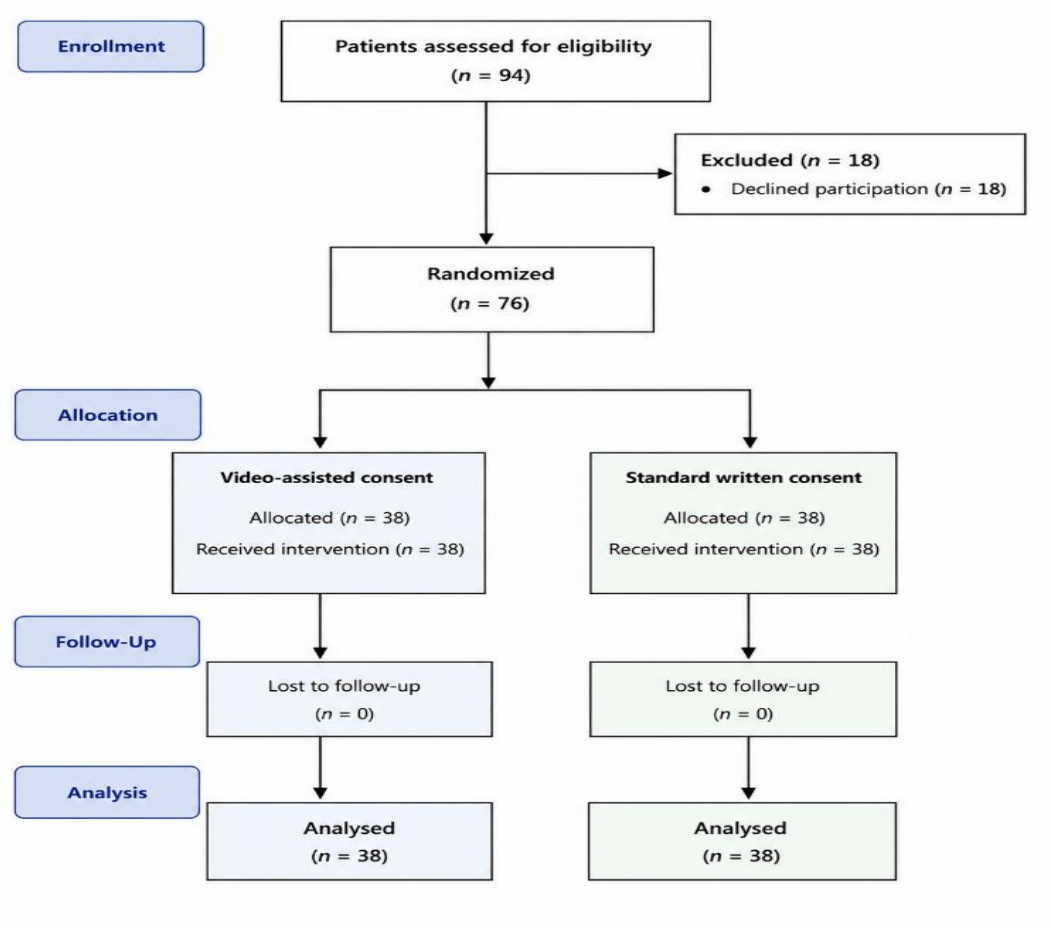

Figure 1. CONSORT flow diagram of the study participants.

The mean age was 53.29 ± 15.34 years in the standard informed consent group and 52.37 ± 15.43 years in the video-assisted informed consent group, with no statistically significant difference between the groups (t = 0.261, p = 0.795). The groups were also comparable in terms of sex distribution (Fisher's exact test, p = 1.000) and education level (Fisher–Freeman–Halton exact test, p = 0.640). Primary school graduates constituted the largest educational category in both the standard (47.37%) and video-assisted (57.89%) groups. Overall, no statistically significant differences were observed in the baseline sociodemographic characteristics between the two randomized groups, as seen in Table 1.

Table 1. Baseline clinical and demographic characteristics of the groups.

Variable		Standard Group (n=38)	Video-Assisted Group (n=38)	p value
Age, years, Mean ± SD		53.29 ± 15.34	52.37 ± 15.43	0.795[a]
Sex, n (%)	Female	26 (68.42)	27 (71.05)	1.000[b]
	Male	12 (31.58)	11 (28.95)	
Education, n (%)	Literate	2 (5.26)	2 (5.26)	0.640[c]
	Primary school	18 (47.37)	22 (57.89)	
	Middle school	5 (13.16)	6 (15.79)	
	High school	7 (18.42)	6 (15.79)	
	Undergraduate	6 (15.79)	2 (5.26)	

[a]: independent-samples t-test; [b]: Fisher's exact test; [c]: Fisher–Freeman–Halton exact test; SD, standard deviation.

There was no statistically significant difference in procedural experience between informed consent groups (Fisher–Freeman–Halton exact test, p = 0.854). In the standard informed consent group, 13 patients (34.21%) reported that the procedure was better than expected, 23 (60.53%) reported that it was as expected, and 2 (5.26%) reported that it was worse than expected. The corresponding numbers in the video-assisted informed consent group were 12 (31.58%), 25 (65.79%), and 1 (2.63%), respectively. Overall, 73 of 76 patients (96.1%) reported that their procedural experience was as expected or better, as shown in Table 2.

Table 2. Procedural experience relative to explanation during intervention

Procedural experience	**Standard Group (n=38)**	**Video-Assisted Group (n=38)**	**p value**
Better than expected, n (%)	13 (34.21)	12 (31.58)	0.854[a]
As expected, n (%)	23 (60.53)	25 (65.79)	
Worse than expected, n (%)	2 (5.26)	1 (2.63)	

[a]: Fisher–Freeman–Halton exact test

Recall of individual procedure-related risks was compared between the standard and video-assisted informed consent groups (Table 3). Recall of bleeding was reported by 32 patients (84.21%) in the standard group and 36 (94.74%) in the video-assisted group. Recall of perforation was reported by 29 (76.32%) and 25 (65.79%) patients, respectively, whereas infection was recalled by 18 (47.37%) and 22 (57.89%) patients, respectively. Pain was recalled by 9 patients (23.68%) in the standard group and 14 (36.84%) in the video-assisted group, while sedation-related risk was recalled by 6 (15.79%) and 9 (23.68%) patients, respectively. Procedure failure was recalled by 5 patients (13.16%) in the standard group and 2 (5.26%) in the video-assisted group. Missed pathology was recalled by one participant (2.63%) in each group. Although recall rates for some individual risks differed numerically between the groups, none of the between-group differences was statistically significant (all p > 0.05).

Table 3. Recollection of individual risks.

Procedure-related risk recalled	**Standard Group n(%)**	**Video-Assisted Group n(%)**	**OR (95% CI)**	**p-value**
Bleeding	32 (84.21)	36 (94.74)	3.38 (0.65–17.62)	0.262
Perforation	29 (76.32)	25 (65.79)	0.60 (0.22–1.65)	0.448
Infection	18 (47.37)	22 (57.89)	1.53 (0.62–3.78)	0.491
Pain	9 (23.68)	14 (36.84)	1.88 (0.69–5.10)	0.318
Sedation risk	6 (15.79)	9 (23.68)	1.66 (0.52–5.26)	0.565
Procedure failure	5 (13.16)	2 (5.26)	0.37 (0.07–2.02)	0.430
Missed pathology	1 (2.63)	1 (2.63)	1.00 (0.06–16.65)	1.000

OR: Odds ratio; CI: Confidence interval.

When the five-point Likert scale items were re-analyzed while preserving their ordinal structure, the median score for the item "I understood the procedure" was found to be 4.00 (IQR: 3.00–4.00) in the video-assisted consent group and 3.00 (IQR: 2.00–4.00) in the standard consent group; however, this difference did not reach the level of statistical significance (U=553.0; p=0.065). No statistically significant differences were found between the groups in terms of understanding why the procedure was performed (U=657.5; p=0.473), having no unanswered questions after consent (U=675.5; p=0.613), and knowing what to expect during the procedure (U=615.0; p=0.247). BAI scores were non-normally distributed and were therefore compared using the Mann–Whitney U test. The median BAI score was 6.00 (IQR, 1.00–15.00) in the standard informed consent group and 5.50 (IQR, 1.25–11.75) in the video-assisted informed consent group. No statistically significant difference in procedural BAI scores was observed between the groups (U=724, p=0.988).

Table 4. Patient-reported outcomes following the standard and video-assisted informed consent processes

Outcome	Standard Group Median (IQR)	Video-Assisted Group, Median (IQR)	U	p value
BAI score, median (IQR)	6.00 (1.00–15.00)	5.50 (1.25–11.75)	724.0	0.988
Understood the procedure	3,00 (2,00–4,00)	4,00 (3,00–4,00)	553,0	0,065
Understood why the procedure was performed	4,00 (3,00–4,00)	4,00 (3,00–4,00)	657,5	0,473
No unanswered questions after informed consent	4,00 (2,00–4,00)	4,00 (3,00–4,00)	675,5	0,613
I knew what to expect during the procedure	3,00 (2,00–3,00)	3,00 (3,00–4,00)	615,0	0,247

IQR: Median; BAI: Beck Anxiety Inventory; IQR: Interquartile range.

DISCUSSION AND CONCLUSION

This randomized controlled trial compared video-assisted informed consent with standard informed consent in patients undergoing thyroid fine-needle aspiration biopsy (FNAB). No statistically significant differences were found between the video-assisted and standard informed consent groups in terms of anxiety scores, recall of individual risks, procedure experience, or patient-reported consent process assessments after the informed consent intervention and before the biopsy. It is assessed that the sociodemographic characteristics of the groups included in the study are similar and will not create any additional differences in the study's implementation.

In our study, no statistically significant difference was found between the video-assisted informed consent and standard informed consent groups regarding procedural experience. The vast majority of participants rated the procedure as expected or better than expected. This indicates that the procedure experience was generally positive in both groups. Looking at previous studies, similar results are seen in studies using additional digital informed consent methods. A systematic review reported that digital consent interventions can improve patient knowledge and understanding, but their effects on satisfaction and anxiety are more variable.[9] Similarly, another study reported no significant difference in patient satisfaction, anxiety, and information acquisition between multimedia-assisted and traditional consent methods. This study demonstrated that pre-procedure multimedia information increased the time efficiency of the consent process.[15] These findings suggest that while multimedia-assisted consent may offer some application advantages, well-executed standard informed consent may have similar effects on outcomes such as patient experience and anxiety.

In our study, there was no statistically significant difference between consent groups in terms of recall rates for biopsy-related risks such as bleeding, infection, pain, sedation, perforation, procedural failure, and missed pathology. Recall rates for bleeding, infection, pain, and sedation were numerically higher in the video-assisted consent group. In comparison, recall rates for perforation and procedural failure were higher in the standard consent group. The recall rate for missed pathology was the same in both groups. In the literature, the effects of multimedia and digital educational tools on patient knowledge and recall vary. A systematic review examining interventions aimed at improving patient understanding in the informed consent process reported that interactive and digital interventions, in particular, have the potential to enhance it.[16] Another recent study shows that multimedia training tools can be useful in improving patient knowledge.[17] In another randomized thyroid surgery study, although an increase in patient knowledge was observed after both video-assisted and standard consent, no significant difference was found between the groups in terms of knowledge acquisition.[18] These findings are consistent with the results of our study.

In our study, assessments of the informed consent process were made using five-point Likert-type items. There was no statistically significant difference between the groups in the patients' reported assessments of the informed consent process. Although the evaluation scores of patients who reported understanding the procedure were numerically higher in the video-assisted group, the difference was not statistically significant. Similarly, no significant differences were observed between the groups in understanding why the procedure was performed, having no unanswered questions after consent, and knowing what to expect during the procedure. In the literature, different results are reported regarding the effect of multimedia tools, such as video, when used in addition to standard informed consent on patient knowledge and comprehension. Several randomized controlled trials have evaluated whether adding video or multimedia support to standard information can improve patients' knowledge and comprehension, with varying results across clinical settings.[11,19,20] However, it appears that this does not always reflect the patient's level of knowledge and understanding. Indeed, although video-assisted electronic consent has been reported to improve understanding, it is not superior to standard consent in terms of patient experience, anxiety, and satisfaction.[19] Similarly, some studies did not find a significant difference in information

gain and satisfaction between multimedia-assisted and traditional consent.[15] These differing findings suggest that the effectiveness of digital consent interventions may vary depending on the clinical situation, the risk of the procedure, the clinical and demographic characteristics of the patients, the content of the intervention, and the method of evaluating the results. Furthermore, differences between studies may stem from variations in the content, scope, and duration of the video or other multimedia tools, the characteristics of the procedure, and the measurement tools used to evaluate the results.

In this study, no statistically significant difference was found in anxiety scores assessed before thyroid biopsy among the informed consent groups. Looking at other studies, the effect on anxiety varies in consent studies conducted with video or other additional tools. Some studies have reported that multimedia-assisted consent does not provide a significant advantage in terms of anxiety compared to standard consent.[15,20] In contrast, a randomized controlled trial in patients undergoing direct thyroid fine-needle aspiration biopsy reported a reduction in situational anxiety after video-based information dissemination.[21] Anxiety before thyroid biopsy may not only be related to the procedure itself or the method of dissemination used. In patients with thyroid nodules, fear and uncertainty regarding the possibility of malignancy and the likelihood of a future cancer diagnosis have also been shown to be a significant source of anxiety.[22] Therefore, the anxiety levels assessed in our study may have been influenced by concerns about a potentially malignant biopsy result, as well as the method of consent. Furthermore, the impact of patient information may depend not only on the format of the information provided but also on the quality of communication. In the context of thyroid cancer, emotionally supportive surgeon communication has been shown to increase perceived physician empathy and trust. However, it did not significantly alter treatment preference or decisional confidence.[23]

This study has several limitations. Anxiety was assessed only after the informed consent intervention, and baseline measurements were not taken before the intervention. Therefore, changes in anxiety levels from before to after the informed consent intervention could not be evaluated. Depending on the study's sample characteristics, recall of procedure-related risks and patients' self-reports of the informed consent process may have been influenced by factors such as health literacy. Another limitation of the study is that participants were not prospectively enrolled in a clinical trial registry system before enrollment began. Future studies are recommended to include pre- and post-intervention assessments, use of situational anxiety-specific measurement tools and objective measures of patient understanding, and larger sample sizes.

In conclusion, no statistically significant differences were found between the video-assisted and standard informed consent groups in terms of anxiety levels, recall of procedure-related risks, procedure experience, and patients' evaluations of the informed consent process. These findings can be interpreted to indicate that neither consent method demonstrated significant superiority. Future randomized controlled trials that include pre- and post-intervention assessments, situational anxiety-specific measurement tools, objective comprehension measures, and larger sample sizes may contribute to a more comprehensive evaluation of the potential benefits of video-assisted informed consent.

Ethics Committee Approval: This study was approved by the Clinical Research Ethics Committee of Sakarya Training and Research Hospital, Türkiye (Date: 31.10.2023, decision no: 335). The study was conducted in accordance with the principles of the Declaration of Helsinki, and written informed consent was obtained from all participants.

Conflict of Interest: No conflict of interest was declared by the authors.

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