Randomized Controlled Trial

Comparison Between Multimedia and Written Informed Consent for Lumbar Transforaminal Epidural Steroid Injection: A Randomized Controlled Pilot Trial

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Background: Informed consent is a crucial ethical and legal requirement in medical practice to ensure thq5- gy65hgbp[8at patients understand the risks, benefits, and alternatives of medical procedures. Recent advances in multimedia technology have facilitated the exploration of multimedia consent, aiming to enhance patient understanding and satisfaction. Ascertaining that patients have full comprehension of the procedures before opting to undergo them is especially important now that instances of such procedures as lumbar transforaminal epidural steroid injections (TESIs) are increasing.

Objectives: To determine the effectiveness of multimedia consent forms for lumbar transforaminal steroid injections.

Study Design: Randomized clinical trial.

Setting: Outpatient multidisciplinary pain medicine center of a tertiary hospital.

Methods: A randomized controlled trial was conducted with 30 patients who received lumbar TESIs for lumbar radiculopathy. Patients were randomly assigned to either the multimedia consent group (Group M) or the conventional paper consent group (Group C). This study evaluated patients' comprehension of the procedure, their anxiety levels (using the State-Trait Anxiety Inventory short form), and the patients' post-procedure satisfaction.

Results: Group M showed significantly greater understanding of the procedure and reported lower levels of anxiety than did Group C ($P = 0.041$; $P = 0.03$). However, there were no statistically significant differences in post-procedure satisfaction between the groups ($P = 0.25$). These findings suggest that multimedia consent can effectively improve patient comprehension and reduce anxiety without significantly affecting patient satisfaction.

Limitations: First, the limited sample size of 30 patients restricts the applicability of our findings to a wider population, suggesting a need for larger studies to better assess the effects of multimedia consent. Second, conducting the study in a single hospital might have introduced bias. Multicenter research may provide a more diverse and accurate evaluation of the efficacy of multimedia consent.

Conclusion: This pilot study contributes to the growing evidence supporting the use of multimedia consent to enhance patient understanding and reduce anxiety, marking a promising direction for improving informed consent practices for less invasive procedures, such as lumbar TESIs. Further research is required to fully explore the benefits and limitations of multimedia consent forms in various medical settings.

Key words: Multimedia, informed consent, video consent, alternative consent form, paper consent, transforaminal epidural steroid injection, pre-procedure anxiety, patient comprehension

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Medical informed consent is the process of educating patients about the risks and benefits of and alternatives to a particular procedure or intervention (1). Physicians are ethically and legally obligated to obtain informed consent from patients before performing medical examinations or treatments (2). Informed consent is the legal implementation of the concept that every individual has the right to make decisions that affect their own health. A proper informed consent process provides information that allows the patient or their representative to make an informed decision about whether to undergo an intervention (3). Proper consent allows patients to freely agree or disagree to a procedure. Despite the importance of this step, both physicians and patients often lack proper preparation for this process. There is no formal education on patient explanation and consent, and explanations of procedures are provided under time constraints, which may result in inadequate delivery of information to patients (4,5).

In recent years, the expansion of healthcare informatization has made electronic consent more common. The focus on patient-centered health care systems has shifted to emphasize effective communication of information at the core of the consent process (6). Furthermore, progress in multimedia technology has facilitated the exploration of multimedia consent across a wide array of fields (6-11). The applications of this technology encompass areas ranging from surgery, invasive procedures, and minimal injections to disease explanation and participation in research studies. The results of this technological progress have revealed the significant effectiveness of video-based consent in enhancing understanding and patient satisfaction across most procedures (12).

Amid the rising prevalence of low back pain, the frequency of interventions, such as transforaminal epidural steroid injections (TESIs), has surged, marking a notable development in interventional pain management techniques since the late 1990s (13,14). The potential for related disputes, which also rises with an increase in these procedures, is particularly apparent in the context of informed consent (15). After the Montgomery vs. Lanarkshire Health Board (2015) ruling, the importance of informed consent was further amplified, as evidenced by a significant increase in consent-related legal disputes within the National Health Service in the United Kingdom. Before 2015, such disputes encompassed 3.76% of the total number; after 2015, the figure rose to 8.12% (116% increase, $P < 0.001$) (16).

However, the exploration of multimedia consent forms for less critical interventions has been limited, with existing literature focusing primarily on surgical or research settings with significant risks. The present study aimed to fill this gap by developing and evaluating a video consent form for patients undergoing lumbar TESIs, a common intervention in pain medicine. When we examined the effects of this consent form on patient comprehension, anxiety, and satisfaction, we discovered new perspectives on the effectiveness of multimedia consent for interventional pain management.

Methods

Patient Selection

This study conducted a randomized controlled trial that examined the comprehension, anxiety levels, and satisfaction of patients who received lumbar TESIs for lumbar radiculopathy. Eligibility for participation was determined in outpatient clinics by discussing the need for the procedure and enrollment in the study, followed by informed consent.

The study was approved by the Institutional Review Board of Bundang Seoul National University Hospital (B-2206-761-303) and registered on ClinicalTrials.gov (www.clinicaltrials.gov) with the identifier NCT05874427. Patients were included if they met the following criteria: 1) diagnosis of lumbar radiculopathy scheduled to be treated by lumbar TESIs; 2) age between 20 and 80 years; and 3) ability to comprehend the purpose and process of the study. The exclusion criteria were as follows: 1) inability to understand the study or refusal to participate and 2) previous history of lumbar TESIs.

Multimedia Consent Form

The public relations team at Bundang Seoul National University Hospital assisted in developing a multimedia informed consent form. The video provides a detailed explanation of the entire procedure for lumbar TESIs, from patient admission to post-procedure recovery, including the purpose and process of the procedure, potential side effects, and precautions. The length of the video is 3 minutes and 44 seconds, and it includes a mix of animation and live footage. This video is accessible via smartphones or computers through this link: https://www.hichart.net/sns/?shortenurl=MhEy (Fig. 1).

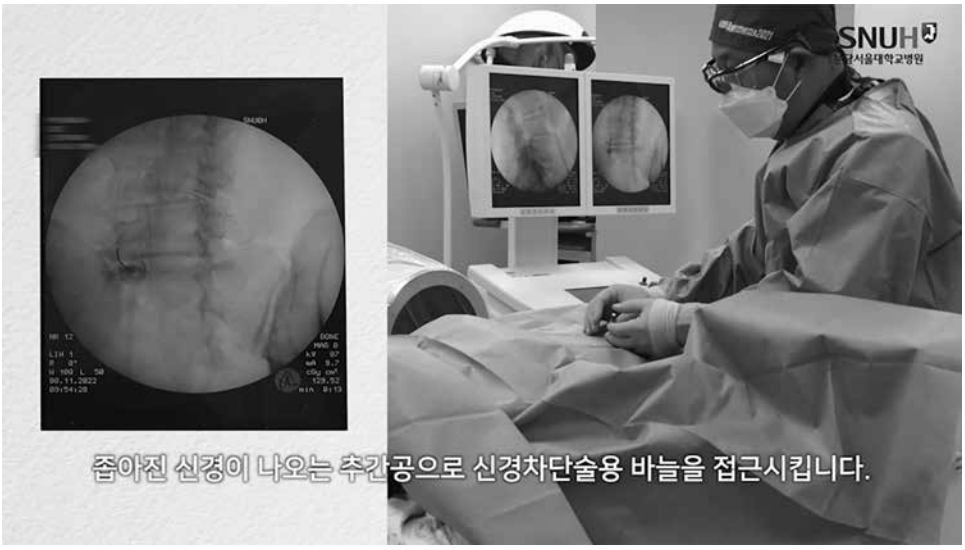

Fig. 1. *A scene from a multimedia consent form for a lumbar transforaminal epidural steroid injection watched by the patient.*

Questionnaires

Prior to the procedure, patients were given a 10-item questionnaire to evaluate their understanding of the procedure and a short form of the State-Trait Anxiety Inventory (STAI) to assess their anxiety levels. The 10-item questionnaire, with scores ranging from 0 to 10, focused on goals, processes, effects, side effects, and precautions associated with the procedure. Higher scores indicated a greater number of correct responses (Table 1). The STAI short form consisted of 6 items rated from one (not at all) to 5 (very much), with total scores ranging from 6 to 24. Higher scores indicated greater anxiety. A 5-point Likert scale ranging from one (strongly disagree) to 5 (strongly agree) was used to assess post-procedure satisfaction, with total scores between 5 and 25 representing greater satisfaction.

Table 1. *The 10-item questionnaire assessing understanding of the procedure.*

No.	Question	Correct Answer
1	Procedure is performed after local anesthesia.	True
2	After the procedure, there is no risk of infection, so taking a shower is safe.	False
3	It may take 3 to 7 days for the treatment effect to become evident after the procedure.	True
4	Weakness in the legs after the procedure is a serious side effect.	False
5	The needle tip is placed in the bone rather than the nerves.	False
6	There is a risk of complications such as infection or hematoma.	True
7	It is performed with the patient lying face down.	True
8	X-ray equipment is used during the procedure.	True
9	There may be discomfort when the medication is injected.	True
10	There may be a temporary increase in pain on the day of the procedure.	True

Consent Process

At Bundang Seoul National University Hospital, lumbar TESIs are typically performed immediately after the decision is made during an outpatient clinic visit. Of the 30 patients, 15 were randomly assigned to receive the traditional paper consent form (Group C), and the other 15 were assigned to the group who received the multimedia consent form (Group M). Group C underwent the standard consent process with a dedicated physician, whereas the patients in Group M received an additional video consent form on their cell phones. Once the video review ended, patients in Group M completed the traditional paper consent form. This step was necessary due to the legal requirements in Korea, which do not allow video-only consent forms. Another physician, who was separate from the doctors who would perform the procedure, conducted the

consent process to ensure the unbiased confirmation of consent and assessment of understanding.

After consent was obtained, a separate physician conducted pre-procedure assessments to assess the patients' understanding of the procedure and their level of anxiety. These assessments included the administration of the aforementioned 10-item questionnaire designed to assess patients' comprehension of the purpose, process, effects, side effects, and precautions of the procedure. As mentioned earlier, the STAI short form was used to assess patients' anxiety levels and current emotional states.

After surgery, patient satisfaction was assessed in the recovery room, using a 5-item scale with scores ranging from 5 to 25. This assessment was designed to measure overall satisfaction with the procedure, information provided, and care received during the procedure.

Statistical Analysis

Continuous variables were presented as means with standard deviations, whereas noncontinuous variables were presented as counts and percentages. The proportion of correct responses for each of the 10 questions in the questionnaire was presented as a risk ratio with 95% confidence intervals. The mean scores of Groups M and C on the 10-item questionnaire, STAI short form, and post-procedure satisfaction were compared using independent t-tests. The cutoff for statistical significance was set at $P < 0.05$. All statistical analyses were performed using IBM® SPSS® Statistics 21.0 (IBM Corp.).

Results

This study included 30 patients who were randomly divided into 2 groups: a multimedia consent group (Group M) and a conventional paper consent group (Group C), with 15 patients in each group. The average age of the patients was 65 years (range: 21–86 years). Specifically, the average age in Group M was 59.73 ± 15.40; in Group C, it was 63.73 ± 16.96. The distribution of patients by gender was unintentional but resulted in an equal mix of 6 men and 9 women in each group due to the random allocation process (Table 2).

In the 10-item questionnaire assessing patients' understanding of the procedure, Group M achieved a significantly higher average score than did Group C (Group M scored 8.27 ± 0.80, while Group C scored 7.40 ± 1.35; $P = 0.041$) (Table 3). When examining the proportion of correct answers for each of the 10 understanding questions individually, the rates were generally similar between Groups M and C, with risk ratios not significantly different from 1.00. The question with the highest rate of incorrect answers across both groups was Question 6 (14, 46.7%), with no significant difference in correct response rates between Groups M and C. The rates of incorrect responses to Questions 4 and 5 were tied for second highest place (15, 50%; 15, 50%, respectively), with both questions showing higher correct response rates in Group M (Q4: Group M, 8, 53.3% vs. Group C, 7, 46.7%; Q5: Group M, 9, 60.0% vs. Group C, 6, 40.0%) (Table 4).

The STAI short form results indicated that Group M reported significantly lower levels of anxiety (Group M, 17.67 ± 3.31 vs. Group C, 14.47 ± 1.09; $P = 0.03$), suggesting that multimedia consent might have had a beneficial effect on patient anxiety. Meanwhile, although Group M reported higher levels of post-procedure satisfaction than did Group C, the difference was not statistically significant (Group M, 23.00 ± 2.54 vs. Group C, 21.87 ± 2.75; $P = 0.25$) (Table 3).

Discussion

In the medical field, informed consent is emphasized to fulfill ethical and legal obligations, ensuring that patients fully comprehend medical procedures and treatments and agree to receive them voluntarily (2). Proper informed consent requires that patients are fully informed about the purpose, benefits, and potential risks of a specific procedure to ensure that they have a complete "understanding" before deciding (17). Additionally, it is essential to provide information about alternative treatments, allowing patients to make a truly informed choice based on a comprehensive understanding of all available options. Conventional consent processes typically involve physicians explaining the purpose, method, and potential side effects of a procedure to the patient face-to-face before obtaining written consent. However, patients often receive insufficient information due to limited clinical staff and time (4,5). Jawaid et al conducted a study on 350 patients awaiting surgery. The study found that although 87.7% of the patients claimed they were informed about their condition and the surgery, only 8.9% were aware of the details of the surgery, and only 3.4% understood the possible complications (5). Furthermore, Joolaee et al reported that 48% of the patients did not read the consent form before signing it. These results raise concerns regarding the effectiveness of informed consent (18).

Multimedia consent, which has been studied in several areas to address the issue of poor information transmission, has been shown to be effective in increasing patients' understanding of invasive surgery (7,19,20). Multimedia consent can be understood more intuitively by patients, since it is not limited by time and provides a wider range of visual information than do textual and spoken explanations alone. Unfortunately, in most countries, the format of patients watching multimedia consent by themselves and signing without the involvement of a physician is not legally recognized in most countries, written and verbal explanations in face-to-face meetings with a physician are mandatory, as is the case in conventional procedures (21). However, other studies have shown that the use of such videos is meaningful in reducing the effort and time required by physicians preparing for surgery (20). Moreover, there is a strong advantage in improving patients' understanding of procedures without necessitating additional time or effort from the physician. Our findings also highlighted that patients who received multimedia consent (Group M) had a significantly greater understanding of the procedure, as shown by their scores on the 10-item questionnaire, than did those who received conventional paper consent forms (Group C). These differences suggest that video consent can be effectively used for procedures, such as lumbar TESIs, which may be perceived as less serious and threatening than invasive surgeries.

Additionally, multimedia consent (Group M) resulted in significantly lower anxiety levels, as measured by the STAI short form. These results imply that multimedia consent forms improve comprehension and reduce patient anxiety, likely by providing clearer and more comprehensive explanations of what the patient can expect during and after the procedure. Reducing preprocedural anxiety is crucial because high anxiety levels can affect patient satisfaction, compliance, and even post-procedure recovery. Studies have shown that the prevalence of presurgical anxiety ranges from 17% to 89% and affects surgical outcomes and postoperative

Table 2. *Characteristics*.

Variables	Group M (n = 15)	Group C (n = 15)
Age (mean ± SD)	59.73 ± 15.40	63.73 ± 16.96
Gender (n, %)		
Men	6 (40)	6 (40)
Women	9 (60)	9 (60)
Diagnosis (n)		
Central stenosis	1	1
Foraminal stenosis	5	6
HIVD	8	5
FBSS	1	-
IDD	-	1
Multiple bone meta	-	1
Sciatic neuropathy	-	1

HIVD: herniated intervertebral disc, FBSS: failed back surgery syndrome, IDD: internal disc disruption.

Table 3. *The scores of the 10-item questionnaire assessing understanding, State-Trait Anxiety Inventory (STAI) short form, and post-procedure satisfaction.*

Questionnaires (Total Score)	Group M (n = 15)	Group C (n = 15)	*P* value
The scores of 10-item questionnaire assessing understanding (10)	8.27 ± 0.80	7.40 ± 1.35	0.20
STAI short form (24)	17.67 ± 3.31	14.47 ± 1.09	< 0.05
Post-procedure satisfaction (25)	23.00 ± 2.54	21.87 ± 2.75	0.25

Table 4. *Number of correct responses and risk ratio for a 10-item questionnaire.*

Question No.	Number of Correct Answers (%)	Group M (n = 15)	Group C (n = 15)	Group M vs. Group C, Risk Ratio (95% CI)
1	29 (96.7)	15 (100%)	14 (93.3%)	2.07 (1.42 – 3.02)
2	25 (83.3)	14 (93.3%)	11 (73.3%)	1.82 (0.98 – 3.39)
3	28 (93.3)	14 (93.3%)	14 (93.3)	1.00 (0.24 – 4.20)
4	15 (50)	8 (53.3%)	7 (46.7%)	1.14 (0.56 – 2.35)
5	15 (50)	9 (60.0%)	6 (40.0%)	1.50 (0.71 – 3.16)
6	14 (46.7)	7 (46.7)	7 (46.7%)	1.00 (0.49 – 2.05)
7	30 (100)	15 (100)	15 (100%)	1.00 (1.00 – 1.00)
8	26 (86.7)	14 (93.3)	12 (80)	1.62 (0.81 – 3.28)
9	24 (80.0)	13 (86.7)	11 (73.3)	1.46 (0.71 – 2.97)
10	29 (96.7)	15 (100)	14 (93.3)	2.07 (1.42-3.01)

CI: confidence interval.

recovery (22,23). Similar findings have been reported in pain medicine for procedures, such as trigger-point injections (24,25).

To reiterate, although the multimedia consent group (Group M) reported higher levels post-procedure patient satisfaction, the difference was not statistically significant. This outcome might be attributed to the small sample size of our pilot study or to the possibility that factors beyond the type of consent form, such as the outcome of the procedure and the health care provider's demeanor, had a greater influence on overall patient satisfaction.

Limitations

Although this study provides valuable insights into the potential benefits of multimedia consent forms, it has some limitations. First, the small sample size limited the generalizability of our findings. Based on only 30 patients, our results may not reflect the experiences and outcomes of the broader patient population. A larger study population would provide a more robust understanding of the effects of multimedia consent on patient understanding, anxiety, and satisfaction. Second, the study was conducted in a single-hospital setting, which might have introduced bias related to the specific patient population, hospital procedures, and health care providers' approaches to patient care. A multicenter study would help mitigate these biases and offer a more comprehensive understanding of the effectiveness of multimedia consent.

Despite these limitations, our study contributes important preliminary findings to ongoing discussions on enhancing informed consent through multimedia tools. Further research addressing these limitations is crucial to fully understand the potential of multimedia consent to improve patient outcomes and satisfaction across the health care spectrum.

Conclusion

In conclusion, our pilot study adds to the evidence supporting the use of multimedia consent forms for enhancing patient understanding and reducing anxiety, presenting a promising avenue for improving informed consent practices in less invasive procedures, such as lumbar TESIs. Further research with larger sample sizes and more detailed assessments is essential to fully understand the advantages and limitations of multimedia consent forms in various medical settings.

Author Contributions:

Sunmin Kim (data curation, writing—original draft); Nam Woo Kim (conceptualization, data curation, methodology); Francis Nahm (data curation, writing—review and editing); Eun Joo Choi (data curation, writing—review and editing); Pyung Bok Lee (conceptualization, data curation, methodology, writing—review and editing).

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