

Patient perspectives on informed consent for medical AI: A web-based experiment

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Abstract

Objective: Despite the increasing use of AI applications as a clinical decision support tool in healthcare, patients are often unaware of their use in the physician’s decision-making process. This study aims to determine whether doctors should disclose the use of AI tools in diagnosis and what kind of information should be provided.

Methods: A survey experiment with 1000 respondents in South Korea was conducted to estimate the patients’ perceived importance of information regarding the use of an AI tool in diagnosis in deciding whether to receive the treatment.

Results: The study found that the use of an AI tool increases the perceived importance of information related to its use, compared with when a physician consults with a human radiologist. Information regarding the AI tool when AI is used was perceived by participants either as more important than or similar to the regularly disclosed information regarding short-term effects when AI is not used. Further analysis revealed that gender, age, and income have a statistically significant effect on the perceived importance of every piece of AI information.

Conclusions: This study supports the disclosure of AI use in diagnosis during the informed consent process. However, the disclosure should be tailored to the individual patient’s needs, as patient preferences for information regarding AI use vary across gender, age and income levels. It is recommended that ethical guidelines be developed for informed consent when using AI in diagnoses that go beyond mere legal requirements.

Keywords

Artificial intelligence, informed consent, decision support tool for diagnosis, duty to disclose, patient autonomy, algorithm, automation

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Introduction

Background

Artificial intelligence (AI) is rapidly transforming the field of healthcare. Many AI applications in health care have demonstrated performance that matches or even surpasses that of human physicians in medical diagnosis, execution of treatment and surgery.^{1–3} A recent survey found that one-third of hospitals are already employing AI in medical imaging, whereas another one-third plan to incorporate the technology in the next two years.⁴ For example, images from standard and dermoscopic cameras can be utilized to assist doctors in classifying skin lesions.⁵ Despite the increasing use of AI in healthcare, it is frequently

used behind the scenes and patients are not often aware of its implementation in their care.⁶

In the context of AI in health care, especially with clinical decision support tools, which are the most common types of AI applications, the problem is whether you should disclose the use of the tool and what type of information should be provided. This is an informed consent problem, which traditionally addressed what information

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should be provided to ensure the patients wield their autonomy in deciding whether or not to receive the treatment. On the one hand, consulting an AI application can be understood similarly to consulting a colleague or a book, which does not need any special mention. On the other hand, AI applications might introduce new types of errors or biases, which could harm the patients in an unexpected fashion or reduce the trust held between the patient and the doctor.

At present, there is no ethical and legal consensus regarding whether disclosing the application of a medical AI is required for informed consent in the United States, the European Union, or South Korea.⁷ In the US, the Food and Drug Administration (FDA), which addresses the safety and effectiveness of ‘Software as a Medical Device (SaMD)’, does not address informed consent.^{8–10} Courts and state legislatures have yet to articulate an AI-specific standard for informed consent.¹¹ Professional bodies have not offered a protocol for obtaining informed consent when using AI tools, which could potentially aid in developing an AI-specific standard of care.¹¹

Prior work

Informed consent in AI-aided health care has received attention from medical law and ethics scholars. From a legal perspective, scholars have analyzed the informed consent issue in AI-aided health care from a tort law or contract law perspective.^{11,12} Cohen suggested that the current US case law would not likely require disclosure of the use of AI except in several extreme cases—‘such as when patients inquire about the involvement of AI/ML, when the medical AI/ML is more opaque, when it is given an outsized role in the final decision-making, or when the AI/ML is used to reduce costs rather than improve patient health’.¹² The majority of courts in the US do not require the disclosure of the physician’s experience or qualifications on the theory that only information about the procedure itself is material.¹²

In the EU context, the GDPR has been cited as a source of law to support the patient’s right to informed consent in addition to the Charter of Fundamental Rights of the European Union (CFR).¹³ Astromske argues that the GDPR establishes the patients’ right to receive a ‘meaningful explanation about the logic involved’ in automated decisions.¹⁴ Miguel et al. suggests that patients should be informed about the existence of automated decision-making and the role played by AI in the final decision.¹⁵ However, other scholars note that the GDPR’s provisions on automated decision-making only apply when a decision is ‘based solely’ on AI, which means that in situations in which AI is used as a decision-support tool, there is no legal obligation to inform patients about its use.^{16–18}

From an ethical perspective, scholars have argued that patients should be informed about the use of AI in their

medical care. Muller et al. state that if AI is involved in the decision-making process, patients should be appropriately informed.¹⁹ Kiener presents three reasons for informed consent, including the risk of cyberattacks, systematic bias and mismatches between AI’s assumptions and patients’ backgrounds.²⁰ Ursin identifies eight novel types of information that should be disclosed for an AI-aided diagnosis.⁸ Kiseleva et al. argue that physicians should notify patients about the use of AI in their diagnosis and treatment, and should provide information about the usage, alternatives and certification of the AI system.²¹

Despite the efforts to draw a line for disclosure from both legal and ethical perspectives, one important aspect has been overlooked: the patients’ perspective. In the United States, individual states are evenly divided between patient-based and physician-based standards for addressing informed consent issues. The patient-based standard requires disclosure ‘when a reasonable person, in what the physician knows or should know to be the patient’s position would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy’.²² On the other hand, the physician-based standard mandates release of ‘those disclosures which a reasonable medical practitioner would make under the same or similar circumstances’.²³ South Korea seems to take a hybrid approach that incorporates elements of both the patient-based and physician-based standards.²⁴

The importance of including patients’ perspectives in the discussion is evident from the patient-based standard. Patients’ information needs can also offer valuable insights for professional bodies in drafting guidelines or protocols, which can in turn inform the physician-based standard. According to the patient-based standard, physicians have a duty to disclose all *material* information to their patients, which includes ‘information which the physician knows or should know would be regarded as significant by a reasonable person in the patient’s position when deciding to accept or reject a recommended medical procedure’.²⁵ Although the value of empirical research on patients’ views regarding information disclosure in the use of AI/ML in medicine has been recognized,¹² no research has yet explored what information patients consider important or significant for making treatment decisions when AI is used in a clinical setting.^{26–28}

Goal of this study

This research fills the gap identified above by addressing the informed consent problem from patients’ perspectives. Specifically, it aims to empirically examine whether physicians should inform patients about the use of AI in diagnosis, and if so, what information should be provided. This will be achieved by estimating the patients’ perceived importance of information regarding the use of an AI tool in diagnosis in deciding whether to receive the treatment.

Hypotheses

Prior work on the patients' and general public's attitudes toward clinical artificial intelligence informed the generation of hypotheses. According to previous studies, patients preferred providers over the AI if the AI and providers were equally effective,^{26,29} and many participants viewed the currently available AI as premature technology.^{26,30–33} Considering the lower trust on the AI tool, when an AI tool is used in diagnosis, compared with the parallel situation in which the image reading was conducted by a radiologist, patients may perceive information regarding the use of the AI tool as more significant to comfortably make a decision to undergo a proposed operation (see H1 in Textbox 1). Previous studies also revealed that participants showed a greater acceptance of AI if the AI were to be applied in a lower risk setting.^{32,34} Therefore, the magnitude of the risk patients is facing with the recommended treatment may increase the patients' perceived importance of information (see H2 in Textbox 1). In addition, considering that participants in previous studies showed a greater acceptance of AI if the AI fit societal and cultural norms,^{35,36} the pervasiveness of the use of the AI tool may decrease the patients' perceived importance of information (see H3 in Textbox 1). Finally, some studies found that participants showed a greater acceptance of AI if the AI was proven to be more accurate than the providers were,^{26,29} and therefore patients may require less information when AI in fact performs better than humans do (see H4 in Textbox 1).

H1: When an AI tool is used, compared with when a referral is made to a radiologist, respondents perceive AI information as more important.

H2: When AI is used, respondents perceive AI information as more important if the risk posed by the recommended treatment is higher.

H3: When AI is used, respondents perceive AI information as less important if the use of the AI tool is prevalent.

H4: When AI is used, respondents perceive AI information as less important if the AI clinical diagnostic support tool performs better than does a human radiologist.

Fourteen dependent variables fall into two categories: a) information regarding the surgery/procedure (surgery information) and b) information regarding the use of an AI tool in diagnosis (AI information). Although the primary focus of this study is on the perceived importance of AI information, I also estimated the perceived importance of surgery information that may be disclosed along with AI information. This enables us to compare the perceived importance of AI information when AI is used with that of surgery information when AI is not used, providing insight into how much importance respondents place on information regularly disclosed before providing consent for a surgery. Additionally, seven dependent variables were

introduced regarding the surgery/procedure (Table 1, Surgery information), which were identified using professional guidelines on informed consent. The study also includes eight dependent variables regarding the use of an AI tool (Table 1, AI information), which were identified using previous research on AI information.

In radiologist scenarios, the dependent variables regarding AI information were worded to describe the corresponding information regarding referral to a radiologist. The seven dependent variables of AI information in radiologist scenarios corresponding to those in AI scenarios are as follows: a) whether the image reading was referred to a radiologist (*used*), b) the qualification of the radiologist (*performance*), c) whether a referral to a radiologist is pervasive in the diagnosis of the given disease (*generally_used*), d) how much experience the doctor has in making a diagnosis considering the image reading of the referred radiologist (*doctor_experience*), e) whether the opinion of the doctor and that of the referred radiologist were the same (*opinion_same*), f) the reason for following or rejecting the recommendation from the referred radiologist when the opinions differed (*reason_reject_accept*), and g) the possibility of receiving a diagnosis without referring to a radiologist (*optout*). Since the corresponding information for the dependent variable, *architecture*, could not be identified, I did not include the question about architecture for radiologist scenarios.

Methods

Pilot study

Prior to the main experiment, a pilot test was conducted in April 2022 to calculate the minimum needed sample size of the main study. Email invitations were sent to the randomly chosen 521 persons ages 20–69 among the national research panel of Embrain in South Korea. Some 50 responses were collected until satisfying the quota of 6 individuals per ten (2 5) combinations of gender (female and male) and age group (20 s, 30 s, 40 s, 50 s and 60 s).

Main study

The study was conducted online in June 2022, and email invitations were sent to the randomly chosen 20,386 persons ages 20~69 among the national research panel of Embrain in South Korea, which maintains a closely representative panel in terms of gender, age and region and the largest panel in Asia (consisting of more than 1.6 million individuals). I limited our sample to 1000 individuals to reflect the a priori power analysis using a pilot study, which indicated that $N = 980$ sample size is needed (effect size = 0.0139, $\alpha = 0.05$, power = 0.80). A quota of 100 individuals per 10 combinations of gender (male and female) and five age groups (20–29, 30–39, 40–49, 50–59 and 60–69)

Table 1. Dependent variables: surgery information and AI information.

Category	Variable	Meaning	Reference
Surgery information			
	<i>benefit</i>	expected benefit of the proposed operation	37
	<i>side_effect</i>	expected risk of the proposed operation	37,38
	<i>risk_without</i>	risks of forgoing the treatment	37,38
	<i>surgeon_quality</i>	participating surgeon's qualification	38
	<i>short_term</i>	a short-term effect of the quality of life	38
	<i>long_term</i>	a long-term effect on the quality of life	38
AI information			
	<i>used</i>	whether the AI-powered medical software was used in diagnosis	39,40
	<i>architecture</i>	the architecture and training of the AI algorithm	7,8,41
	<i>performance</i>	the performance of the AI medical software	8,26,27
	<i>generally_used</i>	whether the AI medical software is pervasively used in the diagnosis of the given disease	12
	<i>doctor_experience</i>	how much experience the doctor has in making a diagnosis using the AI medical software	40
	<i>opinion_same</i>	whether the opinion of the doctor and that of the AI medical software were the same	26
	<i>reason_reject_accept</i>	the reason for following or rejecting the recommendation from the AI medical software when the opinions differed	26
	<i>optout</i>	the possibility of receiving a diagnosis without using the AI medical software	15,42

were set to reflect the view of different gender and age groups and to only include those with the legal capacity to give consent to the treatment under Korean law. Responses were collected until the quota was satisfied while excluding responses with their response time either too short or too long. During the study, the respondents first read a hypothetical scenario and then filled out a survey.

To answer the research questions, I used eight scenarios for vignettes using an AI diagnostic support tool ($ai = 1$): 2 (whether an open surgery to confirm pancreatic cancer is recommended ($high_risk = 1$) or a fine needle aspiration biopsy is recommended to confirm thyroid cancer ($high_risk = 0$)) 2 (whether the use of an AI diagnostic support tool is common ($common = 1$) or rare ($common = 0$)) 2 (whether the AI diagnostic support tool far exceeds average human radiologists in its performance ($superior =$

1) or not ($superior = 0$)) experimental design. To estimate what effect the use of AI would have on the outcome variables, I also used two parallel scenarios utilizing radiologists for image reading ($ai = 0$) only varying the risk posed by the recommended procedure ($high_risk$). Since some of the conditions considered under the AI use cases are not realistic under the radiologist cases (for example, the condition in which referring to radiologists for image reading is rare or the condition under which the referred radiologist far exceeds an average radiologist), I do not vary these conditions for radiologist scenarios. The scenario was kept identical in all other respects. Therefore, I used a total of 10 scenarios (Table 2), and a total of 1000 participants were randomly assigned one of the two radiologist cases and four of the 8 AI cases. The scenarios were developed and improved in consultation with a group of physicians in various specialties including radiology, internal

Table 2. Condition variation in scenarios.

No.	AI/radiologist	High risk	Common	Superior
1	AI	High risk	Common	Superior
2	AI	High risk	Common	Average
3	AI	High risk	Rare	Superior
4	AI	High risk	Rare	Average
5	AI	Low risk	Common	Superior
6	AI	Low risk	Common	Average
7	AI	Low risk	Rare	Superior
8	AI	Low risk	Rare	Average
9	Radiologist	High risk	Common	Average
10	Radiologist	Low risk	Common	Average

medicine and surgery. Since it was deemed impossible to have individual respondents rate all vignettes, each participant received five randomly selected vignettes (one from radiologist scenarios and four from AI scenarios). For the English-translated scenarios, see Online Appendix I.

In ‘high risk’ scenarios (nos. 1–4 and 9), participants were told that they had visited a physician who took a CT scan on their upper abdomen and recommended an open surgery to confirm whether the lesion from the scan was pancreatic cancer ($high_risk = 1$). ‘Low risk’ scenarios (nos. 5–8 and 10) involve a physician visit followed by an ultrasound image scan on the neck and the recommendation of a fine needle aspiration biopsy to confirm whether the lesion from the scan is thyroid cancer ($high_risk = 0$). In ‘radiologist’ scenarios (nos. 9–10), the physician made the recommendation based on the fact that a referred radiologist had read the image and advised the physician of the diagnosis ($ai = 0$). In ‘AI’ scenarios (nos. 1–8), the physician made the recommendation based on the fact that an AI decision support tool read the image and output the diagnosis ($ai = 1$). In some cases, the referral to radiologists or referral to an AI decision support device is common ($common = 1$), whereas, in other types of scenarios, it is rare ($common = 0$). The referred radiologist or AI decision support tool is as good as an average radiologist is ($superior = 1$) or not ($superior = 0$). After receiving the recommendation, participants indicated a rating of importance of information relevant to the decision to undergo the surgery or procedure. The items include standard information provided before surgery/procedure and additional items to be considered for AI use. The importance rating

of the relevant information was measured via 15 items, rated on a 7-point Likert scale. Among others, the items included the following: ‘side effect of the surgery/procedure’, anchored at 1 = not important at all and 7 = very important; ‘whether AI decision support tool was used in the diagnosis’ anchored at 1 = not important at all and 7 = very important.

The questionnaire included respondents’ sociodemographic characteristics such as gender, age, income and education. I investigated the respondents’ medical history by asking how many times they had visited a hospital in the past year and whether they had undergone open surgery or fine-needle aspiration biopsy. Various psychological characteristics were included. Respondents’ preferred level of participation in decision-making (*autonomy*) was measured using a 5-point rating scale (1 = strongly disagree, 5 = strongly agree): ‘I want to make a decision on my own whether to undergo a surgery/procedure, rather than deferring the decision to the doctor’. Similarly, other psychological characteristics such as risk-aversion (*risk_averse*: ‘I visit the hospital even when I am slightly ill’) and being an early adopter (*early_adopt*: ‘I try new technology earlier than others do’) were measured.⁴³ In addition, respondents’ familiarity with AI technology was investigated through the 5-point rating of their understanding of deep learning (*know_DL*: ‘I know the difference between deep learning and regression’) and the number of AI applications in medicine they are familiar with (*know_medical_AI*).

Data analysis

Analyses were conducted using STATA 17. I examined descriptive statistics for the sample. I then conducted multi-level mixed-effect linear regression analyses to test whether the four predictors—the use of AI or radiologist (*ai*), whether the surgery/procedure involves high risk (*high_risk*), whether the use of AI/radiologist is common (*common*), and whether the AI/radiologist far exceeds an average radiologist (*superior*)—influenced the perceived importance of information. Finally, I conducted linear regression analyses with robust standard errors clustered in respondents to determine the association between socio-demographic factors and the perceived importance of information.

Although the correlations among the controls were not highly noticeable (see Online Appendix IV), I checked for multicollinearity by computing the variance inflation factor (VIF) and tolerance values for the predictor variables. The resultant VIF values were between 1.00 and 1.41, which were well below the cutoff value of 5, and the tolerance values were in the range of 0.7111 and 0.9956, which were higher than the threshold of 0.1. Thus, multicollinearity is not an issue in this research.

Ethical considerations

The institutional review board of Hanyang University, which acts as the ethics committee for studies, approved the study (HYUIRB-202206-010). Prior to the start of the study, informed consent was obtained, and the study procedure was explained to the participants. Since the data collection was performed anonymously, respondents only entered their data related to the main variables of interest and some standard demographic variables (such as age, gender, income and education), but their names or identification numbers were not requested in the survey. Participants received credit from the survey company equivalent to 100 Korean Won (approximately equivalent to 0.077 US dollars) per minute for their participation.

Results

Respondents' characteristics

Table 3. depicts the respondents' characteristics. Half (50%) of the respondents were female (*female*), and respondents were equally distributed among 5 age groups (20 s, 30 s, 40 s, 50 s and 60 s) (*age*). Around 57.1% of the respondents had income between KRW 2 M and 6 M (*income*). About 78.0% of the respondents had graduated from undergraduate or graduate schools (*education*). The respondents had visited hospitals or clinics the previous year 7.4 times on average (*hospital_visit*). Approximately 14.2% of the respondents had experienced open surgery (*open_surgery*) and 18.1% had undergone fine-needle aspiration biopsy (*needle*). On a 1–5 rating scale (1 = Not at all, 5 = very much so), respondents chose 2.4 on average that they visit a hospital whenever they feel ill (*risk_averse*), 2.4 on average that they use new technology earlier than others do (*early_adopt*), 3.0 on average that they prefer to decide on their own rather than deferring to the doctor whether to undergo surgery/procedure (*autonomy*), and 2.1 on average that they know the difference between deep learning and regression (*know_DL*). The participants knew 1.7 examples of medical AI applications on average (*know_medical_AI*).

Importance rating of information

What do patients want to know before deciding to undergo an operation? The importance rating of information was measured using 7-point Likert score anchored at 1 = not important at all and 7 = very important. Under the condition of a fine needle aspiration biopsy (*high_risk* = 0), common use of AI tools (*common* = 1), and performance level on par with average (*superior* = 0), the most important type of information for patients was the side effects of the surgery/

Table 3. Demographic characteristics of respondents for individual level.

Variable	N (%) or Mean (SD)
Gender	N (%)
Male	500 (50)
Female	500 (50)
Age group	N (%)
20–29	200 (20)
30–39	200 (20)
40–49	200 (20)
50–59	200 (20)
60–69	200 (20)
Income (KRW)	N (%)
< 1 M	44 (4.4)
≥1 M, < 2M	63 (6.3)
≥2 M, < 3M	152 (15.2)
≥3 M, < 4M	154 (15.4)
≥4 M, < 5M	145 (14.5)
≥5 M, < 6M	121 (12.1)
≥6 M, < 7M	84 (8.4)
≥7 M, < 8M	75 (7.5)
≥8 M, < 9M	52 (5.2)
≥9 M, < 10M	39 (3.9)
≥10M	71 (7.1)
Education	N (%)
Middle school	2 (0.2)
High school	218 (21.8)
Undergraduate	668 (66.8)
Graduate	112 (11.2)
Number of hospital visits in the past year	Mean (SD)

Table 3. Continued.

Variable	N (%) or Mean (SD)
0-100 range	7.4(9.4)
Experience of open surgery	N (%)
yes	142 (14.2)
Experience of fine needle aspiration biopsy	N (%)
yes	181 (18.1)
I visit hospital whenever I feel ill	Mean (SD)
1-5 scale	2.4 (9.2)
I use new technology earlier than others	Mean (SD)
1-5 scale	2.4 (1.0)
I prefer to decide on my own rather than deferring to the doctor	Mean (SD)
1-5 scale	3.0 (0.9)
I know the difference between deep learning and regression	Mean (SD)
1-5 scale	2.1 (1.0)
Number of medical AI applications I am aware of	Mean (SD)
1-5 scale	1.7 (0.7)
Region	N (%)
Seoul	315 (31.5)
Busan	51 (5.1)
Daegu	52 (5.2)
Incheon	66 (6.6)
Gwangju	25 (2.5)
Daejeon	25 (2.5)
Ulsan	16 (1.6)
Gyeonggi	258 (25.8)
Gangwon	21 (2.1)
Chungbuk	16 (1.6)

Table 3. Continued.

Variable	N (%) or Mean (SD)
Chungnam	25 (2.5)
Jeonbuk	27 (2.7)
Jeonnam	18 (1.8)
Gyeongbuk	27 (2.7)
Gyeongnam	43 (4.3)
Jeju	7 (0.7)
Sejong	8 (0.8)

procedure (mean score = 6.11 on the 7-point Likert Scale; Table 4). Not surprisingly, patients place great importance on its long-term effect on the quality of life (mean score = 6.09) and discussing the risk of not undergoing the recommended surgery/procedure (mean score = 6.02). The two least important categories of information were the right to opt out from referring to a radiologist or AI decision support tool (mean score = 5.38) and architecture of the AI tool (mean score = 5.59).

Patients placed more importance on discussing nearly every topic when AI was involved in diagnosis compared with when radiologists were involved (Table 4). For example, respondents perceived 'whether a radiologist was referred to' as less important than 'whether an AI tool was used' (mean difference = -.2863, $p < 0.001$). On the difference of means test, each of the individual pairs for the outcome variables achieves statistical significance, except for surgeon qualification, short-term effects, whether the opinions were the same, and the reason for rejecting or accepting the recommendation. When AI is used, participants perceived *opinion_same* as most important and *opt_out* and *architecture* as least important among AI information on average. Similar results were observed from another combinations of conditions (See Online Appendix II for results under the condition of an open surgery (*high_risk* = 1), common use of AI tools (*common* = 1), and performance level on par with average (*superior* = 0)).

Comparison of importance of AI information and surgery information

To address the question of whether we need to disclose the information related to the AI tool, I estimate

Table 4. Importance of information to patients, based on 7-point Likert score (low risk-common-average).

Type of information	Mean	Radiologist	AI	Difference	P value ($T < t$)
<i>Surgery information</i>					
benefit	5.9127	5.7540	6.0751	-.3211	<.001
side_effect	6.1143	6.0357	6.1947	-.1590	.01
risk_without	6.0200	5.8889	6.1542	-.2653	<.001
surgeon_quality	5.9649	5.9206	6.0101	-.0895	.10
short_term	5.7533	5.6766	5.8316	-.1551	.02
long_term	6.0903	6.0615	6.1197	-.0582	.19
<i>AI information</i>					
used	5.5186	5.3770	5.6633	-.2863	<.001
architecture	5.5862	N/A	5.5862	N/A	N/A
performance	5.7894	5.7143	5.8661	-.1518	.02
generally_used	5.6640	5.5337	5.7972	-.2634	<.001
doctor_experience	5.7432	5.6032	5.8864	-.2832	<.001
opinion_same	5.9067	5.8929	5.9209	-.0280	.35
reason_reject_accept	5.7422	5.7123	5.7728	-.0605	.20
opt_out	5.3831	5.2183	5.5517	-.3335	<.001
observation	997	504	493		

whether AI information when AI was used was rated as important as surgery information was when AI was not used. I compare the short-term effect (*short_term*), which shows the lowest importance rating among surgery information when AI is not used with AI information but AI was used (Table 5). The difference is either not statistically significant or the importance of AI information (*performance*, *doctor_experience* and *opinion_same*) was statistically significantly higher than the surgery information of short-term effect. Similar results were observed from other combinations of conditions (see Online Appendix III).

Effect of four main case conditions

The effect of four main case conditions on patients' information preferences was investigated through regression analysis. As patients responded to five vignettes, with

varying main case conditions, multilevel mixed-effect linear regression analysis was used (Table 6).

The results confirmed H1 that the use of AI rather than human radiologists has a strong and significant positive effect on the perceived importance of most information items (except for *longterm* and *opinion_same*). It is worth noting that not only information related to the AI tool but also standard information regarding the surgery/procedure such as benefits and side effect of the surgery/procedure and risk of not undergoing the surgery/procedure were perceived as more important when AI tool was used. For a robustness check using fixed-effect linear regression analysis, see Online Appendix V.

To test H2-H4 which focuses on the perceived importance of AI information when AI is used, a subgroup multilevel mixed-effect linear regression analysis for scenarios in which AI is used was conducted (Online Appendix VI). The result indicates that the high risk of the recommended treatment did positively and significantly affect the perceived importance of certain information (H2): *opinion_same*

Table 5. Mean difference of importance of surgery information 'short_term' (if ai = 0) and AI information (if ai = 1) (low risk-common-average).

Surgery information	obs	mean	AI information	obs	mean	diff	95% CI min	95% CI max	P value ($ t > t $)
short_term	504	5.6766	used	493	5.6633	.0133	-.1391	.1657	.86
short_term	504	5.6766	architecture	493	5.5862	.0904	-.0628	.2436	.25
short_term	504	5.6766	performance	493	5.8661	-.1895	-.3412	-.0379	.01
short_term	504	5.6766	generally_used	493	5.7972	-.1206	-.2687	-.0275	.11
short_term	504	5.6766	doctor_experience	493	5.8864	-.2098	-.3576	-.0621	.005
short_term	504	5.6766	opinion_same	493	5.9209	-.2443	-.3913	-.0973	.001
short_term	504	5.6766	reason_reject_accept	493	5.7728	-.0923	-.2460	.0535	.21
short_term	504	5.6766	opt_out	493	5.5517	.1249	-.0291	.2788	.11

(b 0.0488, p = 0.008) and *reason_reject_accept* (b 0.0434, p = 0.02). Surprisingly, neither the pervasiveness of the use of AI (*common*) nor the superior performance of the AI tool compared to an average radiologist (*superior*) had a significant effect on the perceived importance of AI information. Therefore, H3 or H4 was not supported. For a robustness check using fixed-effect linear regression analysis, see Online Appendix VII.

Associations of importance ratings with demographic features

The associations of respondents' characteristics on patients' information preferences when AI is used ($ai = 1$) were investigated through regression analyses with robust standard errors clustered in respondents (Table 7). In most specifications, I include an extensive set of controls.

Women found every piece of AI information more important than men did (β 0.1888~0.2695, P < .001). The older participants also found every piece of AI information more important than younger participants did (β 0.0985~0.1540, P < .001). Similarly, higher income levels had a positive and statistically significant effect on every piece of AI information (β 0.0723~0.1131). Interestingly, higher education level had a significant negative effect on certain pieces of information. For example, respondents with higher education found *architecture* (β -0.211, P = 0.001) less important. Another strong predictor of the perceived importance of information was *autonomy*. Patients with a stronger preference for participation in decision-making found every piece of AI information more important (β 0.0688~0.0973), and the effects were all statistically significant (Table 6). However, knowledge regarding technology (*know_DL* and *know_*

medical_AI) did not show a statistically significant association with the perceived importance of AI information.

Interaction between the use of ai and demographic features

To investigate whether sociodemographic factors affect the tendency of increased importance of AI information when AI instead of human radiologist was referred to, I conducted an OLS with interaction terms to check whether gender, age and income moderate the relationship between the use of AI and the perceived importance of AI information (Online Appendix VIII). Gender is a strong positive moderator between the use of AI and importance ratings of some AI information such as *used* (b = 0.1567, P = .02), *generally_used* (b = 0.2402, P < .001), *doctor_experience* (b = 0.2898, P < .001), *opinion_same* (b = 0.2112, P < .001), *reason_reject_accept* (b = 0.1200, P = .03) and *opt_out* (b = 0.1534, P = .03). Moreover, the income level is also a positive moderator between the use of AI and importance ratings of *performance* (b = 0.0248, P = .03), *doctor_experience* (b = 0.0221, P = .049) and *reason_reject_accept* (b = 0.0276, P = .01). However, the effect of the use of AI on the perceived importance of *used* (b = -0.0128, P < .001), *performance* (b = -0.0126, P < .001) and *generally_used* (b = -0.0084, P < .001) decreased when the respondents were older.

Discussion

Principal results

Can consulting an AI application be understood in the same way as consulting a colleague radiologist, which does not

Table 6. Multilevel mixed-effect linear regression analysis.

	benefit		side_effect		risk_without		surgeon_quality		short_term		long_term		used	
	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value
Intercept	5.7648 (0.0399)	<.001	6.0317 (0.0402)	<.001	5.9337 (0.0392)	<.001	5.9802 (0.0400)	<.001	5.6915 (0.0422)	<.001	6.0881 (0.0393)	<.001	5.4735 (0.0473)	<.001
ai	0.2496 (0.0227)	<.001	0.1318 (0.0237)	<.001	0.2075 (0.0237)	<.001	0.05636 (0.0228)	.01	0.1234 (0.0231)	<.001	0.0215 (0.0220)	.32	0.2400 (0.0303)	<.001
high_risk	0.0332 (0.0167)	.04	0.0401 (0.0174)	.02	0.0353 (0.0174)	.04	0.0637 (0.0167)	<.001	0.0558 (0.0169)	.001	0.0296 (0.0162)	.07	0.0119 (0.0222)	.59
common	0.0047 (0.0179)	.79	-0.0036 (0.0187)	.85	-0.0002 (0.0187)	.99	-0.0209 (0.0180)	.25	-0.0162 (0.0182)	.37	-0.0208 (0.0174)	.23	-0.0304 (0.0239)	.20
superior	0.0212 (0.0176)	.23	-0.0019 (0.0184)	.92	-0.0078 (0.0184)	.67	-0.0121 (0.0177)	.50	0.0111 (0.0179)	.54	0.0053 (0.0171)	.76	0.0088 (0.0235)	.71

(continued)

Table 6. Continued.

	architecture		performance		generally_used		doctor_experience		opinion_same		reason_reject_accept		opt_out	
	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value	<i>b</i>	<i>P</i> value
Intercept	5.5870	<.001	5.7866	<.001	5.5767	<.001	5.6487	<.001	5.9479	<.001	5.7115	<.001	5.2714	<.001
	(0.0412)		(0.0460)		(0.0449)		(0.0440)		(0.0423)		(0.0436)		(0.0478)	
ai	N/A	N/A	0.1239	<.001	0.2283	<.001	0.2548	<.001	0.0152	.54	0.0915	<.001	0.3323	<.001
	N/A		(0.0289)		(0.0279)		(0.0269)		(0.0251)		(0.0255)		(0.0290)	
high_risk	0.0197	.34	0.0174	.41	0.0422	.04	0.0591	.003	0.0557	.003	0.0262	.16	0.0494	.02
	(0.0208)		(0.0212)		(0.0204)		(0.0198)		(0.0184)		(0.0187)		(0.0213)	
common	-0.0046	.82	-0.0272	.23	0.0163	.46	0.0120	.57	-0.0185	.35	0.0075	.71	-0.0409	.07
	(0.0201)		(0.0228)		(0.0220)		(0.0212)		(0.0198)		(0.0201)		(0.0229)	
superior	-0.0005	.98	0.0062	.78	-0.0099	.65	-0.0132	.53	-0.0054	.78	0.0054	.78	-0.0006	.98
	(0.0197)		(0.0224)		(0.0216)		(0.0209)		(0.0195)		(0.0198)		(0.0225)	

Standard errors in parentheses.

Table 7. Linear regression models with controls when AI is used (ai = 1).

	used		architecture		performance		generally_ used		doctor_ experience		Opinion_ same		reason_reject_ accept		opt_out	
	β	P value	β	P value	β	P value	β	P value	β	P value	β	P value	β	P value	β	P value
high_risk	0.0147	.29	0.01932	.17	0.02107	.13	0.0275	.04	0.0333	.01	0.0359	.009	0.0317	.02	0.0222	.11
common	-0.0125	.33	-0.0046	.71	-0.0137	.28	0.0059	.64	-0.0019	.88	-0.0151	.21	-0.0078	.53	-0.0234	.06
superior	0.0028	.81	-0.0050	.66	0.0037	.74	-0.0050	.64	-0.0034	.74	-0.0042	.70	0.0004	.97	-0.0035	.74
female	0.2171	<.001	0.1888	<.001	0.2282	<.001	0.2679	<.001	0.2695	<.001	0.2690	<.001	0.2522	<.001	0.2071	<.001
age	0.1420	<.001	0.1566	<.001	0.1422	<.001	0.1202	<.001	0.1434	<.001	0.1540	<.001	0.0985	<.001	0.1480	<.001
income	0.1105	<.001	0.1131	<.001	0.0955	.002	0.0723	.01	0.0929	.002	0.0769	.009	0.0856	.005	0.1032	<.001
education	-0.0428	.12	-0.0935	.001	-0.0498	.09	-0.0206	.47	-0.0272	.34	-0.0183	.52	0.0017	.95	-0.0364	.23
hospital_visit	0.0213	.44	-0.0144	.62	0.0203	.42	0.00311	.90	-0.0013	.96	0.0099	.72	0.0103	.69	-0.0430	.17
open_surgery	-0.0324	.25	-0.0415	.14	-0.0587	.04	-0.0490	.09	-0.0500	.08	-0.0277	.30	-0.0332	.23	-0.0266	.35
Needle	0.0204	.45	0.0414	.12	0.0275	.28	0.0059	.83	0.0131	.61	0.0328	.18	0.0157	.56	0.0173	.55
risk_averse	-0.0017	.96	-0.0027	.93	-0.0387	.22	-0.0202	.51	-0.0096	.75	-0.0339	.26	-0.0334	.27	-0.0067	.84
early_adopt	0.03942	.20	0.0592	.06	0.0802	.007	0.0706	.02	0.0655	.03	0.0571	.06	0.0856	.006	0.0626	.06
Autonomy	0.0849	.002	0.0783	.006	0.0818	.004	0.0770	.005	0.0688	.01	0.0834	.003	0.0851	.003	0.0973	<.001
know_DL	-0.0256	.43	0.0094	.78	-0.0353	.27	-0.0275	.38	-0.0434	.18	-0.0451	.14	-0.0330	.29	-0.0206	.53
know_medical_AI	0.01585	.59	0.0136	.65	0.0156	.61	0.0116	.70	0.0247	.42	0.0133	.66	-0.0134	.66	-0.0167	.62
Region dummies	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes	Yes
Adj R ²	0.095		0.093		0.096		0.105		0.115		0.115		0.096		0.088	
AIC	12663.8		13019.6		12596.2		12385.8		12231.6		12098.1		12405.6		12929.3	
BIC	12865.3		13221.0		12797.6		12587.2		12433.0		12299.5		12607.0		13130.7	
Obs	4000		4000		4000		4000		4000		4000		4000		4000	

Standardized beta coefficients.

need any special mention? Potential patients seem to perceive consulting an AI tool differently from consulting a colleague radiologist. Respondents placed more importance on discussing nearly every topic when AI was involved in diagnosis compared with when radiologists were involved. This result suggests that the mere analogy of consulting a colleague cannot justify extending the existing practice of no mention when using AI decision-support tools. This is consistent with previous studies that showed patients' lower trust in AI algorithms compared with human diagnoses: for conflicts that arise between the AI and physician in clinical decision-making, participants generally indicated they would trust the physician.^{27,29,44–46}

When compared with regularly provided surgery information when AI is not used, information regarding the AI tool when AI is used was perceived by participants either as more important than (the performance of the AI medical software, how much experience the doctor has in making a diagnosis using the AI medical software, whether the opinion of the doctor and recommendation of the AI medical software were the same) or similar to the lower bound of the regularly disclosed surgery information (short-term effect). This result provides support for a disclosure of information regarding AI use when AI is used in diagnosis.

Interestingly, the use of AI, compared with referring to radiologists, noticeably increased the need not only for information related to AI but also for that not related to the use of AI. This might suggest that respondents experience increased anxiety or unease regarding the use of AI.^{41,47} This anxiety can potentially be attributed to the perception of currently available AI as premature technology,^{26,30–33} which could be addressed by providing more information about its effectiveness and exact application in relation to the AI tool. Another explanation might be that participants worry about physicians' automation bias,⁴⁸ that is, physicians might blindly rely on the AI-enabled system's suggestions without critically reviewing them resulting in reduced accuracy⁴⁹ and increased medical errors.⁵⁰ Further research is needed to confirm the source of respondents' increased anxiety regarding the use of AI.

The high risk associated with the proposed treatment was found to increase the perceived importance of some of the AI-related information, such as whether the doctor's opinion was the same as the recommendation of the AI tool or the reason for following or rejecting the recommendation from the AI medical software when the opinions differed. However, for other types of AI information other than the two mentioned above, the high-risk condition did not increase the perceived importance. This result is only partly consistent with those of previous studies, which have shown that participants are more accepting of AI if it is applied in a lower risk setting.^{32,34,51}

Surprisingly, the condition of whether the use of AI is commonplace and whether the performance of the AI tool exceeds that of an average radiologist did not affect the

perception of the participants on the importance of information. This result is not consistent with some legal scholars' projections that as the use of AI becomes more widespread and its performance surpasses that of human doctors, the need for further explanation should decrease.^{11,12} The results of previous empirical studies on patients' acceptance or trust in AI are somewhat conflicting. Some studies have shown that participants are more accepting of AI if it is proven to be more accurate than providers^{26,29} or if the use of AI fits societal and cultural norms.^{35,36} However, other studies have found that trust in AI did not increase when participants were informed that the AI outperforms human doctors.^{34,52,53}

The effect of sociodemographic characteristics on the perceived importance of AI information when AI is used suggests that patient needs for more information are heterogeneous. This supports an individualized approach to disclosure. Gender had a strong and consistent effect on the respondents' perceived importance of AI information. Older respondents and those with higher income levels also tended to perceive every piece of AI information as more important. Surprisingly, however, respondents with higher education viewed the architecture (i.e., the blueprint) of the AI algorithm as less important. If we assume that participants with higher education have a better understanding of which information is actually crucial in deciding whether to accept a treatment, this finding may partly resonate with the argument that explaining the 'inner workings' of the AI algorithm does not necessarily empower patients to make more informed choices regarding their treatment options.¹⁶ Moreover, knowledge regarding technology did not show a statistically significant association with the perceived importance of AI information.

Females, respondents with higher incomes, and younger respondents reacted more sensitively to the use of the AI tool. The perceived importance of AI information increases more for females than for males and for respondents with higher income levels than for those with lower income levels when AI was used. Although older respondents tended to perceive every piece of AI information when AI was used as more important than younger respondents; interestingly, the perceived importance of AI information increased less for older respondents than for younger respondents when AI was used.

Limitations

This study has several limitations. First, the sample was randomly selected from a commercial panel, which may introduce selection bias toward people with a higher affinity for technology compared with the general population. Additionally, the sample was overrepresented by individuals with undergraduate (66.8%, which is higher than 50.5% from 2020 census) or graduate education (11.2%, which is higher than 6.1% from 2020 census) which does

not precisely match the Korean population. The stratified sampling was done to match the quota per gender and age group, but this does not technically match the Korean population. Second, the survey instrument used in this study provided insights into participants' self-reported familiarity with AI technology; however, it did not assess their actual knowledge or depth of understanding of AI applications in healthcare. Future research should employ more objective methods to measure participants' knowledge of AI technologies to clarify how a participant's level of understanding influences their perceptions of the importance of AI-related information in the context of informed consent process. Third, patients rated most types of information as either very important or extremely important. Although the differences in Likert scores were statistically significant, they might not be clinically relevant. Nonetheless, participants had no difficulty using this Likert scale to identify some types of information as less important to their decision-making. Fourth, the study did not directly examine whether providing patients with all desired information related to AI use affects their decisions to undergo surgery or a medical procedure. Future studies should investigate the possibility of patients forgoing necessary treatment due to an unfounded fear or anxiety regarding AI tools and explore measures to encourage patient trust in AI when its performance is on par or better than that of human doctors. Finally, the results obtained from South Korean participants may not be generalizable to other patient populations, practice settings or geographic areas.

Conclusions

According to the study, using an AI tool increases the perceived importance of information related to its use, compared with when consulting with a human radiologist. This suggests that the mere analogy of consulting a colleague cannot justify the current practice of doctors not disclosing AI decision-support tool use. Information regarding the use of AI tools was perceived by participants either as more important than or similar to the lower bound of regularly disclosed information (short-term effect), which supports the disclosure of AI use in diagnosis. The perceived importance of AI information was for the most part not affected by the risk level of the operation, the wide-spread use of the AI tool, or whether the tool performed better than human physicians did. This result cautions against arguments that explanation is not necessary when using AI in lower-risk settings, when AI is widely used, or when AI outperforms human physicians. The study also found that sociodemographic characteristics such as gender, age and income had a statistically significant effect on the perceived importance of AI information, indicating that patients' information needs vary and that a personalized approach to disclosure may be necessary.

To the best of my knowledge, this is the first empirical study to investigate patient perspectives on informed consent for the use of AI tools in diagnosis. While the results of this study alone cannot provide a definitive answer regarding the information that should be legally required for disclosure to patients when AI tools are used in diagnosis, they can contribute to the evidence considered by courts under patient-based standards. This evidence may lead to requirements for physicians to disclose the use of AI and additional relevant information about the AI tool in diagnosis, as these are deemed material by their patients. This study sheds light on patients' information needs, offering valuable insights for professional bodies in drafting ethical guidelines or protocols for informed consent when using AI in diagnosis. These guidelines or protocols will inform the legal requirements under the physician-based standard, thus helping to reduce uncertainty about the risk of informed consent liability for physicians. Moreover, further studies are warranted to explore whether the perceived importance of information about the use of AI is influenced by the type of newly introduced risks associated with AI tools, and the roles AI decision-support tools play in doctors' final decision-making. Such research will provide a more nuanced understanding of patients' information needs regarding AI use in diagnosis and will help establish clear legal requirements.

The informed consent process for the use of AI should be personalized to accommodate individual information needs. This study demonstrates that preferences for information about AI tools differ by socio-demographic factors such as gender, age and income. A brief explanation about the use of AI should precede the assessment of patients' demographics and information needs, followed by an adjustment of the breadth and depth of AI-related information provided. The need for personalized informed consent process, reflecting the diverse preferences of patients, has often been overlooked due to concerns about overburdening medical professionals. However, advances in information technology may soon enable highly personalized disclosures through patient decision aids in the form of interactive software. This new approach could simplify the informed consent process, making it more reflective of individual decision-making styles and information preferences without overburdening physicians. Advances in AI technology, particularly generative AI, might be instrumental in addressing challenges in adapting language and communication strategies based on demographic groups and preferences. Until the point of widespread clinical adoption of interactive, computerized patient decision aids, it should be the priority to formulate clear guidelines and training programs for healthcare professionals. These should be designed to prepare healthcare professionals for delivering patient-centered AI disclosures, ensuring that the communication strategies meet the varied needs of different patient populations.

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