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Attitudes and Experiences With Informed Consent for Percutaneous Coronary Intervention in Korea: A Mixed-Methods Study

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ABSTRACT

Background: Percutaneous coronary intervention (PCI) is one of the most popular invasive cardiovascular procedures performed worldwide. However, patients often overestimate its benefits or underestimate potential risks, which should be addressed during informed consent (IC). In light of this, our study aimed to explore in greater depth the attitudes and experiences with IC regarding PCI in South Korea.

Methods: This mixed-methods study employed a sequential design following the guidelines of the Mixed Methods Reporting in Rehabilitation and Health Sciences. Between December 2022 and January 2023, a cross-sectional survey was completed by 255 patients and 136 physicians. From February to April 2023, in-depth interviews were conducted with 13 physicians were conducted and analyzed using conventional content analysis.

Results: Patients and physicians showed a significant difference in agreement with the purpose of IC with respect to the right to self-determination ($P < 0.001$; mean patient rank 178.1, mean physician rank 228.0). There were gaps between patients and physicians in the degrees of agreement regarding understanding ($P < 0.001$; mean patient rank 182.2, mean physician rank 220.4) and remembering ($P = 0.014$; mean patient rank 185.5, mean physician rank 214.3) information during the IC process. Physicians experienced difficulties due to patients' low comprehension of the information provided during the IC process.

Conclusion: Patients should first be educated on the purpose of IC to prepare them for receiving detailed information about PCI. When they are ready to accept information, strategies suggested by several studies may be applied to improve their understanding. This step-by-step provision of information will elevate patient compliance with IC.

Keywords: Informed Consent; Patient Rights; Personal Autonomy; Disclosure; Percutaneous Coronary Intervention

INTRODUCTION

Healthcare systems are influenced by internal and external factors and are structured to focus on patient needs and preferences for patient-centeredness.[1] Support for patient-focused clinical decision-making is a crucial tool in addressing widespread issues in healthcare systems related to quality and safety. This approach also contributes to better patient outcomes and a higher level of satisfaction.[2] Every patient has the right to receive information and give informed consent (IC), a right supported by the key medical ethics principle of autonomy.[3]

Since its introduction in the 1970s, percutaneous coronary intervention (PCI) using catheters to widen and restore blocked coronary arteries has become one of the most widely performed cardiovascular procedures worldwide,[4] with around two million procedures conducted annually.[5] In Korea, the number of patients undergoing PCI has gradually increased from 68,000 in 2016 to 81,500 in 2021.[6] As a minimally invasive procedure, PCI has advantages such as a shorter procedure and recovery time.[7] However, similar to bypass graft surgery, PCI can lead to complications such as vessel perforation, bleeding, shock, infarction, and death.[8] Therefore, obtaining IC from patients is essential before performing PCI.

Despite the importance of IC, recent evidence on patients' perceptions of PCI suggests that patients often overestimate the procedures' benefits[9] or underestimate its risks.[10] A study found that patients may perceive PCI as extending life expectancy or preventing cardiac attacks, contrary to medical facts.[9] IC is an interactive process between patients and physicians, reflecting their relationship.[11] Each party's attitude, value, and preference shape the disclosure contents and patients' acceptance,[12] naturally influencing clinical decisions.[13] Thus, emphasizing the importance of IC is essential to ensure that patients are accurately informed and fully understand PCI before giving consent.

Numerous studies on IC have been conducted worldwide; however, limitations remain in understanding patients' and physicians' attitudes and experiences regarding IC for PCI.[14] While a literature review on IC[15] and a cross-sectional study examining perceptions[16] have been conducted, qualitative studies are limited in generalizability, and quantitative studies are constrained in hypothesis verification and providing in-depth insights.[17]

A mixed-methods approach allows for more comprehensive findings, addressing the limitations of both quantitative and qualitative methods.[18] Here, quantitative analysis was used to examine patterns in patient and physician attitudes and identify differences, while qualitative analysis of in-depth interviews explored physicians' IC experiences with PCI. This two-phase study provides an integrated perspective for improving IC processes in clinical settings. Therefore, we aimed to gain a deeper understanding of both patients' and physicians' attitudes toward IC for PCI and explore physicians' experiences using a mixed-methods approach.

METHODS

Study design

This study was designed as a sequential explanatory mixed-methods study. In this structure, the quantitative phase (Phase I) was conducted first, followed by the qualitative phase (Phase II).[19] In describing the methods and results, we adhered to guidelines from the Mixed Methods

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Disclaimers
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Reporting in Rehabilitation and Health Sciences wherever possible.[20] In the following sections, P1 refers to physicians participating in Phase I, and P2 refers to those in Phase II.

Phase I: Quantitative

Participants

In Phase I, participants were divided into patient and physician groups. The inclusion criteria for patients were: 1) adults aged 18 years or older, 2) ability to read Korean, 3) experience with PCI at least once, and 4) voluntary participation. For P1s, the criteria were: 1) licensed, 2) at least three years of clinical experience since obtaining their license, and 3) and 4) aligned with the patient criteria.

We used purposive and self-selection sampling methods for both the patients and P1s. To recruit participants, we publicized the study by sending e-mails in cooperation with related associations and posting online advertisements. Participants were invited to voluntarily join the study through a web-based survey link.

Data collection

A British research team developed a measurement tool consisting of five domains and 22 items to assess attitudes toward IC for PCI.[21] Respondents rated their agreement with each item on a 5-point Likert scale (1 = "completely disagree" to 5 = "completely agree"). The chief developer approved the tool's use and modification.[21] Since the items were originally written in British English, they were translated into Korean and validated by two independent physicians. Due to cultural differences, the tool was adapted to fit Korean clinical settings. The survey was conducted online between December 2022 and January 2023.

A total of 255 patients and 136 P1s participated, with one patient's response excluded due to insincerity. The final sample included responses from 254 patients (response rate: 99.6%) and 136 P1s (response rate: 100.0%) for statistical analysis.

Data analysis

Statistical analyses were performed using SPSS software version 27.0 (IBM Corp., Armonk, NY, USA). Descriptive analyses examined the frequency of attitudes toward IC for PCI. To calculate agreement percentages, we identified the proportion of respondents who rated each item as either "agree (4)" or "completely agree (5)" on a 5-point Likert scale. These scores were combined to reflect the overall agreement. A normality test was conducted with more than 30 participants in each group. We used the Kolmogorov-Smirnov test, which indicated that participants' attitudes were not normally distributed ($P < 0.05$).[22] Differences between groups were analyzed using the Mann-Whitney U test, 22 with statistical significance set at $P < 0.05$.

Phase II: Qualitative

Participants

In Phase II, only physicians participated. P2s were selected based on the same criteria as P1s. Purposive and snowball sampling were employed by reaching out to physicians who expressed interest during Phase I and through referrals from the researchers' networks.

Data collection

Prior to the in-depth interviews, the draft of the semi-structured interview guideline was refined based on a scoping review IC for PCI and the results of Phase I.[23] P2s were interviewed either in person or via video conferencing for approximately 30 minutes, between

February and April 2023. A researcher (Min Ji Kim) audio-recorded each interview digitally and took field notes, with the interviewees' verbal and written consent. Interviews continued until data saturation was achieved.[24]

Data analysis

After transcribing the audio recordings, the researcher (Min Ji Kim) reviewed and corrected the transcripts as needed and removed any identifiable personal information. A conventional content analysis was then performed. Three researchers were involved in the analysis. First, Min Ji Kim examined the transcripts through repeated reading to understand the context. Next, after extracting significant statements from each transcript, Min Ji Kim coded the data, which was then reviewed by Won Lee and Ilhak Lee. Finally, similar codes were grouped into sub-categories.[25] This process was repeated until all researchers (Min Ji Kim, Won Lee, and Ilhak Lee) reached consensus on the findings.

Methodological rigor

During the research period, we assessed credibility, transferability, dependability, and confirmability to ensure the study's rigor.[26,27] To increase credibility, the interviewer reviewed the interview content with three P2s at the end of their interviews, and they confirmed its accuracy. For transferability, we consulted another physician who met the eligibility criteria but did not participate in this study, and he confirmed that the Phase II findings aligned with his experience. To maintain dependability and confirmability, Min Ji Kim reviewed any potential biases before the analysis, while Won Lee provided guidance on the overall study process.

Ethics statement

The Institutional Review Board (IRB) approved at Severance Hospital, part of Yonsei University Health System, where some authors have been affiliated, approved the research protocol (IRB No. 4-2022-1042). The requirement of written informed consent for Phase I was waived because data was collected via an online survey, and all subjects submitted informed consent for Phase II before data was collected.

RESULTS

The survey responses of 254 patients and 136 P1s were analyzed statistically, while in-depth interviews with 13 P2s were analyzed through conventional content analysis.

General characteristics of participants

In the Phase I patient sample group (**Table 1**), there were 137 males (53.9%) with an average age of 44.4 ± 10.80 years. The most common employment status was full-time employment (136, 53.5%), followed by part-time (66, 26.0%). Most patients were college graduates (194, 76.4%). Self-reported health status was predominantly average (102, 40.2%) or poor (73, 28.7%). The healthcare professionals obtaining written consent were residents (107, 42.1%) or attending physicians (99, 39.0%). In the P1 sample group (**Table 2**), there were 108 males (79.4%) with an average age of 36.2 ± 7.65 years. The majority worked in tertiary hospitals (74, 54.4%). The group included 61 residents (44.9%) and 56 specialists (41.2%), with an average monthly frequency of PCI explanations below ten in 69 cases (50.7%).

Table 3 shows the 13 male physicians participating in Phase II, including 10 specialists. Their average clinical experience was 13.5 years. Seven were in their 30s, and four were in their 40s.

Table 1. Patient characteristics in Phase I (N = 254)

Variables and categories	No. of patients (%)
Age (mean ± standard deviation), yr	44.40 ± 10.80
Sex	
Male	137 (53.9)
Female	117 (46.1)
Employment status	
Full-time employment	136 (53.5)
Part-time employment	66 (26.0)
Freelancer	20 (7.9)
Unemployment	16 (6.3)
Retired	12 (4.7)
Others	4 (1.6)
Education level	
College graduate	194 (76.4)
High school graduate	50 (19.7)
Advanced degree	10 (3.9)
Self-evaluation of health	
Average	102 (40.2)
Poor	73 (28.7)
Good	64 (25.2)
Very poor	10 (3.9)
Very good	5 (2.0)
Healthcare professionals who obtained written consent	
Resident physician	107 (42.1)
Attending physician	99 (39.0)
Nurse	47 (18.5)
Others	1 (0.4)

Table 2. Physician characteristics in Phase I (N = 136)

Variables and categories	No. of patients (%)
Age (mean ± standard deviation), yr	36.20 ± 7.65
Sex	
Male	108 (79.4)
Female	28 (20.6)
Affiliation	
Tertiary hospital	74 (54.4)
Hospital-level institution	32 (23.5)
General hospital	24 (17.6)
Clinic	3 (2.2)
Others	3 (2.2)
Level of residency	
Resident	61 (44.9)
Medical specialist	56 (41.2)
Intern	13 (9.5)
Others	6 (4.4)
Monthly average No. of explanations on percutaneous coronary intervention[a]	
< 10	69 (50.7)
≥ 10 and < 20	26 (19.1)
≥ 20 and < 30	20 (14.7)
≥ 30	21 (15.4)

[a] According to the time when explanations were actively given.

Nine participants were affiliated with tertiary hospitals. The average monthly frequency of PCI explanations among these physicians was 26.7.

Supplementary Table 1 shows the frequency of each response, and **Supplementary Table 2** presents the scores for each domain. **Supplementary Table 3** shows the results of analyzing the differences in attitudes between the two groups for each domain. **Supplementary Table 4**

Table 3. Phase II participant characteristics

Sex	Age, yr	Clinical experience, yr	Level of residency	Affiliation	Monthly average No. of explanations[a]
Male	38	13	Medical specialist	Tertiary hospital	40
Male	35	5	Resident	Tertiary hospital	40
Male	43	10	Medical specialist	Clinic	5
Male	34	10	Medical specialist	General hospital	12
Male	40	5	Medical specialist	Tertiary hospital	10
Male	34	5	Resident	Tertiary hospital	10
Male	42	17	Medical specialist	General hospital	10
Male	35	3	Resident	Tertiary hospital	10
Male	52	28	Medical specialist	Tertiary hospital	30
Male	39	15	Medical specialist	General hospital	20
Male	47	21	Medical specialist	Tertiary hospital	100
Male	53	30	Medical specialist	Tertiary hospital	30
Male	39	13	Medical specialist	General hospital	30

[a]According to the time when explanations were actively given.

outlines physicians' experiences with IC for PCI, which were analyzed and yielded 281 codes classified into five categories and 14 sub-categories.

Purpose of IC

Approximately 70.9% of patients agreed that IC signifies respect for their right to determine whether to undergo the procedure (average agreement score = 3.96 ± 1.06), while 82.7% saw IC as a process of providing information on the possible risks and complications of PCI (4.14 ± 0.93). Additionally, 88.2% of P1s viewed IC for PCI as a way to respect the patient's right to self-determination (4.39 ± 0.87) and to provide risk information (4.43 ± 0.77). The Mann-Whitney U test revealed significant differences in attitudes between groups, particularly in respecting the right to self-determination ($P < 0.001$; mean patient rank 178.1, mean P1 rank 228.0) and providing information on possible risks ($P = 0.003$; mean patient rank 184.1, mean P1 rank 216.8). One P2 viewed IC as a way to help patients accept unavoidable complications, commenting: *"Depending on how much I communicate various complications, even if patients don't fully agree when problems occur, I can persuade them" (P2; 11)*. A P2 viewed written consent as a safeguard against disputes, stating: *"There's absolutely nothing that can protect physicians from litigation risks these days. Even if I obtain written consent, there's no recourse when patients take legal action." (P2; 3)*. Over half of the patients (77.9%, 4.11 ± 1.10) agreed that physicians should state the purpose of PCI, with a higher percentage of P1s (85.3%, 4.37 ± 0.83) supporting this. The difference in attitudes about the primary purpose of PCI was significant ($P < 0.001$; mean patient rank 177.5, mean P1 rank 229.1) (**Table 4**, **Supplementary Table 1**).

Comprehension of information

A P2 described the IC process for PCI in clinical settings: "*First, staff members inform the patients. Then interns proceed to obtain written consent. This way, if the interns' information is insufficient, a filtering process is already in place" (P2; 1)*. Fewer than half of the patients agreed that they would not understand (40.5%, 2.98 ± 1.40) or remember (39.3%, 2.89 ± 1.42) all the information provided during the IC process. Meanwhile, 47.8% of P1s agreed that patients would not understand (3.38 ± 1.25) or 47.8% agreed that patients would not remember (3.35 ± 1.25) the information, respectively. The differences in agreement levels between patients and P1s regarding understanding ($P = 0.001$; mean patient rank 182.2, mean P1 rank 220.4) and remembering ($P = 0.014$; mean patient rank 185.5, mean P1 rank 214.3) were significant (**Table 4**, **Supplementary Table 1**). P2s identified barriers in the IC process when interacting with patients, noting issues such as limited comprehension. Comments included: *"Although*

Table 4. Attitudes toward informed consent for percutaneous coronary intervention of patients and physicians

Domains and items	Mean ± SD		Mean rank		*U*	*Z*	*P*
	Patients	Physicians	Patients	Physicians			
The primary purpose of informed consent is to							
Inform patients about possible risks and complications related to procedures	4.14 ± 0.93	4.43 ± 0.77	184.1	216.8	14,379.50	−2.968	0.003**
Respect patients' right to determine whether to undergo the procedure	3.96 ± 1.06	4.39 ± 0.87	178.1	228.0	12,847.00	−4.451	< 0.001***
Educate patients about options for alternative treatment	3.91 ± 1.14	4.26 ± 0.87	194.8	196.9	17,082.00	−0.189	0.850
Inform patients about the expected outcomes of the procedure	3.85 ± 1.20	4.01 ± 0.98	185.0	215.2	14,593.00	−2.680	0.007**
Informed consent is NOT appropriate and necessary because							
Most patients depend on physicians for decision-making	3.28 ± 1.41	3.43 ± 1.26	192.1	201.8	16,414.50	−0.829	0.407
Most patients do not usually understand all the information provided by physicians	2.98 ± 1.40	3.38 ± 1.25	182.2	220.4	13,892.00	−3.253	0.001**
Most patients do not usually remember all the information provided by physicians	2.89 ± 1.42	3.35 ± 1.25	185.5	214.3	14,722.50	−2.455	0.014*
During the process of informed consent, physicians should inform							
The methods and contents of the procedure	4.14 ± 0.97	4.40 ± 0.80	186.5	212.3	14,991.00	−2.337	0.019*
The primary purpose of the procedure	4.11 ± 1.10	4.37 ± 0.83	177.5	229.1	12,707.50	−4.580	< 0.001***
Additional procedures that are likely to be necessary	4.07 ± 1.11	4.35 ± 0.79	190.2	205.4	15,931.00	−1.372	0.170
Alternative available treatment options	4.06 ± 1.07	4.35 ± 0.80	199.6	187.8	16,224.00	−1.052	0.293
A realistic outcome that patients can expect	4.00 ± 1.08	4.27 ± 0.89	187.9	209.7	15,336.00	−1.956	0.050
A realistic outcome unless the procedure is performed	3.95 ± 1.23	4.26 ± 0.88	187.7	210.1	15,292.00	−1.992	0.046*
The probability of death	3.93 ± 1.22	4.15 ± 0.97	195.5	195.5	17,265.50	−0.006	0.995
The probability of significant disability (e.g., heart attack, stroke, bypass graft)	3.93 ± 1.14	4.06 ± 0.89	184.5	216.0	14,487.00	−2.813	0.005**
The probability of less significant disability (e.g., bleeding, bruising, pain)	3.77 ± 1.29	4.02 ± 0.90	193.0	200.1	16,640.50	−0.636	0.525
Regarding the explanation of risks							
Physicians should disclose every possible risk related to the treatment	4.04 ± 1.04	3.82 ± 1.04	204.9	178.1	14,894.50	−2.360	0.018*
The significant outcomes of treatments are							
Relief of symptoms	4.15 ± 0.88	4.32 ± 0.80	192.5	201.1	16,510.50	−0.784	0.433
Widening of narrowed coronary arteries	4.02 ± 1.00	4.26 ± 0.73	177.8	228.6	12,777.00	−4.461	< 0.001***
Cure for coronary heart disease	3.98 ± 1.08	4.23 ± 0.79	189.0	207.7	15,619.50	−1.655	0.098
Reduced risk of future heart attack	3.74 ± 1.16	4.15 ± 0.83	192.4	201.3	16,490.50	−0.782	0.434
Longer lifespan	3.74 ± 1.21	3.98 ± 0.89	189.5	206.7	15,753.00	−1.495	0.135

SD = standard deviation.
$^{*}P < 0.05$, $^{**}P < 0.01$, $^{***}P < 0.001$.

I want the patient to understand 100% during the IC process, the actual level of understanding is around 70% or 80%" (P2; 9) and *"I can't expect that every patient will fully understand and remember critical matters in a short time" (P2; 5)*.

Risks and complications to inform

While 61.7% of P1s agreed on the need to disclose every possible risk related to the procedure (3.82 ± 1.04), 76.7% of patients supported this (4.04 ± 1.04). Significant differences in attitudes were found between the two groups ($P = 0.018$; mean patient rank 204.9, mean P1 rank 178.1). More than half of the patients agreed that physicians should disclose the probability of severe disability, such as stroke or death (69.6%, 3.93 ± 1.14). In the P1 group, 86.8% supported the need to disclose severe disability risk (4.06 ± 0.89) during the IC process. The groups showed a significant difference in attitudes ($P = 0.005$; mean patient rank 184.5, mean P1 rank 216.0) (**Supplementary Table 1**, **Table 4**). When asked which PCI risks or complications should be disclosed, one P2 stated that disclosure depends on severity and frequency, explaining: *"The main reason for mentioning risks is the severity of the outcome. For example, although rare, death is the most critical outcome, so I always explain it. For other risks, it depends on the frequency" (P2; 7)*. Another P2 noted that they emphasized personally encountered complications, stating: *"Whenever I mention complications experienced, it reminds me of the risk" (P2; 6)*.

DISCUSSION

This study aimed to explore differences in attitudes and perceptions regarding IC for PCI between patients and physicians through a mixed-methods approach. Phase I identified significant discrepancies in how patients and physicians understood the purpose of IC, while Phase II revealed physicians' challenges with patients' comprehension and retention of information. This study's mixed-methods design provided a comprehensive examination of these attitudes, combining quantitative comparisons with qualitative insights to better understand the practical implications of these differences. Such insights are valuable for improving IC practices in clinical settings by addressing both informational content and communication methods.

First, the results highlight a notable gap in the perceived purpose of IC between patients and physicians. In a study conducted in England, patients who underwent acute PCI, along with 93% of 167 elective PCI, indicated that the purpose of IC was to respect the right to self-determination; similarly 89% of 118 cardiologists agreed.[21] In contrast to this study, no significant difference in attitudes was found between the groups in the English study.[21] This discrepancy may be influenced by cultural and institutional factors in England, where IC guidance has been available for physicians since 1998, helping them understand requirements for protecting patients' rights.[12]

Second, this study identified a significant difference in attitudes between patients and physicians regarding whether patients would fully understand all the information provided during the IC process. Supporting these findings, a previous study in England found statistically significant evidence of a difference between patients' and cardiologists' agreements of patient comprehension during the IC process across 10 healthcare facilities.[21] These results highlight the importance of addressing comprehension and retention issues within IC, as these aspects are crucial for informed decision-making. Physicians are encouraged to confirm patients' understanding by asking whether they comprehend the information provided and by providing opportunities to ask clarifying questions before proceeding to the next step of the IC process.[28] Such practices may reduce patient passivity, which can contribute to difficulties in recalling information.[28]

Finally, this study found a significant difference in attitudes toward the primary purpose of PCI within the IC content. While risks, complications,[29] and alternative treatments[9] were emphasized in discussions during the IC process, the purpose of IC was regarded as less important than these elements. If patients are not aware of IC's purpose or contents, they cannot effectively engage in clinical decision-making. Efforts should focus on educating patients about the purpose of IC before obtaining consent. In other words, the priority should be to inform patients about the purpose of IC—protecting their rights without applying pressure. McCarthy et al.[30] recommended explaining the purpose of patient-doctor conversations to enhance patient understanding and engagement in care and to ensure patients fully comprehend the information shared. In addition, two models can guide clinical decision-making: an 'event' model and a 'process' model.[31] Although the event model was preferred in the past, a shift to the process model has been recommended, emphasizing patient engagement in treatment decisions.[32,33]

Several strategies have been suggested for improving the process of IC to ensure patient safety, such as assessing the patients' health literacy before obtaining IC, providing sufficient time for consideration, using colloquial rather than medical language, and promoting patient engagement at the individual level.[34] At the institutional level, efforts should focus on producing and distributing literacy-appropriate pamphlets or audiovisual materials,[35] as previous studies have demonstrated their efficacy in patient education.[36] Mobile applications or interactive software focused on knowledge delivery may also be an effective strategy.[37] Finally, similar to the approach taken by the UK's General Medical Council,[12] national-level guidelines for optimal IC might be beneficial.[12] Although the Korean Medical Association has suggested some guidelines for IC within its Ethical Codes and Guidelines,[38] these are less detailed than those in the UK[12] and do not fully address whether patients are fully informed.[39] Comprehensive and specific IC guidelines tailored to each department's needs are essential.

Individuals lacking digital literacy may have been excluded, as recruitment in Phase I relied on emails, online channels, and web-based surveys, thereby limiting the generalizability of the results. Additionally, Phase II was an exploratory study targeting only physicians. Physicians' experiences were prioritized as more urgent because the IC process begins when physicians provide information to patients.[34] Since patient experiences are also crucial in the IC process,[40] future studies should focus on exploring them.

Despite these limitations, this study has several strengths. First, it underscores the importance of discussing the purpose of IC with patients. Although several studies have suggested methods for delivering IC content for PCI,[34-37,39] few emphasized the necessity of communicating the purpose of IC. To our knowledge, this study is the first to use a mixed-methods approach to investigate attitudes toward IC for PCI. Without this approach, the challenges faced by physicians with IC would not have been identified, thereby exposing a gap between perception and experience.

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SUPPLEMENTARY MATERIALS

Supplementary Table 1

Items of each group's attitude toward informed consent for percutaneous coronary intervention

Supplementary Table 2

Domains of each group's attitude toward informed consent for percutaneous coronary intervention

Supplementary Table 3

Differences in attitudes toward informed consent between patients and physicians in different domains

Supplementary Table 4

Physicians' experiences with informed consent for percutaneous coronary intervention

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