

# Informed consent for coronary angiography: Patients' level of understanding and opinion

Sir,

Informed consent (IC) is a fundamental principle of autonomy and a critical aspect of medical treatment.<sup>[1,2]</sup> The quality and value of IC are regularly discussed in medico-legal cases. While medical personnel tries to substantiate the obtained written informed consent through documentation, patients often argue that they have not sufficiently been informed.<sup>[3]</sup> This study aims to assess patients' understanding of IC for CAG and to identify their opinion about the IC process.

A cross-sectional survey was conducted among patients undergoing CAG using a convenience sampling technique at a public tertiary care center in South India. With an expected percentage of well-informed participants about IC as 80%, 5% absolute precision, and 95% confidence level, the sample size was estimated as 246. Ethical clearance was obtained, and IC was taken from each participant voluntarily before enrolment. A physician took IC for coronary angiography as per hospital policy. With the help of a self-structured and expert-validated questionnaire, the researchers collected the patient's understanding and opinions about the IC process before undergoing CAG. The split-half reliability of the questionnaire was 0.82.

The mean age of the 246 participants was 51.84 ± 11.59 years, and male preponderance (71.1%) was noted. More than one-third (39.4%) of the participants received primary education only, and the larger proportion of the participants (70.3%) resided in rural areas. The majority of participants (91%) were diagnosed with coronary artery disease, followed by rheumatic heart disease (5.3) and dilated cardiomyopathy (3.7). Sixty-six participants had co-morbidities including hypertension (13.82%), diabetes mellitus (20.33%), and pulmonary hypertension (0.41%).

The information provided during the IC process was well-understood in terms of need and purpose of CAG (98.4%), pre-procedure requirements (91.5%), need for immobilization of hand/groin after procedure (82.1%), and complications of CAG (79.3%). Fewer proportion of participants understood information about arterial access (70.7%), use of contrast medium (65.9%), and necessity of fluoroscopy (64.2%). IC was taken in their own language for 93.1% of the participants.

Half of the patients (48.8%) have a good opinion (12–16 points) about the IC process, while the other half of the participants have an excellent (0.8%), average (47.6%), and poor (2.8%) level of opinion about IC process for CAG. 13.4% of the participants agreed that IC is just a paper to be signed, and one-third of the participants were uncertain about the statement. More than two-thirds of participants (69.5%) opined that explaining the risk of the procedure increases fear and anxiety and 24.8% remains neutral. Half of the participants were uncertain whether they can change their decision once IC is signed, and the majority (72.8%) agreed that they must sign the consent if one is given. 65.9% of the patients do not believe they can deny signing informed consent. Most of the participants (76.4%) opined that they will follow the doctor's choice irrespective of whatever the consent form said. 78.5% of the participants agreed they got a clear picture of the procedure after informed consent [Table 1].

**Table 1: Participants' level of opinion about informed consent process for coronary angiography N=246**

Question	Agree n (%)	Neutral n (%)	Disagree n (%)
Informed consent is a legal requirement that protects both the patients and the doctor.	230 (93.5)	14 (5.7)	2 (0.8)
Doctors will not do the procedure without getting informed consent from me.	225 (91.5)	20 (8.1)	1 (0.4)
If I am not able to give consent, my immediate relative can sign on my behalf.	209 (85)	34 (13.8)	3 (1.2)
Informed consent is just a paper to be signed.	33 (13.4)	78 (31.7)	135 (54.9)
Explaining the risk of the procedure increases the fear and anxiety of patients.	171 (69.5)	61 (24.8)	14 (5.7)
I can change my decision after signing informed consent.	74 (30.1)	121 (49.2)	51 (20.7)
If patients are given with consent form, they must sign it.	179 (72.8)	44 (17.9)	23 (9.3)
The patient has the right not to sign the informed consent.	32 (13.0)	52 (21.1)	162 (65.9)
Whatever the consent form says, I am going to undergo as my doctor's choice.	188 (76.4)	43 (17.5)	15 (6.1)
I got a clear picture of the procedure after the informed consent.	193 (78.5)	39 (15.9)	14 (5.7)

n—number of participants; %—percentage

The level of understanding about informed consent is not associated with the participants' characteristics. However, the opinion about the informed consent process is significantly associated with the participants' level of education ( $P < 0.001$ ) and type of residence ( $P = 0.032$ ).

A related systematic review shows an adequate understanding of patient information in 29% of the studies.<sup>[4]</sup> The information required for effective informed consent is a matter of argument. Studies have revealed that patients desire to be knowledgeable about the risks and benefits of the procedure, while another group of patients criticized that the information is overloaded.<sup>[2,5]</sup>

## Conclusion

The study concludes that most patients undergoing coronary angiography are well-informed about the procedure, while their opinion regarding the IC process is questionable. The informed consent process currently used for CAG can be improved to assist patients in better understanding and decision-making.

## Financial support and sponsorship

Nil.

## Conflicts of interest

There are no conflicts of interest.

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Access this article online	
Quick Response Code:	Website: www.jehp.net
	DOI: 10.4103/jehp.jehp_344_23

**How to cite this article:** Puliakkuth U, Parasar C, Kempriai S, Bhutia SP, Ramamoorthy L, Selvaraj RJ, *et al.* Informed consent for coronary angiography: Patients' level of understanding and opinion. *J Edu Health Promot* 2023;12:335.

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