Original Article

A Comparative Study on Comprehension of Informed Consent Before Emergency and Elective Surgical Operative Procedures

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Abstract

Introduction: A health-care beneficiary should comprehend different aspects of medical and surgical interventions before giving consent to perform those. There is no defined way to find out adequate patient comprehension as part of the decision-making procedure to give consent. This study was conducted to find out the disparity of comprehensiveness between emergency and elective surgical operative procedures both in terms of knowledge dissemination and knowledge comprehension. **Materials and Methods:** A cross-sectional comparative study was conducted at the General Surgery Department of Medical College, Kolkata, during September and October 2021. An interviewer-administered questionnaire was used on patients undergoing emergency and elective surgical procedures. The comprehension level of informed consent (IC) form was scored as 1, 2, and 3 and compared between two groups using an unpaired *t*-test and Mann–Whitney *U*-test. **Result:** Data collection was done from 39 patients for emergency operative procedures and 52 for elective surgical procedures. A composite comprehension score was calculated after adjusting for questions not asked while taking IC. The mean comprehension score for emergency procedures was 18.86 and for planned surgery, it was 20.14. Unpaired *t*-test showed significantly high mean comprehension for planned procedures than the emergency procedures ($P = 0.007$). Comprehension is significantly poorer in emergency conditions even after controlling for age and literacy denoting difficulty in decision-making in emergency scenarios. **Conclusion:** It is suggested that the procedure of consent taking should be more structured and interactive so that even in stressful conditions participant understand better about the procedures and take their own decision instead of relying blindly on doctors.

Keywords: Elective surgery, emergency procedure, informed consent

Introduction

A health-care beneficiary should comprehend different aspects of medical and surgical interventions before giving consent to perform those. As per the Nuremberg code to preserve human autonomy, this is important both ethically and legally, especially before invasive procedures. Informed consent (IC) is nothing but the health-care beneficiary's authorization to undergo an intervention such as surgical operation or use of some drug for research purposes. This authorization is only valid if the health-care beneficiary has the capacity to consent, has discussed and understood all relevant information, consents voluntarily, and communicates their decision. Beneficence, nonmalfeasance, and autonomy these basic human rights are ensured by a properly obtained IC.[1,2] One of the important function of health-care provider is informing patients or accompanying persons about the outcome of the disease and its treatment, risks involved in treatment, and plausible alternatives so that beneficiaries can decide whether to avail of the treatment or not.[2]

According to the American College of Physicians, IC can be defined as "a communication process in which the health-care beneficiary's diagnosis, the nature, purpose, risks and benefits

Submitted: 27-Oct-2022 **Revised:** 17-Nov-2022
Accepted: 21-Nov-2022 **Published:** 29-Dec-2022

Access this article online

Quick Response Code:

Website: www.actamedicainternational.com

DOI: 10.4103/amit.amit_90_22

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How to cite this article: Mondal S, Bhattacharya S, Jana PK, Mitra K. A comparative study on comprehension of informed consent before emergency and elective surgical operative procedures. Acta Med Int 2022;9:153-8.

of the proposed procedure, and the nature, risks, and benefits of alternatives to the proposed procedure, including the option of not receiving any treatment, should be discussed."[3] Standard IC procedure generally consists of communication between health-care beneficiary and health-care provider after which ideally beneficiaries decide to sign the written document with proper comprehension of the intervention.[4-6] But often different constraints such as having less time in emergency situations, emotional turmoil, and the physical morbidity of the patient blur the understanding of the relevant information essential to make decisions for giving consent.[1,2] Effective provider–patient communication is the key to comprehensiveness and lack of shared decision-making often makes the consent-giving procedure a mere formality instead of proper comprehension on beneficiaries' end.[7,8] Limited education or lack of health literacy,[9] language barrier between health-care provider and patient,[10] and lack of understanding of the cultural issues of patients[11] also hamper the comprehensiveness of the decision maker.

IC consists of elements such as proper disclosure of all the aspects relevant to the treatment from the health-care provider, comprehension of those aspects by the beneficiaries, and competence to give consent voluntarily without any pressure.[12,13] An ideal consent should be given by a person who has a clear decision-making capability, which depends on understanding the information provided and who can weigh in good and bad consequences before coming to the conclusion of giving consent.[14] Consent can be obtained from a family member or accompanying person of the patient if the patient is too ill to take proper judgment and lack decision-making power in an emergency situation.[15] IC documents for both emergency and elective procedures are typically generic, containing law-approved language containing hospital policies which have a small blank space for providing details of the medical or surgical procedure and its benefits, risks, and alternatives.[16,17] Those documents are not very comprehension friendly and unless discussed face to face, documents alone hardly serve the purpose of proper comprehension by the beneficiaries.

In current medical practice in India, there is no clear-cut way to find out adequate patient comprehension as part of the decision-making procedure to give consent. In this context, this study was framed to find out the disparity of comprehensiveness between emergency and elective surgical operative procedures both in terms of knowledge dissemination and knowledge comprehension.

Materials and Methods

This cross-sectional comparative study was conducted at the General Surgery Department of Medical College, Kolkata, during September and October 2021. Depending on the urgency of the patient's condition, surgical procedures are usually conducted either as "emergency" basis or as "elective" operation in the General Surgery Department. The department uses same consent form for both elective and emergency surgical procedures. The content of the IC form originally was written in local language (Bengali or Hindi). IC form contains the name of the surgical procedure, possible outcome, and possible risks of surgery.

Participants, admitted into the surgery department for any elective surgical procedure and the participants admitted into the emergency surgery department from September to October 2021 were included in the study. Participants who had more than one surgical operation during the same admission were excluded from the study. Participants below 18 years of age and the participants who were unwilling to give consent for the study were excluded from the study. Approval from the Ethics Committee of Medical College, Kolkata, was obtained for the study (MC/KOL/IEC/NON-SPON/1216/11/21 dated 01.11.2021).

Comprehension of IC varied extensively from study to study. The sample size was calculated using a "*P*" as 86%[18] and taking relative prevalence as 15%. After matching for age and literacy status, the same number of patients was taken from both elective and emergency surgical procedures. The final sample size was calculated as 92. Thirty-nine emergency surgical cases fulfilling inclusion and exclusion criteria during the study period were subsequently recruited for the study. After that, a pool was created using all elective cases admitted to the hospital matching the age and literacy status of the emergency cases. From this pool, samples were collected using simple random sampling with the help of random numbers generated in Microsoft Excel.

Data were collected by investigators using a pretested interviewer-administered questionnaire. The questionnaire particularly focused on the comprehensiveness of IC to the health-care beneficiary. Pretesting was done among the 10 patients who were subsequently excluded from the main study. Face validity and content validity were ensured by the experts in surgery, anesthesiology, and community medicine. A prepared questionnaire was translated into two commonly spoken local languages, namely, Bengali and Hindi and translated back to English with the help of linguist experts to maintain consistency. Interviews were conducted immediately after consent given for the surgical procedure.

The questionnaire consisted of questions about the patient's demographics and the following questions.

1. Purpose of the procedure/intervention
2. The nature of the anesthesia
3. The potential benefits of operation
4. The potential risks of operation
5. The likely result if recommended procedure/intervention is not done
6. The available alternative treatments and their benefits and risks.
7. The most likely risks of the procedure(s)
8. The most serious risks of the procedure(s)
9. I am aware that there may be other risks or complications not discussed

10. During the procedure, due to unforeseen conditions, additional procedures may have to be conducted
11. No guarantees or promises have been made concerning the results of this surgical procedure or any treatment that may follow the procedure in case of unforeseen events.

The questionnaire comprised 11 domains as per the standard international guideline for IC.[19] Comprehension is judged bit a question for each domain in three standards, namely, "not understood," "partially understood," and "completely understood." These three standards were scored as 1, 2, and 3, respectively. A fourth option was also there saying that this domain was not discussed while taking IC. The minimum achievable score was 11 and maximum was 33. The final comprehension score was adjusted for the domain questions not discussed while taking consent.

Descriptive analysis was done for number, percentage, mean, median, and range in Microsoft Excel. Adjusted comprehension scores for two groups of operations were compared by unpaired *t*-test and a number of untold domains were compared by Mann–Whitney *U*-test.

Results

Data collection was done from 91 persons giving consent for surgical procedures, 39 patients for emergency operative procedures, and 52 for elective surgical procedures (ratio 3:4). Persons were matched for their gender and literacy status. It is seen that very few persons completely understood the different points mentioned in IC procedure. For both emergency and elective surgical procedures, comprehension is maximum for question number 1, which dealt with the purpose of intervention. Partial understanding is maximum for question number 7 for emergency surgical procedures, which discussed about most likely risks of the operation. For elective surgical procedures, 98.1% of participants partially understood question number 4, 7, and 8 all dealing with risks involved with operation (potential, most likely, and most severe, respectively). In the case of emergency procedures, 61.5% of participants did not understand question numbers 10 and 11 which covers the points that unforeseen conditions may happen at the time of operation and the number guarantee is there that this procedure is sufficient. In the case of elective surgical procedures, however, in addition to question number 11, incomprehension is quite high for question number 5 which discussed potential outcomes if the procedure is not performed [Table 1, Figures 1 and 2].

On average, three points were not discussed while taking IC, but its range varied from 1 to 6 in the case of emergency operation theater (OT) and 0–5 in the case of planned OT and there is no significant difference between them (*P* value as per Mann–Whitney *U*-test = 0.067).

A composite comprehension score was calculated after adjusting for questions not asked while taking IC. The mean comprehension score for emergency procedures was 18.86,

Table 1: Different questions of comprehension scale and its comprehension level (*n*=91)

Part of IC	Understanding level	*n* (%)
1. Purpose of procedure/ intervention		
Emergency OT	Not understood	1 (2.6)
	Partially understood	35 (89.7)
	Completely understood	3 (7.7)
Planned OT	Not understood	2 (3.8)
	Partially understood	37 (71.2)
	Completely understood	13 (25.0)
2. Nature of the anesthesia		
Emergency OT	Not told	13 (33.3)
	Not understood	15 (38.5)
	Partially understood	11 (28.2)
Planned OT	Not told	9 (17.3)
	Not understood	1 (1.9)
	Partially understood	41 (78.8)
	Completely understood	1 (1.9)
3. Potential benefits of operation		
Emergency OT	Not understood	1 (2.6)
	Partially understood	36 (92.3)
	Completely understood	2 (5.1)
Planned OT	Not understood	1 (1.9)
	Partially understood	49 (94.2)
	Completely understood	2 (3.8)
4. Potential risks of operation		
Emergency OT	Not understood	2 (5.1)
	Partially understood	36 (92.3)
	Completely understood	1 (2.6)
Planned OT	Not understood	1 (1.9)
	Partially understood	51 (98.1)
5. Likely result if recommended procedure/intervention is not done		
Emergency OT	Not told	18 (46.2)
	Not understood	19 (48.7)
	Partially understood	2 (5.1)
Planned OT	Not told	23 (44.2)
	Not understood	24 (46.2)
	Partially understood	5 (9.6)
6. Available alternative treatments and their benefits and risks		
Emergency OT	Not told	36 (92.3)
	Not understood	2 (5.1)
	Partially understood	1 (2.6)
Planned OT	Not told	46 (88.5)
	Not understood	1 (1.9)
	Partially understood	5 (9.6)
7. Most likely risks of the procedure (s)		
Emergency OT	Not understood	2 (5.1)
	Partially understood	37 (94.9)
Planned OT	Not understood	1 (1.9)
	Partially understood	51 (98.1)
8. Most serious risks of the procedure (s)		

Contd...

Table 1: Contd...

Part of IC	Understanding level	*n* (%)
Emergency OT	Not told	1 (2.6)
	Not understood	2 (5.1)
	Partially understood	36 (92.3)
Planned OT	Not understood	1 (1.9)
	Partially understood	51 (98.1)
9. Are you aware that there may be other risks or complications not discussed		
Emergency OT	Not told	32 (82.1)
	Not understood	5 (12.8)
	Partially understood	2 (5.1)
Planned OT	Not told	37 (71.2)
	Not understood	15 (28.8)
10. During the course of the proposed procedure, unforeseen conditions may be revealed requiring the performance of additional procedures		
Emergency OT	Not told	10 (25.6)
	Not understood	24 (61.5)
	Partially understood	4 (10.3)
	Completely understood	1 (2.6)
Planned OT	Not told	2 (3.8)
	Not understood	18 (34.6)
	Partially understood	32 (61.5)
11. Do you acknowledge that no guarantees or promises have been made concerning the results of this procedure or any treatment that may be required as a result of this procedure		
Emergency OT	Not told	10 (25.6)
	Not understood	24 (61.5)
	Partially understood	5 (12.8)
Planned OT	Not told	17 (32.7)
	Not understood	25 (48.1)
	Partially understood	10 (19.2)

OT: Operation theater, IC: Informed consent

and for planned OT, it was 20.14. Unpaired *t*-test showed significantly high mean comprehension for planned procedures than the emergency procedures ($P = 0.007$) [Table 2].

Discussion

IC is of utmost necessity in performing any surgical procedure. It is the right of the patient/patient party to know and decide what should be done on their body. This right should be exercised in written form, although a consent form is signed with information on it, mostly they are explained verbally to the patients/party. In our study conducted in Medical College, Kolkata, similar picture is found. Beneficiaries have the right to discard any surgical method even if discarding it is harmful to their well-being. They can also choose a method which is supposedly less successful. Hence, giving consent is essentially a process of decision-making. Decision-making predominantly

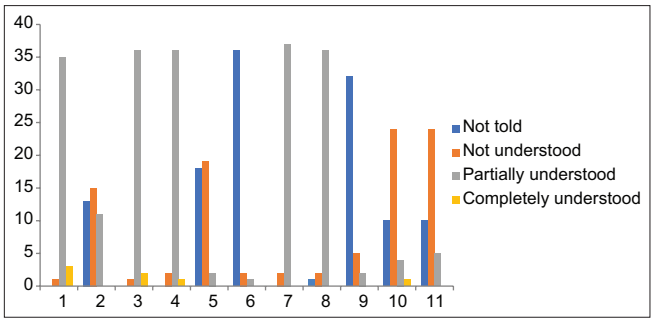

Figure 1: Multiple bar diagram showing different questions of comprehension scale and its comprehension level for emergency OT ($n = 39$). OT: Operation theater

depends on two things, availability of information and comprehension of those information. For consent taking procedure to be successful both dissemination of knowledge and comprehension is necessary. Dissemination depends on the medical person who is the sender of the information and comprehension depends on the receiver who will ultimately take decision and give consent. Hence, any lapse on part of either information disseminator or receiver may hamper proper decision-making procedure. In the present study, we tried to find out whether decision-making regarding consent is hampered by the emergency situation and if so whether information dissemination or comprehension which is altered in emergency. Many similar studies[20,21] showed that comprehension depends on the gender and literacy status of the patients/patients' relatives. To eliminate bias, we matched gender and literacy status in planned and emergency surgical procedures and compared the composite comprehension score regarding the information provided to the patients/patients' relatives.

As per the international guideline of IC,[22] patients/patients' relatives have the right to know about the procedure, its potential benefits, potential risks, most likely and most unlikely risks, and any alternative medical or surgical treatment with their likely outcome and risks.

Regarding knowledge dissemination, it is found in our study that among 11 key points, as many as 6 points were omitted while taking consent and on an average, it is 3 points. This finding is not unique and seen in many other studies worldwide. In Ethiopia,[23] most of the points of SIC were often not discussed. A study conducted in Saudi Arabia pointed that only 4.2% of residents were confident enough to discuss all points of IC.[24] In a study found out that among 2480 IC documents collected from 25 hospitals, only two hospitals had >50% consent forms where at least half of the points were discussed.[25] In Malawi, gynecologists often omit many points of IC to avoid dilemma between benevolence and autonomy of patients in case of their refusal to give consent.[26]

Like the study of Ethiopia,[23] here also patients/patients' relatives are seldom informed about alternate treatments or unlikely complications. Even though most of the domains

Table 2: Central tendency and measures of dispersion for adjusted comprehension score and untold questions (n=91)

Type of OT	Mean (95% CI)	Median	Minimum	Maximum
Adjusted comprehension score				
Emergency	18.86 (18.08-19.65)*	18.33	13.75	26.89
Planned	20.14 (19.78-20.69)*	19.86	14.14	23.37
Number of untold questions				
Emergency		3	1	6
Planned		3	0	5

*Mean difference: 1.27, P=0.007. OT: Operation theater, CI: Confidence interval

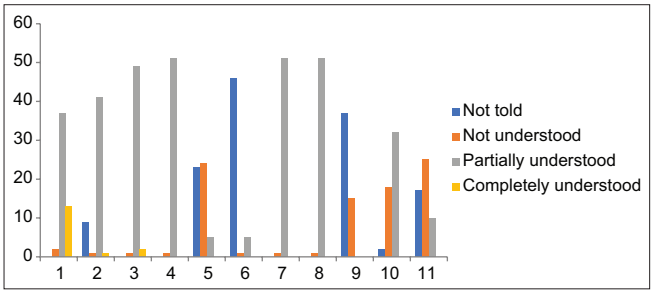

Figure 2: Multiple bar diagram showing different questions of comprehension scale and its comprehension level for planned OT (n = 52). OT: Operation theater

of consent-taking are discussed, absence of alternative makes consent giving almost mandatory for the patient. We also found patients are not being informed about types of anesthesia which tells us that consent takers often althought it is redundant for the patient/patient parties to know about that. It is well established that type and duration of anesthesia have a relationship with patient's survival in surgical procedures. Hence, this information is also vital for decision-making regarding surgeries.

Our study result suggested no significant difference in knowledge dissemination in an emergency situation (P = 0.067). In a previous study conducted in Ethiopia also showed no significant difference in discussion regarding SIC in planned and emergency situations.[23] In some studies, doctors said that IC is not necessary in case of emergency procedures due to time-saving, but in our study, none of the patients were deprived of having IC, even in an emergency situation.

According to our study, comprehension is lowest regarding unforeseen complications and having no guarantee of success. Patients/patients' relatives always want a favorable outcome of operative procedures. The above-mentioned points both point out toward opposite of favorable outcome. Maybe incomprehension of these two points comes from nonacceptance of an unfavorable scenarios after surgical procedures. Although a previous meta-analysis[27] suggested very few studies was conducted regarding the general procedure, alternatives, and benefits of surgical procedures, we found maximum understanding regarding procedural benefits and purpose of operations. The same study[27] also revealed, that due to non-interactive physician centric IC taking procedure, comprehension about risks is poor among the patients. While observing obtaining consent, we also found it to be noninteractive and physician centric. Here also most of the participants partially understood about the risks of operative procedures.

We found significantly lower comprehension score in emergency situations compared to planned surgical procedures (P = 0.007). Even after controlling for age and literacy level, this result suggests that in stressful conditions like surgical emergencies people tend to understand less and rely more on whatever is told to them by someone with authority like the doctor in this situation. This blurring of decision-making in emergency medical conditions is suggested in other studies also from all over the World. So, we can infer that decision-making and giving proper IC in emergency operations is more difficult than the planned surgical operations.

Conclusion

Although information dissemination while taking consent is not significantly different in emergency situations, in general some topics like the type of anesthesia and alternates are not discussed. Comprehension is significantly poorer in emergency conditions even after controlling for age and literacy denoting difficulty in decision-making in emergency scenarios. Hence, we suggest that the procedure of consent taking should be more structured and interactive so that even in stressful conditions participants understand better about the procedures and take their own decision instead of relying blindly on doctors.

Acknowledgment

The authors acknowledge the contribution of Dr. Sourav Roy, formerly an intern at Medical College, Kolkata.

Financial support and sponsorship

This study was self-funded.

Conflicts of interest

There are no conflicts of interest.

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