

Separate written consent for anaesthesia: What does the patient perceive of it? An observational study from rural India

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ABSTRACT

Background: Obtaining a separate consent for anaesthesia is rather new in medical practice and remains a subject of debate. Despite adequate disclosure by anaesthesiologists, obtaining separate written consent for anaesthesia is not easy. Therefore, this study was planned to evaluate patient's knowledge and perception of separate written consent for anaesthesia in a rural part of India. **Methods and Materials:** This prospective, single-centre, nonrandomized, observational study was conducted in a tertiary care medical college hospital in a rural part of India. Patients undergoing elective surgery from 01 December 2015 to 31 January 2016 were included in this study. Each of the patients was asked to fill a questionnaire having two parts with seven questions each. A correct answer was awarded one mark while wrong answers were given zero marks. **Results:** Out of 200 participants, only 124 (62%) knew that they should fully read and understand anaesthesia consent form before signing it. Similarly only 35.5% patients knew that they could inquire about the benefits of proposed anaesthesia technique over other available options. **Conclusions:** Patients lack awareness about separate consent for anaesthesia and about vital role; they are supposed to play in anaesthesia related decision-making.

Key words: Anaesthesia Consent, Patient's Perception, Questionnaire

Key Messages: Patients should be educated about their ability to make informed choice and should be actively involved in discussions formulating anaesthesia plan.

INTRODUCTION

By definition, a written informed consent is a medico legal agreement signed by patient after obtaining sufficient and satisfactory information about the proposed medical intervention before being subjected to that. Doctor supposed to perform the proposed intervention should also sign the consent form for it to be valid. Proper written informed consent can strengthen doctor patient relationship by allowing a degree of autonomy that the patient desires in medical decision making^[1].

Obtaining a separate consent for anaesthesia is rather new in medical practice and still remains a subject of debate^[2]. While some anaesthesiologists continue to rely on surgical consent

form, those who favour a separate consent form for anaesthesia argue that anaesthesia procedure and patient specific risks could be discussed more effectively resulting in greater protection from anaesthesia related litigation^[3]. Even though certain aspects of anaesthesia are included in surgical consent form, it may not be enough for patient to understand all aspects of anaesthesia care. As such a patient capable of giving surgical consent might

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not be able to understand consent for anaesthesia^{4,5}. Therefore, it becomes important for an anaesthesiologist to personally discuss various aspects of anaesthesia with the patient and take a written informed consent.

However, despite adequate disclosure by anaesthesiologists obtaining separate written consent from patients is not easy especially in a rural set up. This in part may be due to lack of anaesthesia related knowledge among patients, further compounded by lack of proper medical facilities, excessive burden of patients and relatively low level of literacy. All this makes it very difficult for anaesthesiologist to decide what and how much the patient should know before being able to understand and sign consent for anaesthesia. Therefore, this study was planned to evaluate patient's knowledge and perception of separate written consent for anaesthesia in a rural part of India.

SUBJECTS AND METHODS

This prospective, single-centre, nonrandomized, observational study was conducted in a tertiary care medical college hospital in a rural part of India. This study was planned as per guidelines of Helsinki Declaration of 1975, as revised in 2000. Patients undergoing elective surgical procedures under various specialties like general surgery, orthopaedics, urology, plastic surgery, gynaecology, ENT and ophthalmology, from 01 December 2015 to 31 January 2016 i.e., over a period of two months were considered for this study. Inclusion criteria were American society of Anaesthesiologist physical status III or less, with normal neurological status. Patients, who were sedated or not mentally sound, had hearing problems were excluded from this study. In case of minors, their parents or guardians who signed anaesthesia consent on behalf of patients were included in this study. Written consent was obtained from all patients or their relatives (in case of minors) in local language for participating in this study. If a patient refuses to sign consent, he or she was excluded from the study.

Patients had already undergone pre anaesthesia evaluation and were cleared from pre anaesthesia check-up clinic. They had already signed surgical consent form. We were not using separate anaesthesia consent forms in our set up and some information about anaesthesia was included in surgical consent forms. However, on the day of surgery, anaesthesiologist responsible for providing anaesthesia would personally interact with patient before surgery. He/she would discuss the anaesthesia plan in detail, document the discussion and obtain written informed consent as standard practice in our institute.

On the day of surgery, all the patients were taken into pre-operative room. None of the patient participating in the study received any sedative or anxiolytic premedication. Before

morning visit by anaesthesiologist to obtain consent for anaesthesia, each of the patients was taken into a separate room and was asked to fill a questionnaire to determine their knowledge and perception regarding consent for anaesthesia. If the patients couldn't understand it or need help, same was provided by anaesthesiologist present there. In case of minors the accompanying parent or guardian who would sign anaesthesia consent form, filled the questionnaire.

The questionnaire was provided both in English and in Hindi (local language). It was divided into two parts each having seven questions. First part was related to the basic aspects of obtaining an anaesthesia consent like who should sign consent, its benefits etc. The second part was related to what the patients should know before signing the consent form. Each question had three responses i.e., yes, no or can't say and patients were supposed to mark the most appropriate one. A correct answer was awarded one mark while wrong answers were given zero marks. After completing the questionnaire all the patients were sent back to preoperative room. The anaesthesiologist who helped the patients complete the questionnaire was different from those who collected and later on statistically analysed the information.

STATISTICAL ANALYSIS

Data was collected on a Microsoft Excel sheet and analysed using SPSS® version 23 (Statistical Packages for the Social Sciences, Chicago, IL). Data was expressed as numbers and percentage or mean + standard deviation. Chi-square and t tests were applied respectively for qualitative and quantitative data. ANOVA test was also used to find out significant difference among subgroups. A p value of < 0.05 was considered statistically significant.

RESULTS

214 patients posted for elective surgical procedures under various specialties were considered for this study. 11 of them refused to participate while 03 patients could not understand the questionnaire and left. Therefore, 200 patients or guardians/parents (in case of minors) finally participated in the present study. Among these 32% (68 patients) were less than 30 years of age, while 19.5% were 30 to 45 and 45 to 60 years of age (Table 1). Remaining 27% were more than 60 years of age. Of the 200 participants, 106 (53%) were males while rest were females. As far as education level was concerned 12% were illiterates, 40.5% studied up to primary level, 18.5% till secondary school, 23.5% were graduates and remaining 5.5% were postgraduates (Table 1). Economically, 57% were poor, 39% belong to middle class while 4% were rich. On the basis of ASA physical status 41% belonged to ASA class I, 34.5% belonged to class II and rest 24.5% belonged to class III (Table 1).

Table 1: Demographic Profile of the Patients			
DEMOGRAPHIC CHARACTERISTICS		NUMBER OF PARTICIPANTS	PERCENTAGE
AGE (YEARS)	LESS THAN 30	68	32
	30–45	39	19.5
	45–60	40	20
	60 AND ABOVE	53	26.5
SEX	MALE	106	53
	FEMALE	94	47
EDUCATION	ILLITERATE	24	12
	PRIMARY SCHOOL	81	40.5
	SECONDARY SCHOOL	37	18.5
	GRADUATE	47	23.5
	POST GRADUATE AND ABOVE	11	5.5
SOCIO-ECONOMIC STATUS	POOR	114	57
	MIDDLE CLASS	78	39
	RICH	08	4
ASA CLASS	I	82	41
	II	69	34.5
	III	49	24.5

Table 2: Patients response to Questionnaire				
S. no.	QUESTION	RESPONSE	FREQUENCY	PERCENTAGE
1.	Did you fully read and understand consent form before signing it?	Yes	124	62
		No	28	14
		Can't say	48	24
2.	Is written informed consent for anaesthesia beneficial for the patient?	Yes	115	57.5
		No	43	21.5
		Can't say	42	21
3.	Is consent for anaesthesia different from surgical consent?	Yes	72	36
		No	17	8.5
		Can't say	111	55.5
4.	Do you wish to verbally interact with anaesthesiologist before signing written informed consent form?	Yes	86	43
		No	65	32.5
		Can't say	49	24.5
5.	Is it essential for mentally sound adult to personally sign anaesthesia consent form?	Yes	58	29
		No	108	54
		Can't say	34	17
6.	Do you think that separate consent for anaesthesia add to paper work and result in unnecessary delays?	Yes	83	41.5
		No	22	11
		Can't say	95	47.5
7.	Can a patient refuse to sign anaesthesia consent form?	Yes	37	18.5
		No	69	34.5
		Can't say	94	47
8.	Is it necessary for anaesthesiologist to document the discussion with patient before obtaining written informed consent?	Yes	98	49
		No	82	41
		Can't say	20	10

S. no.	QUESTION	RESPONSE	FREQUENCY	PERCENTAGE
9.	Does the patient have the right to know which type of anaesthesia he/she is going to receive?	Yes	66	33
		No	57	28.5
		Can't say	77	38.5
10.	Can a patient inquire about benefits of proposed anaesthesia technique?	Yes	71	35.5
		No	38	19
		Can't say	91	45.5
11.	Can a patient choose type of anaesthesia he/she wishes to receive?	Yes	92	46
		No	89	44.5
		Can't say	19	9.5
12.	Is it important for anaesthesiologist to explain the important risks involved in proposed anaesthesia technique?	Yes	47	23.5
		No	48	24
		Can't say	105	52.5
13.	Can a patient further inquire about the anaesthesia planned and risks involved?	Yes	64	32
		No	99	49.5
		Can't say	37	18.5
14.	Is the prognosis or outcome of proposed intervention to be explained to the patient at the time of obtaining written informed consent?	Yes	65	32.5
		No	73	36.5
		Can't say	62	31

In the first part of the questionnaire, when patients were asked if they should fully read and understand consent from before signing it, only 124 patients answered 'yes' (62%) while 14% of patients said 'no' (Table 2). Remaining 24% couldn't say anything. Similarly when asked if the practice of obtaining written informed consent for anaesthesia beneficial for the patient, only 57.5% of participants could correctly answer 'yes' (Table 2). On being asked whether consent for anaesthesia was different from surgical consent only 36% answered correctly while most (55.5%) had no clear idea of that. Similarly, when asked if they wanted to interact with the anaesthesiologist before signing consent for anaesthesia only 43% said 'yes' while 32.5% felt it was not required and 24.5% had no opinion about it (Table 2). In answer to a question if an adult patient should personally sign anaesthesia consent form only 29% said 'yes' while majority 54% answered 'no'. When asked if separate anaesthesia consent result in unnecessary paperwork and delay in surgery only 11% answered 'no' (Table 2) while 41.5% agreed. Similarly, only 18.5% of patients knew that they can refuse to sign anaesthesia consent form (Table 2).

In response second part of same questionnaire, only 49% felt that anaesthesiologist should document the discussion with patient before obtaining consent (Table 2). On being asked if the patient has the right to know type of anaesthesia he/she

is going to receive, only 33 answered 'yes' while 28.5% said 'no' and 38.5% had no opinion on that. Similarly only 35.5% patients knew that they could inquire about the benefits of proposed anaesthesia technique over other available options (Table 2). Likewise only 46% patients knew that they could make an informed choice of type of anaesthesia they wish to receive. In response to a question regarding risks of anaesthesia, only 23.5% felt that it is important for anaesthesiologist to explain important risks involved in proposed anaesthesia technique, 24% thought it was not required and remaining 52.5% had no definite opinion (Table 2). Only 32% of patients knew that they can further inquire about anaesthesia plan and risks involved. Lastly, only 32.5% felt that prognosis or outcome of proposed intervention was required to be explained to the patient at the time of obtaining written informed consent.

Scoring was later done with each correct answer receiving '1' mark while wrong answers were given '0' marks. Patients were divided into various subgroups based on age, sex, education level, socio-economic status and ASA grade and mean score achieved by each subgroup was analysed (Table 3). No significant difference was found among these subgroups of patients on applying statistical tests (Table 3).

Table 3: Comparison of patient's characteristics and mean score obtained					
DEMOGRAPHIC CHARACTERISTICS		NUMBER OF PARTICIPANTS	MEAN SCORE	STANDARD DAVIATION	P VALUE
AGE (YEARS)	LESS THAN 30	68	5.029	2.259	0.9785
	30–45	39	5.179	2.694	
	45–60	40	5.175	2.319	
	60 AND ABOVE	53	5.019	2.390	
SEX	MALE	106	5.151	2.258	0.6782
	FEMALE	94	5.011	2.517	
EDUCATION	ILLITERATE	24	6.208	2.734	0.0745
	PRIMARY SCHOOL	81	4.889	2.525	
	SECONDARY SCHOOL	37	4.946	1.929	
	GRADUATE	47	5.212	2.196	
	POST GRADUATE AND ABOVE	11	4	2.00	
SOCIO-ECONOMIC STATUS	POOR	114	5.132	2.382	0.6319
	MIDDLE CLASS	78	4.949	2.406	
	RICH	08	5.75	2.188	
ASA CLASS	I	82	5.073	2.199	0.9122
	II	69	5.014	2.336	
	III	49	5.204	2.746	

DISCUSSION

Anaesthesia might have started just to facilitate surgical specialty, but over period of time it has evolved into a complete and wholesome domain concerned not only with peri-operative patient care in operation theatres but also in intensive care units and pain clinics. Yet in spite of playing such a vital role in patient care, numerous studies had shown that patients^[6-8] as well as general public^[9] lack essential awareness regarding different aspects of anaesthesia. Patients were often less concerned about various aspects of anaesthesia, thus expose themselves to unknown risks and also resulting in under utilization of services provided by anaesthesiologists.

Consent is one aspect of patient care where both patient and doctor gets an opportunity to interact, discuss the intervention planned and understand each other perception. Here it becomes very important for doctor not to withhold anything and for the patient to actively involve oneself and freely ask questions if required. However it has been seen that patients remain primarily concerned about management and outcome of surgery. One reason that has been attributed to this is that the patient comes to hospital with surgical complaints. Another reason could be that anaesthesia is generally considered as safe by patients as well as surgeons^[10]. Nevertheless it is a well-known fact that anaesthesia is an inseparable part of most surgical interventions and comes with its own set of risks and complications. So, although the practice of anaesthesia has become much safer in present times anesthetizing a patient exposes him/her to a set of

known yet rare risks about which patient must have thorough knowledge before proceeding.

Many institutions these days emphasize on separate written consent forms for anaesthesia. However, just signing the consent form doesn't mean that the patients had fully understood what he/she had been offered^[11]. Patients often don't read the documents they were told to sign and even if they do, they rarely understand it completely. Some patients choose to blindly sign such documents in order to be through with surgery. In our study we had found that only 62% of patients said that they should fully read and understand anaesthesia consent before signing it. In a similar study, Rosique *et al.*, found that 21% of patients didn't read the pre anaesthesia consent form before signing it while 64% had no or very little recall of information provided^[12].

One study by Naidu *et al.*,^[13] had shown that there is lack of standardization in terms of amount of anaesthesia related information imparted to the patients. They also found that only 57% of the patients were given information about anaesthesia plan pre-operatively^[13]. Due to increased patient load and long waiting lists patients sometimes try to rush through the surgery without waiting for anaesthesia related information. Our study found that a little more than half (57.5%) of the participants felt that separate consent for anaesthesia might be beneficial for them. Similarly only 43% wanted to interact with anaesthesiologist before signing anaesthesia consent form. Among the participants 41.5% believed that a separate

consent for anaesthesia might only add to paper work resulting in unnecessary delay in surgery (question-6, Table 2). This not only shows lack of awareness but also a rather care free attitude towards anaesthesia. Similar findings were reported by Singh *et al.*, who reported that 83.6% of patients had no knowledge of the contents of pre anaesthesia consent form they had signed before surgery^[14].

In fact, studies^[15,16] done in various public hospitals to find out patient's perception of anaesthesiologist and anaesthesia have found that only 10 to 30% of patients knew that anaesthesiologist is a physician. Such situation makes the job of anaesthesiologist responsible for obtaining consent, very difficult. One study by Waisel *et al.*, has found that anaesthesiologists had reported ethical, practical, and relational challenges while obtaining informed consent for anaesthesia^[17]. To counter this various methods have been tried, to improve communication with patient and to increase patient recall after anaesthesia^[18].

Similar scenario though may not be present in developed world. In places where patient awareness is high and medical facilities are adequate patients desire more information regarding anaesthesia plan. Various studies^[19,20] done in western countries had shown that parents desired detailed anaesthesia related information including that of risks involved. Though, it was also seen that parents had important knowledge deficits^[21] on the day of surgery, in spite of receiving printed information leaflets and printed consent forms as such could not replace verbal communication between patients and medical staff^[21]. So, anaesthesiologist should take maximum care while obtaining anaesthesia consent^[22].

Our study had clearly shown that patients lack awareness about various aspects of anaesthesia including the process of anaesthesia consent. So, it becomes duty of anaesthesiologist to educate not only patients but also the society as a whole regarding the importance of various aspects of a proper consent for anaesthesia. Anaesthesiologist should interact with patients at the time of their visit to pre anaesthesia clinic and discuss various aspects of anaesthesia care including consent for anaesthesia. Patients should be educated about their ability to make informed choice and should be actively involved in discussions formulating anaesthesia plan. Printed sheets containing information about anaesthesia, charts or audio visual aids should also be used to for this purpose. This will not only improve patient satisfaction but also save hospitals from unnecessary litigations. In addition to this, workshops, seminars can also be organized not only in hospitals but universities and schools as well to improve awareness regarding various aspects of anaesthesia care.

Our study had certain limitations. Firstly, only patients coming to a public hospital in rural part of a developing country were included in this study. Whether similar perception regarding separate anaesthesia consent exists in urban areas and metros was not studied. Second, the impact of lack of understanding and participation in anaesthesia consent process on peri-operative patient satisfaction was not assessed. Third, this study didn't invite suggestions from patients as to what according to them should be done to improve the process of anaesthesia consent. Hence, further studies may be required to fully assess the magnitude of this problem and improve patient care.

CONCLUSION

Patients lack awareness about separate consent for anaesthesia and about vital role they are supposed to play in anaesthesia related decision-making. So, anaesthesiologists as peri-operative physician should personally meet the patient before surgery, discuss the anaesthesia plan, document the discussion with patient and complete the process of consent.

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