

Does Written Informed Consent Comprehensively Inform Surgical Patients and is This Effective in Patient's Decision-Making?

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Submitted for Publication: 21-10-2019

Accepted for Publication: 28-11-2020

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ABSTRACT

Background: Informed consent (IC) is first fundamental principal step in health care helps patients to be conscious of consequences of their treatment decisions. The importance of obtaining a valid informed consent before any procedure well established with surgery and it is an important aspect of doctor patient relationship. **Objective:** To assess outcome of different management strategies in women presenting with primary postpartum hemorrhage (PPH). **Study Design:** Observational, prospective. **Settings:** General surgery department of Pakistan Institute of medical Sciences Hospital Islamabad Pakistan. **Duration:** Five months from March 2019 to July 2019. **Methodology:** All the patients were asked a set of standard questions, which related to the information they had provided before the operation as a part of standard informed consent practice. The surgeons had taken all the interviews with privacy and confidentiality after postoperatively at the earliest time the patient is comfortable to do so. The questions were asked in the simple languages, which were understandable to patients, so that patients could easily understand and respond to the same. The questionnaire sought information risks/benefits associated with a surgical procedure, alternate treatment options, whether providing additional detailed verbal and/or written information improved their understanding. All the information was recorded via study proforma. **Results:** Total 183 patients were interviewed post-operatively regarding informed consent and most of them 42.1% were between age 18-40 years. Males were 58.5% and females were 41.5%. Almost all cases had received informed consent, while some said they received just before the surgeries. There were some controversial answers regarding question of oral information influence the decision to proceed to the surgical procedure. Almost all patient had answered that they were informed regarding their conditions, surgical and anesthetic complications prior the surgery. Only 7.7% patient said that the time was not given for the questions and 10.4% patient were unsatisfied regarding informed consent, while the most of the cases were satisfied. **Conclusion:** In the study observation mostly, patients were satisfied and because mostly surgical consent element is generally understood, but some remained controversial and should consider its importance, beyond risks of the procedures, as well as acceptability and feasibility of intervention to surgical team and patients. Written information has not provided patients with adequate decision-making tools for imminent health matters, so pre-operative oral information also needed to adequate decision-making.

Keywords: Pre-operative, Informed consent, Decision making.

How to Cite: Ahsan MF, Irshad A, Rashid I, Waqar SH, Faisal J, Khuram AQ. Does Written Informed Consent Comprehensively Inform Surgical Patients and is This Effective in Patient's Decision-Making?. APMC 2020;14(4):318-22. DOI: 10.29054/APMC/2020.xxx

INTRODUCTION

Informed consent (IC) is first fundamental principal step in health care helps patients to be conscious of consequences of their treatment decisions.^{1,2} The importance of obtaining a valid informed consent before any procedure well established with surgery and it is an important aspect of doctor patient relationship.^{3,4,5} It is vitally important for patients to understand the risks and

benefits of the procedure and decide accordingly. In contrast to Western cultures, which adhere to more conscious about health and individually oriented philosophies, traditional our cultures place more value on the collective role of family in decision-making. Due to this reason in the hospital practice of our region, most often patients are giving inadequate information about their surgery before operation.^{1,5,6,7,8} Seeking informed

consent is often a formal act in which a patient's signature is obtained, with physicians believing that an important obligation has been fulfilled regardless of whether the patient has been provided with adequate information about the medical intervention that is about to take place.¹ Although this general observation, there is limited research is available from our country about the usual practice of preoperative informed consent.^{8,9} The aim of this study was to determine the degree to which patients understood the risks associated with a surgical procedure after giving routine consent and whether providing additional detailed verbal and/or written information improved their understanding. It was further determined whether the provision of more extensive information altered patients' anxiety levels.

METHODOLOGY

Study Design: Observational Prospective study.

Settings: General surgery Department, Pakistan Institute of medical Sciences Hospital Islamabad Pakistan.

Duration: Study duration was five months from March 2019 to July 2019.

Sample Technique: Non probability-convenience sampling.

Sample Size: Total 50 patients were enrolled after sample size calculation.

Inclusion Criteria: Patients who underwent elective and emergency surgery at Pakistan Institute of medical Sciences Hospital Islamabad and either of gender were included.

Exclusion Criteria: Patients with neurological diseases and those aged below 18 or above 60 and patients who required intensive care or were taken back into surgery were excluded.

Data Collection Procedure: Study was conducted after ethical approval from Pakistan Institute of medical Sciences Hospital Islamabad. Informed consent was taken from all the cases. All the patients were asked a set of standard questions, which related to the information they had provided before the operation as a part of standard informed consent practice. The surgeons had taken all the interviews with privacy and confidentiality after postoperatively at the earliest time the patient is comfortable to do so; which were on the bedside of the patients without the presence of the treating surgical team. The questions were asked in the simple languages, which were understandable to patients, so that patients could easily understand and respond to the same. The questionnaire sought information risks/benefits associated with a surgical procedure, alternate treatment options, whether providing additional detailed verbal and/or written information improved their understanding. It was further determined whether the provision of more extensive information altered patients' anxiety levels. All the information was recorded via study proforma.

Data Analysis: Data analysis was done by using SPSS version 20. Numerical data was analyzed in form of mean and standard deviation. Categorical data was analyzed in the form of frequency and percentage. Chi-square test was applied and p-value <0.05 was considered as significant.

RESULTS

In this study total 183 patients were interviewed post-operatively regarding inform consent, most of the cases 42.1% were between age 18-40 years, followed by 30.6% were between age of 40 -60 years and 12.5% were seen with age of >60 years. Males were 58.5% and females were 41.5%. Out of all 63.9% cases were married. 49.7% patient underwent elective surgeries and remaining were undergone emergency surgeries. According to the types of surgeries, cholecystectomies, appendectomies and laparotomies were commonest as showed in Table.1

Table 1: Demographic information of the patients (n=183)

Variables	Frequency	Percent	
Age groups	<18 years	27	14.8
	18-40 years	77	42.1
	40-60 years	56	30.6
	>60 years	23	12.5
Gender	Male	107	58.5
	Female	76	41.5
Marital status	Unmarried	55	30.1
	Married	117	63.9
	Widow/widower	08	04.4
	Separate/divorced	03	01.6
Type of admission	Elective	91	49.7
	Emergency	92	50.3
Types of the surgeries	Cholecystectomy	43	23.5
	Appendectomies	46	25.1
	Laparotomy	41	22.4
	Solid organ surgeries	20	10.9
	Hemorrhoids surgery	12	6.6
	Urinary bladder surgery	09	04.9
	Prostate surgery	12	6.6

Almost all cases had received informed consent, some said they received just before the surgeries and mostly informed consent was taken via house surgeons and nurses. Most if the cases 43.2% signed their consent form himself and by their parents and mostly after signed after reading it. 77.1% answered that the consent form was understandable, results shown in Table 2.

Table 2: Written information regarding inform consent (n=183)

Variables		Frequency	Percent
Have you received a written Informed Consent (IC)?	Yes	179	97.8
	No	04	02.2
How long before the surgical procedure have you received the IC form?	Just before	19	10.4
	Some hours before	67	36.6
	The day before	90	49.2
	Other	07	03.8
Who delivered the IC form?	Operative surgeon	16	8.7
	Registrar	52	28.4
	House surgeon	99	54.1
	Nurse	16	8.7
Who signed the IC form?	Patient	79	43.2
	Parent	49	26.8
	Relative	40	21.1
	legal representative	15	8.2
Did you read the IC form before signing it?	Yes	130	71.0
	No	27	14.8
	They just made me sign it; due to lack of time	25	13.7
	I did not want to read it	01	0.5
Was the IC form understandable?	yes	141	77.1
	No	22	12.0
	Partially understandable	20	10.9

Mostly patient and their parents replied that the informed consent was explained before the surgeries and it was understandable according to language, but there were some controversial answers regarding question of oral information influence the decision to proceed to the surgical procedure. Out of all 86.8% receive instructions on the behaviors to keep after the discharge and they have followed. Almost all patient had answered that they were informed regarding their conditions, surgical and anesthetic complications prior the surgery. Only 7.7% patient said that the time was not given for the questions and 10.4% patient were unsatisfied regarding informed consent, while the most of the cases were satisfied. Table.3

Table 3: Oral information regarding inform consent (n=183)

Variables		Frequency	Percent
Was the IC form explained?	Yes	166	90.7
	No	06	03.3
	Partially	11	06.0
Did you understand what was proposed to you, was the language understandable?	Yes	152	83.1
	No	07	03.8
	Partially	24	13.1
Did IC form and/or oral information influence the decision to proceed to the surgical procedure?	A lot	75	41.0
	Somewhat	70	38.3
	A little	22	12.0
	No	14	8.8
Have you had the opportunity to ask any questions and have you obtained exhaustive answers?	Yes, I asked questions and I had exhaustive answers	62	33.9
	No, I didn't ask any questions	52	28.4
	Yes, I asked questions but I didn't have exhaustive answers	69	37.7
Compared to the information received, how much would you want to know?	More	46	25.1
	No more, no less	67	36.6
	Less	38	20.8
	Less about risks and complications	32	17.5
Did you receive instructions on the behaviors to keep after the discharge?	Yes	159	86.8
	No	21	11.5
	Yes, but I wanted more information	03	01.6
Did you follow post-operative care indications?	Yes	153	83.6
	No	04	02.2
	Partially	26	14.2
Have you told about your condition and surgery prior to surgery?	Yes	179	97.8
	No	04	02.2
Have you told about the anesthesia and its complications prior to surgery?	Yes	175	95.6
	No	08	04.4
Was time given to you to ask question?	Yes	169	92.3
	No	14	7.7
Are you satisfied by pre-operative consent procedure	Yes	164	89.6
	No	19	10.4

DISCUSSION

Informed consent in surgical practice sometimes involved a process of sharing decisional authority with the patient when the choice hinged on personal values or preferences. In this study total 183 patients were interviewed post-operatively regarding informed consent, most of the cases 42.1% were between age 18-40 years, followed by 30.6% were between age of 40 -60 years. Males were 58.5% and females were 41.5%. Similarly, Souza MK *et al*¹⁰ conducted study regarding written informed consent, they found males 53% and females 47% with age range of 17 - 96 years and mean age 58.2±16 years. On other hand Yesuf NN *et al*¹¹ reported that 42 respondents (52.5%) were males while 38(48.5%) were females, their ages ranged between 22 and 65 years with a mean of 42.5years. Inconsistently Agozzino E *et al*¹ reported that 65.2% were females and 34.8% were males. In this study most if the cases 43.2% signed their consent himself and by their parents and majority signed it after reading it. However, Amir M *et al*¹² reported that 58 (29%) signed their own consent form, the rest of them were signed by relatives. On other hand Siddiqui FG *et al*¹³ reported that 12 (11%) patients actually signed the consent forms themselves. In rest of the cases the consent was signed either by the family members (36%), spouses (21%), siblings (18%) or friends (14%).

In this study 49.7% patient underwent elective surgeries and 50.3% were undergone emergency surgeries. However, Siddiqui FG *et al*¹³ reported that elective surgeries were done in 21.7% patient and 78.3% underwent emergency surgeries.

In this study informed consent was taken from 8.7% patients by operative surgeons, from 28.4% patients by registrars, from 54.1% by house officers and from 8.7% patients informed consent was taken by nurses. On other hand Siddiqui FG *et al*¹³ reported that (91.5%) consents were taken by junior doctors or the paramedics and included registrars and postgraduates (94 cases), interns (2 cases) and nurses (1 case)

In this study mostly patient and their parents replied that the informed consent was explained before the surgeries and it was understandable according to language, but there were some controversial answers regarding question of oral information influence the decision to proceed to the surgical procedure. Amir M *et al*¹² reported that 96 patients (48%) admitted having been informed about possible complications of surgery as against 156 (78%) who were informed of complications or sequelae of not having the surgery done.

In this study 89.6% cases were satisfied and almost all patient had answered that they were informed regarding their conditions, surgical and anesthetic complications prior the surgery and only 7.7% patient said that the time was not given for the questions and 10.4% patient were unsatisfied regarding informed consent. Similarly, Amir M *et al*¹² reported that most of the patients (N=187, 93.5%)

felt satisfied with the process of informed consent. The patients' perception of satisfaction appears to be dependent upon engagement in the discussion and decision-making rather than complete understanding of the information being provided and it needs to be further explored with targeted and specific studies.

CONCLUSION

In the study observation mostly patients were satisfied and because mostly surgical consent element is generally understood, but some remained controversial and should consider its importance, beyond risks of the procedures, as well as acceptability and feasibility of intervention to surgical team and patients. Patients' perceptions of what constitutes informed consent are diverse and many patients undergo surgery without knowledge of the identity of the surgeon or the reason for the surgery. Written information has not provided patients with adequate decision-making tools for imminent health matters, so pre-operative oral information may suited to meet patients' needs to adequate decision-making.

LIMITATIONS

This was limited sample size and single center study.

SUGGESTIONS / RECOMMENDATIONS

Written informed consent including verbal consent should be taken by operative surgeon, because operating surgeon can inform accurately regarding disease and surgical procedure in terms of surgical risks and positive complications.

CONFLICT OF INTEREST / DISCLOSURE

None.

ACKNOWLEDGEMENTS

The authors thanks all the colleagues who make this effort possible.

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