What patients really got and what they wanted in surgical informed consent: a cross-sectional survey in China

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Abstract

Background Informed consent (IC) is a fundamental element of modern clinical medicine based on the spirit of individual autonomy. Patients' comprehension of the key elements of clinical IC is often poor. Aims and Objectives This study aimed to explore patients' perceptions and expectations of IC process in invasive and surgical procedures. Design A cross-sectional descriptive study was carried out in Shanghai, China. Methods A self-administered structured questionnaire was developed to evaluate patients' perceptions and expectations of the IC process. In total, 317 individuals were included in the final analysis. Results Majority (73.8%) of the process was undertaken one day prior to the procedure and nearly half (47.6%) lasted less than 15 minutes. Most (96.8%) patients were given verbal explanation information by healthcare professionals. The nature of illness, potential risks and complications (74.1%) and the necessity of the procedure (69.4%) were mostly memorized while alternative treatments rarely (13.6%). Patients expected their family members involved in the decision making and could be provided more time to read the IC document and prepare for the decision-making. What the patients got was significantly different from what they expected in the following aspects, such as who participated in IC, where and when it took place, how long it lasted and main contents that should be discussed in IC ($P < 0.05$). Statistically significant relationship was found in expectations of IC patients and their income and payment type of medical expenses ($P < 0.05$). Discussion This study explored patients' expectation and perception of IC process regarding invasive procedures. Patients wanted to be more involved in IC process. To promote patient participation, more time should be given to the patients to comprehend and understand the IC document. In addition, information related with long-term issues should be discussed as a focal point. There is a need to re-consider IC process and to develop methods to promote the patients' satisfaction in achieving autonomy.

1. Introduction

Informed consent (IC) is imperative and necessary prior to lots of patients' medical treatments, especially in surgical and invasive or high-risk procedures, because it is a fundamental element of modern clinical medicine based on the spirit of individual autonomy[1, 2]. Within IC, health professionals inform patients about the diagnosis, current disease stage, purpose of the proposed treatment, risks and benefits of the treatment, reasonable alternatives and the course of the disease without treatment[3, 4]. Then patients reach autonomous decisions about whether to undergo medical procedures and sign the IC document which stands for their consent. Consent must be voluntary, and patients must demonstrate capacity for consent and understanding of the provided information [1, 5, 6].

Despite its critical importance to the provision of safe, high-quality, patient-centered health care, practical problems remain in the IC process [1, 7, 8]. Prior research has demonstrated that patients' comprehension and recollection of the key elements of IC are often poor [9-13]. Adequate overall understanding of the IC process by the patients was reported in less than one third of the studies [10, 11]. A retrospective survey about IC for spinal surgery showed the percentage of correctly answered questions was almost as low as the likelihood of nearness in guessing[12]. In one aspect, patients might be burdened with too much

information [14-16], which contributed to the poor recall rate. In another aspect, probably the informed information was not what patients really want. Although several studies explored what kind of information should be informed to patients, few studies explored the differences between what the patients want and what the doctors inform. A qualitative study which explored differences in information provided by surgeons and patient preferences for information in consultations for oesophageal cancer surgery showed that patients really wanted details about long-term issues including recovery, impact on quality of life and survival, which was rarely included in discussion by the surgeons[17]. Char et al[18] explored the patients' and surgeons' opinion on importance of different information regarding innovative surgery. There was no study exploring the differences between what the patients want and what they really get in IC process quantitatively.

Our goal was to: (1) broadly explore what the patients really want and what they get in IC process in China, (2) to analyze the differences between the reality and their expectation and (3) to analyze the factors influencing their expectation.

2. Methods

2.1 Participants and settings

This cross-sectional descriptive study was carried out in Shanghai, China, from January 2014 to January 2017. Participants were recruited at surgical, medical and orthopedics department from four tertiary hospitals and four secondary hospitals, which was chosen based on the facility, number of beds, and clinician credentials. The four secondary and tertiary hospitals respectively located in east, west, south and north Shanghai. Hospitals and participants were selected by convenience in each district. Eligible participants were over 18 years of age, recovering from certain kind of invasive or surgical procedures, and able to understand the survey information. participants were recruited from two tertiary hospitals and two secondary hospitals, chosen based on

2.2 Tools

A self-administered structured questionnaire was developed based on literature review and a semi-structured interview. The questionnaire was evaluated by a panel of ten experts, which included surgeons, nurses, patient safety researchers and hospital administrators. Items were revised according to the experts' recommendation. Then, it was tested among a convenience sample of 30 patients, who were interviewed to obtain feedback on the overall acceptability of the questionnaire in terms of length and language clarity.

The final questionnaire included a general information sheet and a questionnaire to evaluate patients' perceptions and their expectation of the IC process for their surgical or invasive procedures.

2.3 Data collection

Firstly, investigators visited the hospitals according to area distribution. Questionnaires were distributed among all patients who were requested to fill in the written IC form and were asked to rate each item of the questionnaire choosing the most appropriate response. An envelope was sent to each patient to packet the filled questionnaire. Then, the investigators revisited the hospitals one day after to collect the filled questionnaires. A total of 340 questionnaires were distributed and 320 were collected, with 94.1% return rate. Among them, 317 (93.2%) were complete and eligible to be included in the final analysis.

2.4 Data analysis

The data was analyzed using SPSS version 23.0（IBM Corporation, Chicago, IL, USA). Descriptive statistics were used to summarize the characteristics of respondents included in the survey sample, and to examine the distribution of responses. χ^2 test were used to examine the relationship among variables. Statistical significance was set at $p < .05$.

3. Results

3.1 Patient characteristics

Table 1 summarized the sample characteristics. The sample was 49.5% female. Participants ranged in age from 18 to 79 years (M=44.3, SD=12.25), with at least a senior high school degree (63.4%). Over half of the patients were from surgical departments (55.8%) and another 34.1% from orthopedics department.

3.2 patients' expectation for IC process

As is shown in Table 2, most participants indicated that their preference in participants in the informed consent information were lineal family only (34.7%) and patient and family members together (39.4%). More than two thirds (68.5%) felt doctors' office was appropriate for informed consent. With regard to time points and length of the informed consent process, one day before the procedure (82.6%) and 15~30 min (71.3%) were preferred. Although verbal explanation was preferred most, nearly 60% of the participants expressed the need to use pictures, and 46.8% hoped written information was provided. Information about long-term issues (74.8%), Chances of success (73.2%), Nature of illness (70.0%) and potential risks and complications (66.9%) were identified as desired information topics by most of the patients.

3.3 Patients' perception of the IC process

As shown in Table 2, 77.9% of the IC process involved lineal family members. 66.6% of the process happened in doctor's office, but there were still 20.5% occurred at the patients' wards. Majority (73.8%) of the process was undertaken one day prior to the procedure and nearly half (47.6%) lasted less than 15 minutes. Most (96.8%) patients were given verbal explanation information by health professionals in the IC process. Many patients could remember some of the information, such as the nature of illness (77.6%),

potential risks and complications (74.1%) and reasons for the procedure (69.4%). Alternative treatments were rarely remembered (13.6%).

As summarized in Table 3, majority (79.5%) of the patients indicated that they could understand the document. Most of the health professionals gave the patients' positive impression during the IC communication, such as kind and patient (75.1%), confident (45.7%), and encouraging (37.9%). Moreover, most of the patients (77.6%) were provided opportunity to question.

3.4 Differences between patients' expectation and perception of the IC process

As is shown in table 3, what the patients get was significantly different from what they expected in the following aspects, such as Participants, places, time point and duration of the IC interview.

3.5 Influencing factors of patients' expectation of IC

Statistically significant relationship was found between the expectations of patients and their income and payment type of medical expense (Table 4).

4. Discussion

This study explored patients' expectation and perception of IC process regarding invasive or surgical procedures. Analyses of data found that there were differences between what the patients want and what they really get in several aspects, including who participated in IC, where and when it took place, how long it lasted and main contents that should be discussed in IC.

Our results indicated a low ratio of patient participation in IC process (54.6%) and decision-making (35.65%), which was similar to previous research results in China[15], while it was lower than those in western countries. Meanwhile, patients expected to be more involved in IC process. It meant that some patients hoped to but didn't actually participate. One of the reasons might be that patients were worrying about whether they could deal with the stress stemming from the information discussed in IC process, especially the risks and the complications[15, 16]. 55.1% of the participants told that "Listed potential risks are intimidating". Another reason might be related with Chinese culture, in which families maintain common obligations to share each others' burdens and protect the common interests of the whole family. Sometimes the family plays a significant role in healthcare decisions, even if the patient is cognitively capable of acting autonomously. In such circumstances, the patient needs to sign a proxy to have someone as his/her surrogate decision-makers. In our study, patients' family not only played an important part in what they really got (77.9%) and also in the patients' expectation(74.1%). Besides, the health professionals' concern contributed to patients' low involvement in some extent. When unexpected instances occur during the operation, health professionals could consult with the informed family member, who was thought to know what the patient wanted[19]. Family members were sometimes the smart set's choice for participation in IC when majority of treatment cost was paid by them [20, 21]. Cost of treatment was often an important factor of decision-making for those patients in poor economic

condition[22]. It was validated by a significantly difference in the patients' expectation of IC process by different income and payment type of medical expense. As we call know, patient participation in decisions about their own health serves to improve patient care and outcomes [23]. In future, patients' demand should be expressed and involved in the health professionals' communication plan for IC. Health education should be encouraged to make sure the patients recognize their rights and roles in IC. In addition, family members should be enrolled in the IC process based on the patients' will [15, 24].

The results also showed the information which patients could remember were mainly those about explanation of disease (77.6%), potential risks and complications (74.1%), and indications and necessity for the procedure (69.4%). On one hand, health professionals might spend more time to explain these information, which was helpful for patients' understanding and recollection. Studies argued that health professionals spend much time in explaining the risks and complications in order to protect themselves from medical conflicts[25]. On the other hand, patients took those information seriously and remembered. Our results showed what patients expected to get most included explanation of disease (70.0%), potential risks and complications (66.9%). Patients expected information about long-term issues (74.8%) and chances of success of the operation (73.2%) as well. Even if the patients were waiting for surgery, they had been thinking of the life after discharge. Health professionals had to take account of the patients' interest, inform these information and help the patients make realistic plans for recovery and then the future life [3, 4].

The findings revealed that patients expected more time to understand IC documents and prepare for decision-making. The reason why health professionals did not give enough time to patients might be the shortage of doctor. The low doctor and patient ratio lead to limited communication time between doctors and patients. It is counted that from 2002 to 2012, the number of patients who seek medical care in hospitals increased by 104.5%, while the number of healthcare providers increased by 56.3%[26]. In order to fulfill the need of more patients, the doctors had to either work long hours or cut down the time for single patient. In a recent study of doctors' workload in China[27], the results showed that every doctor worked 54.06 hours per week. Because time for operations or various procedures was hard to control, they chose to shorten communication, which resulted in the poor comprehension of the IC. To settle this problem, strengthening of cultivation of health professionals[28] and balance of regional development[29] are worthy of attention. Alternatively, health professionals can seek help from others, such as nurses, who can serve as a decision coach [30]. In addition, flexible and multiple forms could be explored to reveal the information and improve comprehension. Studies had shown reliable effects of written information[31], decision aids[32], multimedia interventions[33], time-lapse movie[34]. With these interventions, health professionals can focus on answering patients' questions and doubts with limited time.

This study compares patients' expectation and perception regarding IC. Regarding our data, more efforts are to be provided to reach the patients needs. It would be interesting to present further data to explore the measures to minimize the gap between the differences with consultations/interviews. Similarly, the

use of other forms of data collection or analysis, such as video recording and conversation analysis, would provide further insights into the IC process.

Declarations

The study was approved by Committee on Ethics of Biomedicine Research, Second Military Medical University. We wanted to show our thanks to Luo Xu for her assistance with writing and revising the manuscript.

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Ethics, consent and permissions

The study got consent from the participants.

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Tables

Table 1 Characteristics of participants (N=317)

Variables	Frequency（%）	Variables	Frequency（%）
Gender		Department	
Male	160（50.5 ）	medicine	32（10.1）
female	157（49.5 ）	Surgery	177（55.8）
		orthopedics	108（34.1）
Education		Numbers of invasive experiences	
Elementary school or lower	9（2.8 ）	Never	170（53.6）
Junior high school	107（33.8 ）	1-2 times	130（41.0）
Senior high school	115（36.3）	3-5 times	10（3.2）
College or higher	86（27.1））	（5 times	7（2.2）
Income (month in RMB)		Perceived economic burden of surgery	
<1000	13（4.1）	Not at all	22（6.9）
1000-2000	44（13.9）	A bit	32（10.1）
2000-5000	148（46.7）	Moderate	107（33.8）
5000-10000	93（29.3）	Much	109（34.4）
>10000	19（6.0）	Very much	47（14.8）
Payment type of medical expense			
Total out-of-pocket	80（25.2）		
Partial reimbursement	226（71.3）		
Total reimbursement	11（3.5）		

Table 2 patients’ expectation and perception of the IC process（N=317）

Variables	Expectation n(%)	Perception n(%)	χ^2	p
Participants in the IC interview			208.156	.000
The patient only	48（15.1）	70（22.1）		
lineal family only	110（34.7）	144（45.4）		
Patient and lineal family together	125（39.4）	103（32.5）		
Patient or lineal family	34（10.7）	—		
Places of the IC interview			103.125	.000
Doctor’s office	217（68.5）	211（66.6）		
Nursing station	7（2.2）	40（12.6）		
Patient’s room	26（8.2）	65（20.5）		
Others	67（21.1）	1（0.3）		
Time points of the IC interview			37.108	.000
One day before the procedure	262（82.6）	234（73.8）		
The operation day	21（6.6）	72（22.7）		
It doesn’t matter /Forgotten	34（10.8）	11（3.5）		
Length of the IC interview			122.369	.000
（15 min	30（9.5）	151（47.6）		
15-30min	226（71.3）	132（41.6）		
30-60min	27（8.5）	17（5.4）		
（60min	6（1.9）	2（0.6）		
It doesn’t matter /Forgotten	28（8.8）	15（4.7）		
Methods of information disclosure（multiple choice）				
Verbal explanation/oral instructions	266（83.9）	307（96.8）		
Pictures	185（58.5）	33（10.4）		
Written information	148（46.8）	119（37.7）		
Models	103（32.6）	18（5.7）		
Structured sheets	103（27.5）	19（6.0）		
videos	71（22.5）	12（3.8）		
Information Contents （multiple choice）				
long-term issues (recovery, impact on quality of life and survival)	237（74.8）	94（29.7）		
Chances of success of the operation	232（73.2）	116（36.6）		
Explanation of disease/Nature of illness	222（70.0）	246（77.6）		
Potential risks and complications	212（66.9）	235（74.1）		
Treatment of the potential risks	182（57.4）	126（39.7）		
Peri-procedural precautions	177（55.8）	113（35.6）		
Indications and Necessity for the procedure	141（44.5）	220（69.4）		
Estimated time needed for the procedure	138（43.5）	101（31.9）		
Who operates during surgery	114（36.0）	69（21.8）		
Materials at private expense	108（34.1）	110（34.7）		
Process of procedure	99（31.2）	148（46.7）		
Anesthesia	87（27.4）	122（38.5）		
Alternatives	69（21.8）	43（13.6）		
Self-introduction of the informing doctor	67（21.1）	63（19.9）		
Decision maker of the operation				
The patient only	33（10.4）	46（14.5）		
Doctor and the patient	63（19.9）	47（14.8）		
Linear family	1（0.3）	7（2.2）		
Doctor and Linear family	23（7.3）	31（9.8）		
The patient and the Linear family	59（18.6）	69（21.8）		
The patient, the Linear family and doctor	138（43.5）	117（36.9）		

Table 3 Patients’ perceptions of IC (multiple-choices)

Variables	Participants (%)
Understanding of the IC document	
Totally understand	189（59.6）
Mostly understand	63（19.9）
Mild understand	33（10.4）
Understand a little	31（9.8）
Can’t understand at all	1（0.3）
Perception of the IC document	
Listed potential risks are intimidating	173（55.1）
Time is limited to understand the document comprehensively	167（53.2）
There is no opportunity to read the document thoroughly	122（38.9）
Information is comprehensive	115（36.6）
Medical terms are hard to understand	97（30.9）
Chances to question	
Yes	246（77.6）
No	73（22.4）
Perception of the doctor	
Kind and patient	238（75.1）
Confident with the procedure	145（45.7）
Attentive	139（43.8）
Encouraging	120（37.9）
Hasty	45（14.2）
Egocentric	10（3.2）

Table 4 Patients’ expectation differences in demographic data

Variables	Expected IC interview (χ^2, P)			
	Participants	Places	Time points	Length
Gender	7.293, 0.063	4.888,0.18	8.284*,0.040	2.657,0.617
Education	6.413,0.698	16.573,0.056	13.111,0.158	21.481*,0.044
Income	21.199*,0.048	26.458*,0.009	27.973*,0.006	30.818*,0.014
Department	22.416*,0.001	43.490*,0.000	3.794,0.704	4.051,0.853
Payment type of medical expense	14.224*,0.027	14.306*,0.026	21.198*,0.002	28.446*,0.000
Numbers of invasive experiences	15.797,0.071	10.007,0.35	6.068,0.733	21.412*,0.045
Perceived economic burden of surgery	25.641*,0.012	6.859,0.867	17.332,0.138	32.465*,0.009

*P <0.05