Association between Consultation Frequency and Satisfaction With Informed Consent Quality of Information in Preoperative Elective Surgery Patients

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Abstract: Informed consent is a process of sharing information with patients which is essential to their ability to make rational choices among multiple options in their perceived best interest. This cross sectional study was designed to investigate the association between consultation frequency and satisfaction between doctor-patients with information quality of informed consent in preoperative elective surgery patients from their perception, along with other factors. Ninety eight subjects were included from Cipto Mangunkusumo General Hospital in Jakarta, Indonesia. Data obtained from interview included quality of information and Consultation Satisfaction Scale (CSS) and from medical record included medical background and consultation frequency. This study showed Frequency of consultation and CSS were significantly associated with the quality of information (p=0.048 and p<0.001, respectively). Education, socio-economic status, type of disease, and prognosis of disease were not associated with the quality of information (p>0.05). In conclusion, this study suggests consultation frequency and satisfaction in communication between doctor-patients are key factors in informed consent process.

Keywords: consultation frequency, consultation satisfaction, informed consent, quality of information

Hubungan Frekuensi Dan Kepuasan Konsultasi Terhadap Kualitas Informasi Persetujuan Tindakan Medis pada Pasien Preoperatif Bedah Elektif

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Abstrak: Persetujuan tindakan medis adalah proses memberikan pasien informasi yang penting untuk menunjang kemampuan membuat pilihan yang rasional terhadap prosedur medis yang akan dilakukan. Penelitian potong lintang ini dirancang untuk meneliti hubungan antara frekuensi dan kepuasan konsultasi antara dokter-pasien dengan kualitas informasi yang didapat pada pasien preoperatif bedah elektif serta faktor-faktor lain yang mempengaruhi. Subyek penelitian meliputi 98 orang pasien bedah elektif Rumah Sakit Umum Pusat Nasional Cipto Mangunkusumo, Jakarta, Indonesia. Data yang didapat meliputi data primer berupa kualitas informasi dan Skala Kepuasan Konsultasi (SKK) serta data sekunder berupa latar belakang kesehatan dan frekuensi konsultasi. Penelitian ini menunjukkan frekuensi konsultasi dan SKK berhubungan secara bermakna dengan kualitas informasi ($p=0.048$ dan $p<0.001$) sementara pendidikan, status sosio-ekonomi, jenis penyakit serta prognosis penyakit tidak menunjukkan hubungan yang bermakna ($p> 0.05$). Dapat disimpulkan bahwa frekuensi konsultasi dan kepuasan berkomunikasi antara dokter-pasien merupakan faktor utama proses persetujuan tindakan medis.

Kata Kunci: frekuensi konsultasi, kepuasan konsultasi, *informed consent*, kualitas informasi

Introduction

Informed consent is an important part of medical practice. Informed consent is a process of sharing information with patients which is essential to their ability to make rational choices among multiple options in their perceived best interest. Babar[1] believes that "'Informed consent, on the other hand, is a similar process to some extent but lays essential emphasis on what the patient would want to know, including about adverse effects, risks of failure, alternative choices and how that individual patient could be affected by the treatment or of its lack. Here, the patient decides on what he wants to know".

Informed consent often becomes the source of complaint between doctor-patient. It has been shown in many studies that poor communication were the highest causes of patient's complaints, 13-22% in Australia[2], 80,6 % in Oslo[3], and 70-80 % in Thailand[4]. Informed consent minimally should make the patient understand (informed) in the context of giving information before he/she gives approval (consent). This will ideally happen if and only if there's an effective communication and same perception before the agreement reached.[1,5]

Beuchamp and Childress[5] said that one element that must be fulfilled is disclosure of material information. Adequacy of information given would give influence to patients' ability in deciding what is best for him as an admiration of patients' autonomy. [6,7]

Communication, as the main factor in giving informed consent, will strongly influence patients' information adequacy in informed-consent process. This study was designed to investigate the association between consultation frequency and satisfaction between doctor-patients with information quality of informed consent in preoperative elective surgery patients from their perception, along with other factor. We consider it was important to construct effective communication between doctor-patients to reach adequate information in informed consent.

Methods

Sample

A cross-sectional study was conducted in April-June 2005 at IRNA A Cipto Mangunkusumo General Hospital, Jakarta, Indonesia. The participants were selected by means of convenient sampling from preoperative elective surgery patient with patient's competency ($\geq$21 years old and or married, conscious and without mental retardation) of signing consent form for surgical procedure as inclusion criteria. Primary data, obtained using a structured questionnaire-based interview technique, were age, sex, education (year or formal education taken), marital status, socio-economic status (based on Statistics Center Bureau Indonesia/BPS, 2001), methods of disclosure of information and sources of obtained material information. Secondary data, obtained from medical record, were characteristics of disease: surgical location, type and prognosis of disease. The subjects signed the written informed consent before participated in this study.

Consultation Frequency and Consultation Satisfaction

Consultation Frequency data between doctor-patients were obtained from medical record. To measure consultation satisfaction, we developed an instrument called Consultation Satisfaction Scale (CSS). CSS contained 5 items: length of consultation, chance to ask freely, understanding of doctor's disclosure, rapport created and discussion. Each items used Likert-type scale[6], ranging from 0=very dissatisfied, 1=dissatisfied, 2=satisfied and 3=very satisfied. Total score for CSS is between 0–15. Pre-sampling was done to test this CSS reliability and validity with 30 respondents. The result of this pre sampling is *Cronbach alfa* 0,719 with *r* coeffisien correlation to total interval between 0,474–0,865 (table r : df = 28, *r* = 0,374, for p<0,05).

Quality of Information

Quality of information of the study participant was assessed using checklist. This checklist contains 7 disclosure of material information: diagnosis, surgical procedure, goal of surgical procedure, alternative of medical treatment, risk of medical treatment,

complication of medical treatment and prognosis of medical treatment.[8] We interviewed each participant in the simplest way to be understood. Each disclosure was scored 1 if respondent's answer matched with data in medical record. Score of 0, was given if the respondent did not know or understand their condition, or if their understanding did not match with data from the medical record. The maximum total score was 7. Three independent medicolegal experts determined the cut-off point of the total score. Quality of information was considered adequate if total score was 5 or higher.

Data Analysis

SPSS for Windows version 14 (SPSS Inc, Chicago, Illinois) was used for inputting, processing, and analyzing the data used in the study. To determine the possible effects of consultation frequency, consultation satisfaction and education on the quality of information, we analyzed the associations using independent T-test or Mann Whitney U test depend on the normality of the data distribution. As to determine the associations of categorized data such as sex, socio-economic status, type of disease and prognosis of disease with quality of information, *Chi-square* or *Fisher's* exact test was used.

Result

A total of 98 subjects were interviewed. The characteristics of participants are presented in **Table 1**. The mean for age was 44.58 (SD 14.96) years with age minimum 19 and maximum age 82. There were relatively equal distribution of sex, socio-economic status, type of disease and prognosis of disease among participants. Based on surgical location, urogenital, head and neck, and musculoskeletal were more frequent than other location. All participants got disclosure of material information from doctor using verbal method.

Tabel 1. Characteristics of Participants (n=98)

Characteristics	n (%)[a]
Age, mean, (SD), year	44.78, (14.96)
Male (%)	50 (51)
Education, mean (SD), year	10.06 (4.08)
Economic status not poor	51 (52)
Marital status	

▪ Married	82 (83.6)	
▪ Single	8 (8.2)	
▪ Widow/er	8 (8.2)	
Surgical Location		
▪ Urogenital	37 (37.8)	
▪ Head and Neck	21 (21.4)	
▪ Musculo-sceletal	15 (15.3)	
▪ Breast	13 (13.3)	
▪ Gastrointestine	11 (11.2)	
▪ Respiratory	1 (1)	
Type of disease		
▪ Tumor	57 (58.2)	
▪ Non tumor	41 (41.8)	
Prognosis of disease		
▪ Good	56 (57.1)	
▪ Poor	42 (42.9)	

[a] Data presented in absolute number (%) except stated otherwise

The consultation frequency, CSS, quality of information and disclosure of material information are presented in **Table 2**. The consultation frequency ranged from 1 to 10 times. The minimum and maximum CSS score were 4 and 11, respectively. Most participants (66.3%) had inadequate information quality. Based on disclosure of material information, diagnosis, chosen surgical procedure and its goal were more frequently given than other material information. Alternative of medical treatment was the lowest material information disclosed among participants.

Tabel 2. Consultation Frequency, CSS[a] and Quality of Information

Variable	n (%)[b]	
Consultation frequency, mean, (SD)	2.87 (2.22)	
CSS[a], mean, (SD)	7.8 (1.6)	
Quality of Information, mean, (SD)	4.31 (1.14)	
▪ Adequate	33 (33,7)	
▪ Inadequate	65 (66,3)	
Information material		
▪ Diagnosis	97 (99)	
▪ Surgical procedure	85 (86.7)	
▪ Goal of surgical procedure	97 (99)	
▪ Alternative of medical treatment	13 (13.3)	
▪ Risk of medical treatment	47 (48)	
▪ Complication of medical treatment	37 (37.8)	
▪ Prognosis of medical treatment	45 (45.9)	

The association of frequency consultation, CSS and education with the quality of information in the participants is presented in **Table 3**. No significant association of education (p = 0.405) with the quality of information were found. Association between frequency and satisfaction of consultation with quality of information were found to be significant (p = 0.048 and p < 0.001, respectively).

Table 3. Association of Consultation Frequency, CSS[a] and Education with Quality of Information

	Quality of information		p value
	adequate	inadequate	
	Mean (SD)		
Frequency of consultation	3.52 (2.33)	2.54 (2.10)	0.048
CSS[a]	8.61 (1.52)	7.38 (1.58)	< 0.001
Education (year)	10.55 (4.07)	9.82 (4.09)	0.405

a Satistified Consultation Scale

Associations between socio-economic status, type and prognosis of disease with quality of information are presented in **Table 4**. There was no significant association between socio-economic status, type of disease, or prognosis of disease with quality of information.

Tabel 4. Association of Socio-economic Status, Type and Prognosis of Disease with Quality of Information

	Quality of information		p value
	adequate	inadequate	
	N (%)		
Socio-economic status			
not poor	21 (21,43)	30 (30,61)	0.102
Poor	12 (12,25)	35 (35,71)	
Type of disease			
Tumor	13 (13,27)	28 (28,57)	0.727
non tumor	20 (20,41)	37 (37,75)	
Prognosis of disease			
Good	19 (19,39)	37 (37,75)	0.951
Poor	14 (14,29)	28 (28,57)	

Discussion

In Indonesia, informed consent was regulated according to article 53 Health Law No 23/1992, article 45 The Medical Practice Act No 29/2004 and Minister of Health regulation regarding informed consent No 585/MEN.KE./PER/IX/1989. Until now, there is no standard for information adequacy given to patients but there is a standard to see how well is the information given which is: reasonable physician standard, subjective standard and reasonable patient standard. Reasonable patient standard is guidance recommended to disclose information sufficiency in informed consent. In legal context, according to point 3 article 45 The Medical Practice Act No 29 / 2004, stated minimal information that should be given before patient approved any medical procedure suggested.[8]

Our study showed that all participants received information from their doctor. This was appropriate with point 1 article 6 Regulation of the Minister of Health Regarding Informed Consent No 585/MEN.KE./PER/IX/1989. Ideally this information should be given by the surgeon though regarding point 2 article 6 Regulation of the Minister of Health Regarding Informed Consent No 585/MEN.KE./PER/IX/1989 it can be delegated to another doctor.[8] Study in Auckland showed the quality of information, as perceived by patient was related to the seniority of the person giving the information.[7]

For method of information disclosure, our study showed all participant only received information in verbal. In another study in different health center, 48 % patient were given verbal and written information and 3 % patient where shown a video in addition to the verbal and written information though it still resulted in bad quality of informed consent.[9]

In our study most of participant (66,3%) had inadequate information quality. Only 37,8 % of participant informed regarding complication of medical treatment and even less (13,3 %) for alternative of medical treatment. In another study[9] it was reported that no information was received by 55,5 % of patients regarding complication of surgery and 79,5 % of patients received no information about alternative of medical treatment. In legal context, according to Medical Practice Act No 29 / 2004[8] we must give material

information, as appropriate. Although, there was no standard for sufficient information in each material of information for patient, we could use reasonable patient standard, where the quality of information was considered adequate if the patient was satisfied with the given information.

This study showed that consultation frequency and satisfaction between doctor-patient were associated with the quality of information in informed consent. Frequent consultation and higher CSS led to better quality of information. We found no association between education, socio-economic status, type and prognosis of disease showed with the quality of information in informed consent. Our study proved consultation satisfaction was a key factor in reducing misunderstandings, disputes and ultimately litigation. Providing sufficient information during informed consent process is an area in which patients satisfaction can be gained or lost.[2]

However, several limitation of this study must also be considered. First, doctor's consideration to disclose or not each information in ethically perspective depend on their patient's condition. Second, the use of checklist methods about each material of information, which must be disclosed in legal context, is not the ideal quality of information assessment tool in reasonable patient standard.

Conclusion

In conclusion, the present study suggests that consultation frequency and satisfaction in communication between doctor-patients are key factors in informed consent process. Quality of information is adequate if patient was satisfied with doctor's information disclosed.

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