

The relationship between quality of informed consent and perioperative care, and patient satisfaction: A tertiary-care hospital's experience

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Abstract

Objectives: To assess the association between patient satisfaction and the quality of the informed consent (IC) obtaining process in a tertiary-care hospital.

Methods: A cross-sectional study was carried out between December 2014 and April 2016 using a modified Leiden Perioperative care Patient Satisfaction questionnaire (LPPSq) in the form of pre- and postoperative structured interviews in King Khalid University Hospital (KKUH).

Results: A total of 198 eligible subjects were included. The LPPSq score was found to be significantly related to patients having children ($P= 0.003$). Patients with children were the most satisfied, with a mean score of 84.12 ± 9 SD. The most satisfied age group were those between 56 and 65 years of age with a mean score of 85.07. Disclosure and understanding score showed a strong positive relationship with the level of satisfaction using the Pearson correlation coefficient. Fifty percent (50%) of the participants were not informed about other therapeutic options. Of those who did not understand the form, 79.6% did not actually read it. Otherwise, there were no significant differences between the other variables of the LPPSq score including patient educational level. Spending more time obtaining informed consent was unrelated to higher patient-physician score and/or higher level of satisfaction.

Conclusion: There was no statistically significant relation between quality of informed consent and patient satisfaction. Quality of informed consent was found to be moderate in KKUH. No significant difference was found between the demographic characteristics with respect to the quality of informed consent. Older patients (56 - 65 years) and those with children were most satisfied.

Keywords: KKUH, IC, LPPSq, Patient Satisfaction of perioperative care

1. Introduction

Medical ethics form an integral part of any successful health care system, and codes of medical ethics have evolved over the years and have been adopted both nationally and internationally by many healthcare centers. Informed consent however, is among the most susceptible yet important areas in the medical field. It is key in building good patient-physician relationships as it reflects doctors' respect to their patients' autonomy. It has been defined internationally as the process in which a healthcare provider or a clinical researcher obtains permission from an individual before delivering a certain health intervention (such as therapy, anaesthesia, surgery) or before any study enrollment.

Across various contexts and cultures, the process of obtaining informed consent has become essential even in studies that do not involve intervention. Although some regions of the world still approach this process paternalistically, presumably out of complying with tradition, there is still doubt that this approach has no disadvantages.

The process of informed consent encompasses more than signing a prescribed form. It involves sharing a satisfactory amount of information with the consenting individual, addressing their concerns, fears, questions and discussing possible outcomes whether positive or negative. All of which

enable them to make responsible, informed decisions regarding their healthcare.

Patient satisfaction has always been a target that health-care providing organizations keep aiming for^[1]. Dissatisfaction is defined as "an emotional reaction to a disease and its care, such as sadness and anger". It is a qualified outcome indicator that reflects quality of healthcare services^[2].

Surgeons in Saudi Arabia were found to have a more paternalistic approach to consenting their patients compared to surgeons in the United Kingdom according to a study that was conducted in both countries^[3]. The word paternalism is of Latin origin meaning "father". Paternalism is the practice of governing people in a patriarchal manner by providing for their needs without giving them rights or responsibilities^[4]

Patient satisfaction is not easily achieved as there are many factors that might play a role in it. Some factors are patient-related (e.g. socio-demographic features, health status, and patient-physician relationship) while others are organizational (e.g. number of beds, staff performance, and using electronic medical records). In contrast to patient-related factors, improving organizational-factors was found to have a minimum positive impact on patient satisfaction^[2].

The aim of this study is to assess the relationship between postoperative patient satisfaction level and the quality of

informed consent obtaining process in King Khalid University Hospital, Riyadh, Saudi Arabia.

2. Methods

2.1 Study design, Setting, Subjects, and Sampling

A cross sectional study was carried out using pre- and postoperative structured questionnaire-based interviews in King Khalid University Hospital (KKUH) between December 2014 and April 2016. The questionnaires were previously validated and used by previous studies [7, 8].

The target sample size was calculated to be 196 patients assuming that 50% of postoperative patients are satisfied [5]. Accepting 7% precision, and 95% confidence interval. Two consecutive samples of patients admitted for elective general surgery were taken.

2.2 KKUH

King Khalid University Hospital (KKUH) is the affiliated teaching hospital of King Saud University. It is an 850-bed facility with both general and subspecialty medical services. It has a special outpatient building, more than 20 operating rooms, and a fully equipped and staffed laboratory, radiology, and pharmacy services in addition to all other ancillary services. The hospital provides primary, secondary, and tertiary care services to all Saudi citizens on a referral bases. All care is free of charge for all King Saud University staff and students.

2.3 Inclusion/Exclusion Criteria

A total of 198 patients were included in the final analysis. Patients who did not give a valid consent (i.e. under guardianship), diagnosed with cognitive impairment, or undergoing an emergent surgical procedure were all excluded; as these factors interfere with the process of obtaining proper informed consent. The consecutive sampling technique was used since the accessible sample does not sufficiently represent the target population.

2.4 Data collection

Data collection was done in two stages. Initially, structured, face-to-face interviews of preoperative patients undergoing general surgery to assess the quality of informed consent one day before their procedures. The second stage involved structured, face-to-face or telephone interviews two days postoperatively, to assess patients level of satisfaction about perioperative care. The reason why interviews took place within 2 days after the operation/procedure was to decrease the possibility of mixing between issues with medical ward care and possible issues in the operating theatre centre (perioperative care).

A pre-developed questionnaire was used for preoperative interviews with some modifications (See appendix A). The study questionnaire consists of four domains: A) General Information, including demographic characteristics and the name of the surgery/procedure. B) Disclosure and understanding. C) Perception of significance, proper application and comprehension of the informed consent process. D) Patient-physician relationship.

2.5 Data analysis

Quality of informed consent was represented by two scores:

Patient-physician relationship and Disclosure and understanding scores. One point was given to every “positive” answer to a question on the Disclosure and understanding score (indicating that the certain element was successfully achieved) with a maximum of 10 points. A Likert scale was used to record the degree to which a respondent agreed or disagreed with an item in the questionnaire. For the Patient-physician relationship score, the options ranged from 1 to 5 (1-Always, 2-Often, 3-Sometimes, 4-Seldom, 5-Never) for each of the five questions, with a maximum score of 25.

The Leiden Perioperative Care Patient Satisfaction questionnaire (LPPSq) was used for postoperative interviews with some modifications to assess patient satisfaction on perioperative care (See appendix B). The questionnaire consists of six domains: A) Patient satisfaction of information delivery in the informed consent process. B) Discomfort and Needs. C) Fears and Concerns. D) Patient satisfaction of patient-staff relationship. E) Professional competence. F) Patient satisfaction about the services.

For Information Delivery and Patient-Staff Relationship domains, the options ranged from 1 to 5 (1- Completely dissatisfied, 2- Dissatisfied, 3- Not satisfied nor dissatisfied, 4- Satisfied, 5- Completely satisfied) with a maximum score of 20 and 65 for these domains respectively. Also, for Discomfort and Needs as well as Fears and Concerns, options ranged from 1 to 5 (1- Not at all, 2- A little bit, 3- Moderately, 4- Quite a bit, 5- Extremely) with a maximum score of 35 and 20, respectively. The first question in the professional competence had the same options of the two previous domains while the remaining three questions were yes/no questions with one point given to each positive answer with a maximum score of 8. The Service domain score ranged from 1 to 4 (1- Too long, 2- Long, 3- Just right, 4- Short) and one yes/no question with a maximum score of 9. The patient satisfaction with perioperative care (LPPSq) was represented by calculating the mean satisfaction scores in the Information Delivery, Fear and Concerns, and Patient-Staff Relationship domains with a maximum score of 105.

2.6 Statistical Methods

The total scores for different items (i.e. Disclosure and understanding score, Patient - physician relationship score, LPPSq, Information delivery, Patient-staff relationship, Discomfort and needs, Fears and concerns, Professional competence and Service) were calculated.

Pearson correlation coefficient was used to find the relationship between the three total scores of Disclosure and understanding, Patient - physician relationship and LPPSq scores.

We used the Student t-test for independent groups and non-parametric Mann-Whitney test to compare the scores for two independent groups (i.e. gender, level of education, having children and nationality). Also, one way analysis of variance (ANOVA) and non-parametric Kruskal-Wallis test were used to compare the scores in more than two groups of patients (i.e. age groups, marital status, number of children, profession, and type of procedure, comprehension of the patients' rights regarding the informed consent process, time spent on the consent procedure and the duration of knowing the surgeon).

Chi-square tests were used for comparison between different

genders and age groups for the perception of the importance, proper application, and comprehension of the informed consent obtaining process. (i.e. how important do you think is the informed consent procedure, did you ask any questions concerning the operation, what was the average time spent on the consent procedure with the surgeon/medical staff, did you comprehend your rights concerning the informed consent.)

A statistically significant difference was assumed when the P-value was less than 0.05.

Statistical analysis was performed using Statistical Package for the Social Sciences (SPSS) version 15 software (SPSS Inc., Chicago, IL, USA).

2.7 Pilot study

A pilot study was conducted earlier to assess the suitability and clarity of the questions posed in each interview, assure equal patient comprehension as well as to estimate the amount of time needed for the overall process of data collection. Interviewers were well-trained in order to standardize the data collection process. Some modifications were applied to the original questionnaires in order to adapt to what was found in pilot study.

2.8 Ethical considerations

Written informed consent was signed by all patients/participants after a full explanation of the study requirements and assurance of confidentiality and anonymity. The study was approved by the Ethics Review Committee of King Saud University.

3 Results

3.1 Demographics

The number of participants was 198 patients, chosen among general surgery patients operated on in a period of 8 months. Females comprised 60.6% of the patients, 71.7% were married, and 45.9% were above 45 years of age. In regard to the level of education, 58.8% of subjects were highly educated, with either a high school degree or higher. Socio-demographic characteristics of study participants are shown (Table 1).

3.2 Quality of Consent

The responses to Disclosure and Understanding score ranged from 0 to 10. The mean score was 6.75 with a standard deviation (SD) of 2.129. The responses to Patient-Physician Relationship score ranged from 5 to 19. The mean score was 10.14 with a standard deviation (SD) of 2.911.

Of all participants, 57.6% stated that they understood their rights regarding the informed consent, while 33.8% reported the opposite.

It was also found that half of the participants (50%) in this study were not informed about other possible therapeutic options.

In contrast to 69.2% of study participants, 30.8% did not ask any questions concerning their operation. Upon further questioning on the reasons behind that, it was found that 66.7% reasoned that it was very clear to them, 13.3% said there was not enough time, and 8.3% said they felt pressured by the medical staff. Only 67.7% of the patients understood the informed consent form. Of those who did not understand

the form, 79.6% did not actually read the consent form. In addition, 48% thought they could change their mind even after giving consent, 36.9% did not, while 14.1% were not sure.

The average time spent on the consent obtaining process with the surgeon/medical staff varied among patients. The majority of patients, 34.8%, reported spending between 5 and 10 minutes on the consent process, 33.3% of them spent less than 5 minutes, and 31.8% spent more than 10 minutes.

Most of the participants were found to have known their surgeons for a long period of time, ranging from months 29.3% to years 30.3%. A significant relationship was found between the duration of knowing the surgeon with respect to the Disclosure and Understanding score and the Patient-Physician Relationship score ($p=0.005$ and $p=0.002$, respectively.) However, spending more time in the informed consent process was not associated with a higher Patient-Physician score and/or a higher level of satisfaction ($P > 0.05$). Time spent on the consent process was only significantly related to disclosure and understanding score ($p=0.001$.)

3.3 Patient Satisfaction

The responses to staff dimension score ranged from 38 to 65. The mean score was 57.56 and the standard deviation (SD) was 8.056. The LPPSq score ranged from 57 to 103. The mean score was 82.52 and the standard deviation (SD) was 9.903.

The LPPSq score was found to be significantly related to patients having children ($P= 0.003$.) Patients with children were the most satisfied with a mean score of 84.12 ± 9 SD.

Most demographic characteristics were found to be unrelated to the LPPSq score. There was no significant difference between the LPPSq score and different age groups ($P= 0.053$.) The most satisfied age group were patients between 56 and 65 years old with a mean score of 85.07. In addition, the difference between single and married patients with respect to the LPPSq score was insignificant, $P = 0.117$. The mean LPPSq score of single patients was 78.81 ± 10.9 while the mean score for married patients was 83.78 ± 9.4 .

LPPSq score was not significantly related to patients' educational level as well as patients' city of permanent residence. Otherwise, no significant difference was found between the rest of the variables with respect to LPPSq score ($P > 0.05$.)

The relationships between profession, comprehension of the patient's rights regarding the informed consent process, and the time spent on the consent procedure, with respect to disclosure and understanding score, were all statistically significant ($p=0.025$, $p=0.000$, $p=0.001$ respectively.)

Eighty point eight percent of participants believed that the informed consent process is very important. Different educational levels and age groups showed a significant difference in terms of asking questions concerning the operation ($p=0.014$, $p=0.006$ respectively.) The higher a patient's level of education, the more likely it was they would pay attention to the process and therefore be aware of postoperative complications that could cause them dissatisfaction ($p=0.021$.)

Regarding the average time spent on the consent procedure with the surgeon/medical staff, a significant difference was

found between genders ($p=0.037$.) There were no differences among age groups or educational levels. In terms of comprehension of the informed consent obtaining process, there were no significant differences among groups.

3.4 Correlation Between Quality of Consent and Patient Satisfaction

There was no significant difference in the Patient-Physician score and the level of satisfaction among patients who comprehended their rights regarding informed consent and those who did not ($P > 0.05$), whereas a significant difference was found in the Disclosure and Understanding score among the same groups ($p=0.000$.)

Spending a longer time in the informed process was not associated with a higher Patient-Physician score and/or higher level of satisfaction ($P > 0.05$), while time spent on the consent process was significantly related to the Disclosure and Understanding score ($p=0.001$).

4. Discussion

There is a difference between some of our results and what was found in the literature. This difference might be the result of the sample size in this study or due to cultural and other demographic differences between the samples.

Quality of informed consent in KKUH demonstrated by Patient-Physician Relationship and Disclosure and Understanding scores did not show a significant relationship with the level of perioperative care patient satisfaction. This finding was supported by some studies, [6, 7, 9, 10] where an association was found between the quality of informed consent and patient satisfaction [9, 10]. One study found that adding new modalities in the informed consent process was ineffective in improving its quality, since patients eventually had the same satisfaction level [6]. Another study showed that informed consent format did not significantly affect patients level of anxiety, comprehension or satisfaction [7]. However, several studies have shown that providing adequate information during the process of obtaining informed consent or adding new modalities had increased patient satisfaction level [8, 11, 12, 13, 14]. Contrary to our study results, one paper had shown that the level of patient satisfaction is affected by patient-physician relationship [15].

Our results show a moderate level of quality of informed consent in KKUH. Although substandard, it is considered higher compared to other local centers such as King Abdulaziz Medical City (KAMC), where informed consent was found to be generally poor. However, it can be concluded that the quality of informed consent in central Saudi Arabia is not good enough and needs to be improved [6].

This can be due to a defect in the disclosure and explanation part, as a local study supports evidence of Saudi surgeons' negligence to some informed consent guidelines [16]. In our study, half of the participants stated that they were not informed about other possible therapeutic options which is consistent with findings in previous studies [6]. However, this might be explained by the possibility of recall bias, as this is a patient-based study [13, 17].

Our study showed that about 79.6% of those who did not understand the consent form, did not actually read it. This was a common issue reported in many other studies, and was

hypothesized to be the result of the patient being illiterate, or having been instructed to sign the form without giving time to read, or that the patient was satisfied with the explanation [11, 17]. In contrast to 69.2% of study participants, about one third of patients did not ask any questions concerning their operation and 66.7% of them reasoned that it was simply very clear to them.

The average time spent on the consent obtaining process with the surgeon /medical staff in this study varied among patients. More than one third of patients reported spending 5-10 minutes on the consent obtaining process, which is similar to time spent on the same process reported in other studies [18, 19, 20]. One of these studies also found that more than half the respondents spent around 10 minutes informing their patients about the procedure and out of these specialist physicians, internists reported spending more time in comparison to others. Furthermore, internists also reported that their patients accepted the method of treatment they recommended in most cases, compared to others (i.e. anesthesiologists). This brings us to the possibility that the more time spent informing patients about the surgery/procedure they are undergoing, the more likely they are to trust their physician and therefore, be satisfied with the outcome. A study showed that the more time spent by surgeons during the informed consent process, the more likely it is that the patient will understand [21].

Patient satisfaction about information delivery was moderately high, which is consistent with one of the studies in the literature. Our study also shows that patients with children are the most satisfied according to patient satisfaction score. There was a similar finding in another study that looked at the effect of patient sociodemographic characteristics on patient satisfaction levels [22]. Another study showed that about 70% of the patients were satisfied with the explanation regarding their disease [23]. Although there were noticeable variations between individuals, the patient-staff relationship score still represents a good relationship. In another study, 30% agreed that they trust, feel comfortable with, feel respectful towards, and express their worries to their surgeons [7].

Certain demographic characteristics were found to be related to the level of patient satisfaction. For instance, a Japanese study has suggested that physicians are more likely to deliver incomplete explanations to younger patients [23]. Our study found that the older the patient is, the more satisfied they will be (Table 2). The same findings were reported in two other studies [23, 24]. This could be explained by the possibility that a physician's explanation of a procedure to younger patients is not specific, when they would have preferred a more detailed explanation of their procedure. However, these findings were inconsistent with what was found in a local cross-sectional study that assessed the quality of informed consent, where the quality of informed consent was found to be higher when the patient was younger [6].

However, a study investigating patient satisfaction level after undergoing surgery for obstructive sleep apnea has found an inverse relationship between patient age and their level of satisfaction [25]. This result could be confounded by the fact that their study participants were surveyed three months after surgery, while in our study, interviews were done two days postoperatively.

Our study shows that patient education level is not

significantly related to the satisfaction score, similar to what was documented in another study suggesting no relationship between educational level and overall patient satisfaction^[9]. However, there is controversy in the literature over this. As one study suggests, patients with a low level of education may face difficulties understanding, that could affect the comprehension of their rights, which can be associated with a higher level of satisfaction^[25]. Contrary to this, another study suggested that a high level of education is more likely to be associated with higher patient satisfaction^[23].

This study was a patient-based questionnaire study in a single tertiary care institution (KKUH), carried out over a period of 8 months. Limitations of this study were the cross-sectional study design, the chance of recall bias, as in some instances the procedure was explained three months before patient admission, and the small sample size, due to poor patient response rate.

We faced many difficulties while conducting this research project. Patient response rate to postoperative phone-call interviews was low. Therefore, much effort was spent to collect data within their hospital stay period (i.e. two days postoperatively). However, many patients were tired to some extent and were giving quick answers that might be inaccurate. Moreover, other health care institutions were uncooperative and the process of obtaining their approval took too long, which was beyond the planned timeframe.

The data collection phase was halted for two weeks since all elective surgery was postponed as a protective measure against the Middle East respiratory syndrome coronavirus (MERS-CoV) hospital outbreak. Even after resuming surgery in KKUH, not all booked surgical procedures were performed. For that reason, the number of patients was below expected. Data collection resumed 8 months later and stretched out till late March of 2016.

5. Conclusions

In conclusion, there was no statistical significant relation between quality of informed consent and patient satisfaction. However, the quality of informed consent was found to be moderate in KKUH. No significant difference was found between the demographic characteristics with respect to the quality of informed consent. The majority of patients were satisfied. Significant patient factors related to perioperative satisfaction were found to be patient age and having children. Future studies should look into the length of time spent during obtaining consent and its effect on level of postoperative satisfaction. Observational studies should be conducted in order to assess the quality of informed consent to see if physicians adhere to hospital policies and international guidelines.

6. References

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