Cross-sectional Study

Patient experience and decisional satisfaction with the informed consent process for elective gynecologic surgeries: A cross-sectional study

Glaiza S. de Guzman *, Melissa D.L. Amosco

Department of Obstetrics and Gynecology, University of the Philippines Manila – Philippine General Hospital, Philippines

ARTICLE INFO

Keywords: Decision Satisfaction Informed consent

ABSTRACT

Background: The informed consent process is a vital component of daily medical practice. It involves providing patients with sufficient, accurate, and understandable information to decide on a contemplated therapy. The study aims to evaluate the patient experience and satisfaction with the preoperative informed consent process.

Methods: A cross-sectional study was performed on adult women admitted for elective gynecologic surgery in a tertiary training hospital. Participants were recruited on their second postoperative day and were asked to answer a structured questionnaire assessing decisional satisfaction and experience with the informed consent process. Satisfaction was measured using a 6-item Satisfaction with Decision Scale. Knowledge of the surgery and experience with the informed consent were measured using an Informed Consent Questionnaire. Bivariate associations between highly satisfied and not highly satisfied groups were tested using Fisher exact test.

Results: A total of 150 patients were enrolled in the study with a mean age of 44.5 years. The resident-in-charge provided the information and assisted in the documentation of the informed consent in 86.7% and 67.3% of patients, respectively. There was an overall high decisional satisfaction with a mean score of 27.4 and 52.7% of patients strongly agreeing to all statements of the Satisfaction with Decision Scale. The majority of the respondents were informed and acknowledged comprehension of the surgery including its risks, benefits, and alternative treatment options. Knowing the success rate and benefits of the procedure as well as being informed of the need for postoperative catheterization were significantly associated with high satisfaction.

Conclusion: Knowledge and understanding of the key components of informed consent influence patient satisfaction. The current study highlights the high decisional satisfaction rates of patients who underwent elective gynecologic surgery. Strategies to further improve this patient-physician encounter include the establishment of standard policies on personnel involved, timing, and quality of information given to patients. Patient satisfaction should serve as an indicator of the quality of healthcare rendered and guide for continuous improvement of services.
2. Methodology

A cross-sectional study was conducted among adult patients admitted for elective gynecologic surgery in a tertiary training hospital in the Philippines from January to July 2021. Patients were recruited on their second postoperative day. Patients who were unable to provide informed consent to be involved in this study or were uncomfortable because of postoperative pain were excluded. Non-probability sampling and consecutive enrollment of patients were done until the sample size was met. The sample size was calculated at 150 by using the difference between two proportions in GPower 3.1. The values for proportions were extrapolated from the study of Hallock (2017) which reported that 46.8% among those with pelvic organ prolapse were highly satisfied with the consent process compared to only 25% among those with pelvic organ prolapse and urinary incontinence who were highly satisfied with the consent process [5]. The power was set to 80% and the type I error was set to 5%.

A structured questionnaire patterned from the study by Hallock et al. was used [5]. The questionnaire had three sections which included questions on socio-demographic data, and satisfaction and experience with the informed consent process. The primary outcome, decisional satisfaction, was measured using the Satisfaction with Decision Scale (SDS). The mean total score was 27.4 (SD 3.4) indicating high overall satisfaction. Seventy-nine respondents answered yes or no questions and listed responses to-ward the patient decisional satisfaction scores while Table 4 shows the distribution of total SDS scores. Two respondents were dissatisfied with their decision.

Most participants agreed or strongly agreed with the statements on the satisfaction with decision scale (SDS). The mean total score was 27.4 (SD 3.4) indicating high overall satisfaction. Seventy-nine respondents (52.7%) strongly agreed with all six statements. Table 3 summarizes the respondent decisional satisfaction scores while Table 4 shows the distribution of total SDS scores. Two respondents were dissatisfied with their decision.

There was no significant correlation between religion ($P = .303$), educational background ($P = .507$), civil status ($P = .075$), and occupation ($P = .476$). Table 5 shows the results for individual items from the

| Table 1 | Sociodemographic characteristics of the study population. |
|----------|----------------------------------------------------------|
|          | n | % (N = 150) |
| **Age**  |    | 44.5 ± 12.7 |
| **Educational Status** | | |
| Graduate school | 24 | 16.0% |
| High school graduate | 57 | 38.0% |
| College level | 18 | 12.0% |
| College graduate | 43 | 28.7% |
| Vocational course | 8 | 5.3% |
| **Religion** | | |
| Catholic | 131 | 87.3% |
| Protestant | 2 | 1.3% |
| Pentecostal | 7 | 4.7% |
| Iglesia ni Cristo | 9 | 6.0% |
| **Civil Status** | | |
| Single | 43 | 28.7% |
| Married | 67 | 44.7% |
| Widowed | 14 | 9.3% |
| Separated | 8 | 5.3% |
| Common-law partner | 18 | 12.0% |
| **Occupation** | | |
| Agriculture/Farming | 10 | 6.7% |
| Private Sector | 91 | 60.7% |
| Housewife/Unemployed | 14 | 9.3% |
| Government Employee | 35 | 23.3% |
provided affirmative response to the individual questions pertaining to their informed consent questionnaire. Knowing the success rate, being informed of the risks, and the need for a urinary catheter after the surgery were significantly associated with high satisfaction among the respondents. Among those who answered yes to knowing the success rate of the procedure, 76.1% were highly satisfied. Moreover, 76.4% of patients who affirmed being informed of the benefits of the procedure were also highly satisfied with their decision. Most of the respondents provided affirmative response to the individual questions pertaining to their knowledge and experience of the informed consent process. Majority informed of the risks, and the need for a urinary catheter after the surgery were significantly associated with high satisfaction among the respondents. Among those who answered yes to knowing the success rate of the procedure, 76.1% were highly satisfied. Moreover, 76.4% of patients who affirmed being informed of the benefits of the procedure were also highly satisfied with their decision. Most of the respondents provided affirmative response to the individual questions pertaining to their knowledge and experience of the informed consent process. Majority
(96–98%) were able to list discomforts and benefits of the procedure, and consequences of not having the surgery. On the other hand, a lower proportion (82.7%) was able to identify a minor or major risk of surgery.

4. Discussion

The informed consent process is a fundamental part of the legal and ethical practice of medicine [7,8]. It provides an avenue to discuss vital information necessary to guide patients in decision making and assist them in recognizing the best course of treatment for their condition [9]. Though there have been efforts to standardize information provided to patients, evidence shows disparity in the type and level of detail disclosed and how patient decisions are influenced [8].

It is imperative that the physician providing the information about the procedure be a part of the surgical team. Several authors have suggested that the person obtaining the informed consent should be knowledgeable about the procedure and be capable of performing the procedure [10–12]. A physician who fulfills both criteria would be able to effectively explain data relevant to the surgery. Likewise, a physician must assess the patient’s competency to understand the information presented. Our results showed that residents-in-charge, assigned surgeons, students, and nurses presented information about the surgery to the respondents. The residents-in-charge also obtained the informed consent in majority of the study population. In our institution, patients for elective surgeries are admitted under the care of junior trainees who most often do not perform the procedure themselves. The surgery is assigned to a senior trainee with more advanced surgical skills. In this study, only 43.4% of the patients received informed consent counseling from the assigned surgeon. The resident-in-charge assisted majority of the respondents in signing the informed consent form while 38.0% were assisted by the assigned surgeon. Assigned surgeons or senior trainees should be encouraged to actively participate in the preoperative counseling of patients. This should also be seen as an opportunity to ease a patient’s anxiety and establish rapport. Reinforcing this practice may be a strategy to improve patient satisfaction and hospital experience.

The minimum elements of an informed consent form include the specific procedure, physician performing the procedure, statement that the procedure was explained, name and signature of the patient or legal representative, and date and time the form was signed. Explanation of the procedure should include its anticipated benefits, risk, and alternative therapies [7]. Although the institutional informed consent form was not evaluated in this study, the patient’s knowledge and experience were assessed through a standardized questionnaire. Majority of the participants acknowledged being informed of the success rate, procedure, risks, and benefits. They reported understanding the information given to them. A small proportion of the respondents responded “no” to the items in the Informed Consent Questionnaire. It should be recognized that the responses may be affected by subjective recall of the process.

To ensure that key components of the informed consent are presented, Shamir et al. suggested some practice changes [11]. These include formal training on the practice of acquiring informed consent, use of a consent checklist, use of aids to improve patient recall and comprehension, and implementation of a staged consent process. In a staged process, counseling and documentation of the informed consent done at the outpatient clinics. This will then be reaffirmed during the patient’s admission. This makes the informed consent an ongoing and evolving process which is strengthened at each patient-physician encounter [11].

Patient satisfaction is a principal indicator of healthcare quality. Although patient satisfaction questionnaires are established measures for quality improvement plans, they are not being used extensively for development of amended policies. This study is the first to assess patient decisional satisfaction with the informed consent process locally and among gynecologic patients. Our data shows that patients undergoing elective gynecologic surgeries had a high decisional satisfaction score after informed consent counseling. This correlates well to the high number of affirmative responses in the informed consent questionnaire. Knowing the benefits and success rate of the procedure significantly resulted to high satisfaction rates. A similar study assessed the quality of the informed consent process among surgery patients in Turkey [4]. Majority of the participants were satisfied with the information provided to them on why the operation was necessary. However, only 42% responded that they received adequate information on the potential side effects and complications of the surgical procedure [4]. In this study, majority reported being provided adequate information and time to make an informed decision. It should be noted that two of the study respondents reported dissatisfaction. Dissatisfaction may be attributed to patient, information, and communication-related factors. Communication of complex, technical information should be made at a level understandable by the patient. Although this study did not show significant association between sociodemographic parameters and high satisfaction, physicians should acknowledge the diverse socioeconomic background and literacy of patients when performing preoperative counseling. It is similarly influenced by the patient’s overall experience with her treatment.

Kadam (2017) identified challenges to the informed consent process to include poor communication techniques, lack of time for the consent process, inability to detect lack of patient comprehension, legal outlook toward consent process, patients’ anxiety and fear of new procedures, health status confounded by terminal and debilitating illnesses, cognitive impairment, denial of disease state, complex language, use of medical terminologies, and lengthy consent documents [3]. This underscores the need for formal training of physicians to the informed consent process. These factors were not assessed in the study and may be evaluated subsequently.

The use of instructional material may be useful adjuncts to the informed consent process [7]. Patients might prefer the use of instruction booklets over verbal conversations and may make the process less intimidating. Ghulam and colleagues proposed that combined written and oral preoperative information are adequate tools to the process of obtaining informed consents [13]. The use of decision aids is not broadly observed in our institution. This is a meaningful strategy that may be explored to improve the preoperative informed consent counseling and patient knowledge.

5. Conclusion

The informed consent process should be regarded as an opportunity to forge a therapeutic alliance between patients and physicians. Patient decisional satisfaction is related to the quality and adequacy of information provided to them. The study highlights the high decisional satisfaction and knowledge of patients undergoing elective gynecologic surgeries in a tertiary training hospital. Further recommendations for improving this process may include establishment of standard policies on the personnel, timing, and information provided to patients. An informed consent form and checklist specific to the various procedures being performed by a department or service should be established.

6. Strengths and limitations of the study

This is the first study to evaluate patient experience and decisional satisfaction in the local setting. However, the study only evaluated the preoperative informed consent process received by the patient. Emergency consent provided by attendants was not assessed in the current study. The timing of the informed consent, patient comprehension, and surgical outcomes were not assessed in the study. Data are obtained from a single hospital during the COVID-19 pandemic. Differences in practices of the informed consent process before and during the pandemic were not evaluated. The study was limited to patients admitted in the Gynecologic Wards of the Philippine General Hospital. The results may not be applicable to patients admitted to other departments or hospitals.
7. Recommendations

Further studies may look into patient anxiety and/or preparedness for surgery in relation to the informed consent process. Measuring the patient’s level of understanding may allow physicians to better manage patient expectations and improve decisional satisfaction. The use of informational material may also be seen as an intervention to further improve knowledge and satisfaction of patients.

Ethical approval

Ethics approval was obtained from the University of the Philippines Manila Research Ethics Board prior to conduct of the study (UPMREB 2020-0554-01).

Funding

Funding was provided by the University of the Philippines Manila – Philippine General Hospital, Expanded Hospital Research Office (EHRO). The views and opinions contained in this article were those of the authors and do not necessarily represent those of Philippine General Hospital.

Author contributions

All authors were responsible for the conception and design of the study, revisions, and final approval of the paper.

Registration of research studies

Name of the registry: Philippine Health Research Registry.
Unique identifying number or registration ID: PHRR210504-003510.
Hyperlink to the specific registration: registry.healthresearch.ph.

Guarantor

Glaiza S. de Guzman, MD.
Melissa D.L. Amosco, MD, PhD.

Consent

Written informed consent was obtained from the respondents.

Provenance and peer review

Not commissioned, externally peer reviewed.

Declaration of competing interest

All authors declared no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.amsu.2022.104551.

References

[1] K. Slim, J.E. Bazin, From informed consent to shared decision-making in surgery, J. Vis. Surg. 156 (3) (2019) 181–184.
[2] B. Pesut, S. Thorne, M.L. Stager, C.J. Schiller, C. Penney, C. Hoffman, M. Greig, J. Roussel, Medical assistance in dying: a review of Canadian nursing regulatory documents, Pol. Polit. Nurs. Pract. 20 (3) (2019) 113–135.
[3] R.A. Kadam, Informed consent process: a step further towards making it meaningful, Perspect Clin Res 8 (3) (2017) 107–112.
[4] M. Egri, O. Celbis, M. Karaca, B. Ozenemir, A.N. Kok, The informed consent status for surgery patients in Eastern Turkey: a cross-sectional study, Indian Journal of Medical Ethics 5 (1) (2008) 26–28.
[5] J.L. Hallock, R. Rios, V.L. Handa, Patient satisfaction and informed consent for surgery, Am. J. Obstet. Gynecol. 217 (2017) 181.e1–181.e7.
[6] G. Mathew, R. Agha, for the STROCSS Group, STROCSS 2021: strengthening the Reporting of cohort, cross-sectional and case-control studies in Surgery, Int. J. Surg. 96 (2021), e106165.
[7] C.S. Cocanour, Informed consent – it’s more than just a signature on a piece of paper, Am. J. Surg. 214 (2017) 993–997.
[8] C. Grady, Enduring and emerging challenges of informed consent, NEJM 372 (9) (2015) 855–862.
[9] Informed consent and shared decision making in obstetrics and gynecology. ACOG Committee Opinion No. 819. American College of Obstetricians and Gynecologists, Obstet. Gynecol. 137 (2021) e34–e41.
[10] O.A. Anderson, I.M. Wearne, Informed consent for elective surgery – what is best practice? J. R. Soc. Med. 100 (2) (2007) 97–100.
[11] P. Sharma, A. Arya, S. Singh, Informed consent for orthopaedic surgery: a prospective audit. Clinical Governance, Int. J. 8 (3) (2003) 236–241.
[12] O. Shamir, D.M. Gawich, T. Alan, et al., From the patient’s perspective: is there a need to improve the quality of informed consent for surgery in training hospitals? Perm. J. 17 (4) (2013) 22–26.
[13] A.T. Ghulam, M. Kessler, L.M. Bachmann, U. Haller, T.M. Kessler, Patients’ satisfaction with the preoperative informed consent procedure: a multicenter questionnaire survey in Switzerland, Mayo Clin. Proc. 81 (3) (2006) 307–312.