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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

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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.

1. Introduction

Patient safety is a major determinant of healthcare and vital to it is obtaining effective informed consent from patients. Informed consent is the process by which a patient makes a voluntary decision to receive a treatment or intervention after being provided adequate information. It is required for medical treatment, dissemination of patient information, surgeries, procedures, blood transfusions, and anesthesia [1]. The fundamental components of an informed consent discussion include the nature of the procedure, risks and benefits of the procedure, alternative management options, risks and benefits of the alternative options, and assessment of the patient's capacity to comprehend the first four elements [1,2]. It is the legal and ethical duty of the healthcare provider to uphold the elements of informed consent and document the process through a signature [3].

The practice of acquiring informed consent should be a collaborative process between the physician and the patient. Aside from describing the proposed treatment plan or surgery, the patient's role in the decision-making should be emphasized. The patient's preference should be elicited and documented [1,3]. A full-bodied informed consent improves patient satisfaction, compliance, and treatment outcomes and reduces complaints [4].

* Corresponding author. Department of Obstetrics and Gynecology, University of the Philippines Manila – Philippine General Hospital, Taft Avenue, Manila, Philippines.
E-mail address: gsdeguzman1@alum.up.edu.ph (G.S. de Guzman).

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For elective gynecologic surgeries admitted in our institution, the patient is educated on the different management options to her condition after diagnosis and decision to treat have been made. The patient then makes verbal consent to undergo a recommended procedure. The process of admission and preoperative preparation for elective surgery is then explained. Once scheduled for elective surgery, the patient is admitted to one of the charity surgical wards and decked a resident-in-charge and surgeon. It is the responsibility of the assigned surgeon to obtain the informed consent of the patient through signing a hospital form that exists in English and Filipino versions. The process of obtaining the preoperative informed consent involves counseling and educating the patient with her attendant present. Standard to this practice is the documentation of the physician who explained the procedure and a witness to the process.

The patient's perception of the informed consent is not well known, and patients tend to perceive the process as a purely administrative act [4]. Although the significance of informed consent has continually been proven and emphasized, there have been no recent studies on the informed consent process in the institution. This is a cross-sectional study that evaluates the patients' experiences and satisfaction with the informed consent process in a tertiary training hospital. The current study aims to highlight barriers to effectively obtaining informed consent, identify potential strategies to improve key clinical practices that affect patient decision and safety, and ultimately improve service delivery to the patients.

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). It is composed of six items graded on a Likert scale of 1–5, with higher scores indicating higher satisfaction. The third part of the questionnaire included an Informed Consent Questionnaire (ICQ) where participants were asked to answer yes or no questions and list responses in some items.

The questionnaire was translated to Filipino and back-translated to English. Content and face validity testing were done among hospital management personnel and patients, respectively. Comments and suggestions were incorporated into the questionnaire. The questionnaire was pretested among a similar group of patients.

2.1. Data analysis

Univariate descriptive statistics were reported as mean for continuous variables and frequency with percentage for categorical variables. To obtain a binary outcome of the decisional satisfaction, the scores in the SDS were added. Those with cumulative scores of 26–30 were considered highly satisfied while those below were not highly satisfied. Bivariate associations between highly satisfied and not highly satisfied groups were tested using Fisher exact test. A P value of $< .05$ was considered statistically significant. All analyses used STATA 14 (Stata Corp Inc).

2.2. Ethics approval and registration

Ethics approval was obtained from the University of the Philippines Manila Research Ethics Board prior to conduct of the study (UPMREB 2020-0554-01). Written informed consent was obtained from the participants. The work is reported in line with the STROSS 2021 criteria [6]. The study was registered in the Philippine Health Registry available at registry.healthresearch.ph (UIN: PHRR210504-003510).

3. Results

A total of 150 patients were recruited and enrolled in the study. The mean age of the respondents was 44.5 ± 12.7 years. The majority were high school graduates (38.0%), married (44.7%), Catholic (38.0%), and worked in business or are employees of private sectors (60.7%). Table 1 summarizes the sociodemographic data of the respondents.

The resident-in-charge and assigned surgeon provided information about the surgery to 86.7% and 43.3% of the respondents, respectively. Students-in-charge and nurses-in-charge also presented information to 4.7% of the patients. Majority of the patients were assisted by residents-in-charge (67.3%) and assigned surgeons (38.0%) in signing the informed consent. Moreover, 11.3% of the patients were influenced in their decision to give consent. Relatives and friends were among those who influenced the informed consent process. Data about personnel involvement are presented in Table 2. There was no need for emergency consent in any of the enrolled patients. Study participants underwent their planned procedures.

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		
Grade school graduate	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%
Widwed	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%

Table 2
Personnel involved during the informed consent process.

	n	% (N = 150)
1. Who provided information about your surgery?		
Resident-in-charge	130	86.7%
Assigned surgeon	65	43.3%
Student-in-charge	7	4.7%
Nurse-in-charge	7	4.7%
2. Who assisted you with signing the informed consent?		
Resident-in-charge	101	67.3%
Assigned surgeon	57	38.0%
Student-in-charge	9	6.0%
Nurse-in-charge	26	13.3%
3. Is there anyone who influenced your final decision in giving the consent?		
Yes	17	11.3%
No	133	88.7%

Patients were allowed to choose more than one response for items 1 and 2.

Table 3
Respondent decisional satisfaction scale, presented as n (%).

Parameters	Strongly Disagree	Disagree	Neutral	Agree	Strongly Agree
I am satisfied that I was adequately informed about the issues important to my decision	2 (1.33%)	1 (0.67%)	2 (1.33%)	44 (29.33)	101 (67.33)
The decision I made was the best decision possible for me personally	1 (0.67%)	1 (0.67%)	2 (1.33%)	52 (34.67%)	94 (62.67%)
I am satisfied that my decision was consistent with my personal values	1 (0.67%)	1 (0.67%)	4 (2.67%)	53 (35.33%)	91 (60.67%)
I expect to successfully carry out (or continue to carry out) the decision I made	1 (0.67%)	1 (0.67%)	5 (3.33%)	51 (34.00%)	92 (61.33%)
I am satisfied that this was my decision to make	0	1 (0.67%)	4 (2.67%)	49 (32.67%)	96 (64.00%)
I am satisfied with my decision	1 (0.67%)	1 (0.67%)	4 (2.67%)	49 (32.67%)	95 (63.33%)

Table 4
Summary of overall satisfaction with decision scale.

Score Range, Interpretation	n	% (N = 150)
Highly satisfied (26–30)	109	70.7%
Satisfied (21–25)	39	28.0%
Neutral (16–20)	0	0%
Dissatisfied (11–15)	1	0.7%
Highly dissatisfied (6–10)	1	0.7%

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

Table 5
Responses to the informed consent questionnaire comparing patients who were highly satisfied to those who were not highly satisfied.

Question	Yes Response	Highly Satisfied (N = 109)		Not Highly Satisfied (N = 41)		P value
		n	%	n	%	
Do you know the success rate of the procedure?	142	108	99.08	34	82.93	**0.028**
Do you know enough about the procedure that you could basically explain to another person how it would occur?	141	106	97.25	35	85.37	0.24
Was the procedure explained to you?	146	109	100.00	37	90.24	0.277
Did you understand the explanation of the procedure?	145	108	99.08	37	90.24	0.605
Were you informed of the risks of the procedure?	142	105	96.33	37	90.24	1.000
Were you informed of the benefits of the procedure?	143	109	100.00	34	82.93	**0.013**
Do you understand the risks of the procedure?	138	104	95.41	34	82.93	0.3
Do you understand the benefits of the procedure?	139	105	96.33	34	82.93	0.155
Were you informed of the rare possibility of a life-threatening complication from the procedure?	132	98	89.91	34	82.93	1.000
Were you informed of the common risk of need for a urinary catheter after the procedure?	140	107	98.17	33	80.49	**0.020**
Did you know that you could refuse the procedure?	137	103	94.50	34	82.93	0.324
Were you given the opportunity to refuse the procedure?	136	103	94.50	33	80.49	0.196
Were you informed about the alternatives to the procedure?	136	102	93.58	34	82.93	0.359
Were you informed about possible consequences of not having the procedure?	144	108	99.08	36	87.80	0.182
Did you get all the information you need to make a good decision about the procedure?	141	105	96.33	36	87.80	0.697
Did you feel that adequate time was spent to provide you with all the information you need?	145	108	99.08	37	90.24	0.605
List a discomfort of the procedure	144	103	94.50	41	100.00	
List a benefit of the procedure.	147	106	97.25	41	100.00	
List a risk (minor or major) of the procedure	124	85	77.98	39	95.12	
List one consequence of not having the procedure	147	106	97.25	41	100.00	

(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).

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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) 113–130.
[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. Ozdemir, 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), 106165.
[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) e34–41.
[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. Cawich, 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.