Volume 3, Issue 2
September 2022

SLJOM The Sri Lanka Journal of Menopause

Original Article

Assessment of Effectiveness of Pre-Operative Consenting in Major Gynecological Surgeries

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Abstract

One of the key elements of gynecological surgeries is proper consenting for procedures. The patient has the right to know details of interventions about to undergo for her condition. Effectiveness of obtaining valid consent influence patient care and deficits of consent process creates gaps in management. When unanticipated or anticipated complications encounter during surgery, in the presence of valid consenting clinicians can make decisions to alter desired procedure and this minimize legal issues as patient is already explained and accepted the risks and complications. Despite of many patient care guidelines, safety precautions or check lists still marked reductions of valid consenting process is observed in many clinical settings. This audit conducted to evaluate strengths and deficiencies of consenting process conducted in Professorial Unit, Kalubowila. 56 patients awaiting major gynecological procedures were questioned with self-administered questionnaire following initial consenting process for pre-planned surgical intervention by intern medical officers. Each patient's understanding for surgery re-evaluated and we used pictorial consent formats as a tool. Questionnaire prepared in Sinhala, English and Tamil formats to overcome language issues.

Post-evaluation analysis revealed surprising results as 3.47% of the selected population was not aware of the surgical procedure they are to undergo, and the same percentage of population was not aware of the indication for their respective surgeries. 21.42% of the population was not aware of the mode of anesthesia used for their surgery whereas site and type of incision was not known to 17.85% of the study population. The route of surgery (Laparoscopy/Laparotomy/vaginal) of their respective surgeries was not known by 50% of the selected population and the possibility of conversion of laparoscopic surgery into an open laparotomy was not known to 39.28% of the study population. 28.57% was not aware of the possible complications of the surgery. Only 50% of the patients had prior knowledge regarding the surgical procedure they undergo while the rest was educated only during the consent taking procedure. 21.42% declared that the time duration was not adequate for them to consent with proper knowledge regarding the procedure. 17.85% had not gotten adequate opportunity to clarify their doubts and postoperative management plan was not known by 53.54% of the study population. Furthermore 10.72% was not satisfied with the health education and the clarifications done by the medical team for their queries regarding the surgical procedure.

Introduction And Justification

In surgical interventions accurate and timely informed surgical consent is considered as one of the most essential elements. The patient possesses the right to know the details of the surgical procedure he/she undergoes hence in clinical practice; clear and precise consent assures a high level of health care provision. The consent process has several important components, and deficiencies or absence of any one of these can contribute to unfa-

vorable consequences. Consent should be viewed as a critical safety process that aims to provide the safest and best quality surgical care for patients. In particular, patients who are to undergo elective surgeries must be fully informed before consenting to surgery. The importance of the consenting process is clearly highlighted in "Obtaining Valid Consent" RCOG article. The effectiveness of the consenting process can be improved via maintaining high quality in completing the consent forms. In addition, the deficits of consent forms may result the clinician and patient to deal with many troubles tarnishing the trust of patient regarding surgeon and the institute. The international standards provide guidance on the best practice when it comes to obtaining consent for surgical procedures.

It is important to recognize that seeking consent for surgical intervention goes beyond obtaining a signed and completed consent form: It is the process of providing the information that enables the patient to make a decision to undergo a specific surgery.

One of the roles of clinical members of the surgical team is to ensure that consent has been adequately taken. Patients must understand their diagnosis and prognosis, the purpose of the intervention, the benefits and potential risks and any existing alternatives including non-operative and conservative measures. The discussion of risk must include ones "inherent in the procedure; however, small the possibility of their occurrence, side effects and complications. The patient should also be aware of plans for follow-up, and for additional surgical and other relevant interventions. It is also a good practice to include information about anesthesia.

The clinician needs to diverge information regarding the surgical intervention, by using a patient-friendly language free of medical jargon with possible written information (usually in the form of a patient information leaflet with pictorial aspects). In the ideal setting, there should be a period of time for the patient to understand and digest the information provided to them via the information sheet, before the consent discussion and procedure, to allow them to clarify any doubt that may arise.

International guidelines state that either the person who is providing or is actively involved in the provision of treatment should obtain consent. Surgeons have a duty to maintain patient trust, and by extension, ensure they are suitably prepared for the role of consenting. The aim of this study is to assess the quality of consenting process in our department and to identify potential areas for improvement.

Methodology

In Obstetrics and Gynaecology usually consenting for routine surgeries are performed by internal house officers as a part of their training. It is usually done one to two days prior to the surgery by informed written consenting pattern. As we detect several deficits in this process as post graduate trainees, we planned to assess effectiveness and deficiencies for progressive changes. Senior registrar and the registrars of obstetrics and gynecology department were actively involved in this process.

After routine consenting for obstetrics and gynecology surgeries done by intern house officers, we planned to assess their understanding and satisfactory level by using a self-administered questionnaire in a systematic sampling method of collecting data within one month of period among a sample of 56 patients from Gynecology professorial unit, Colombo South Teaching Hospital, Kalubowila, Sri Lanka. The information sheets and the questionnaires were provided in their respective languages. The patients with less literacy were explained of the audit and the investigators were involved in completion of the data sheets.

Analysis

The study was carried among 56 patients who got admitted to the gynaecology professorial unit of Colombo South Teaching Hospital, Kalubowila for their respective gynaecological surgeries.

No.	Inquired information	Yes (%)	No (%)
1	Awareness of the type of surgery the patient is to undergo	96.42	3.57
2	Awareness of the patient regarding the indication for the surgical intervention	96.42	3.57
3	Awareness of the alternative treatment options for the disease condition other than the surgery	32.14	67.85
4	Awareness of the surgery is preferred over the alternative treatment options	64.28	35.71
5	Awareness regarding the pre-operative preparation for the surgery	78.57	21.42
6	Awareness regarding the importance of pre-operative preparation	50	50
7	Pictorial illustration of the surgical procedure done before obtaining consent	78.57	21.42
8	Awareness regarding the mode of anesthesia	78.57	21.42
9	Awareness regarding the removal of organs or tissues during the surgeries	67.85	32.14
10	Awareness regarding the site/type of the incision	82.14	17.85
11	Awareness regarding the type of surgery (Laparoscopy/Laparotomy/ vaginal)	50	50
12	Awareness of the advantages of the laparoscopic surgeries over laparotomy	53.57	46.43
13	Awareness of possibility of conversion of a laparoscopic surgery in to an open surgery	60.71	39.28
14	Awareness of the advantages of the surgical intervention	50	50
15	Awareness regarding the complications of the surgical procedure	71.42	28.57
16	Awareness regarding the management/treatment options of the complications that could arise during the surgery	42.85	57.14
17	Awareness of the surgery via other media resources	50	50
18	Individually educated regarding the surgical procedure	78.57	21.42
19	Adequacy of time duration for consenting from the time of patient education	78.57	21.42
20	Adequacy of opportunity to clarify the doubts regarding the surgery	82.14	17.85
21	Awareness of the post-operative management plan	46.42	53.54
22	Satisfaction regarding the clarifications of the arisen problems	89.28	10.72
23	Satisfaction regarding the information provided by the medical team	89.28	10.72

Conclusion

In conclusion, surprisingly 3.47% of the selected population was not aware of the surgical procedure they are to undergo, and the same percentage of population was not aware of the indication for their respective surgeries. 21.42% of the population was not aware of the mode of anesthesia used for their surgery whereas site and type of incision was not known to 17.85% of the study population.

The route of surgery (Laparoscopy/Laparotomy/ vaginal) of their respective surgeries was not known by 50% of the selected population and the possibility of conversion of laparoscopic surgery into an open laparotomy was not known to 39.28% of the study population. 28.57% was not aware of the possible complications of the surgery. Only 50% of the patients had prior knowledge regarding the surgical procedure they undergo while the rest was educated only during the consent taking procedure.

21.42% declared that the time duration was not adequate for them to consent with proper knowledge regarding the procedure. 17.85% had not gotten adequate opportunity to clarify their doubts and postoperative management plan was not known by 53.54% of the study population. Furthermore 10.72% was not satisfied with the health education and the clarifications done by the medical team for their queries regarding the surgical procedure.

Suggestions

- The patients should be offered all possible management options for the respective disease condition and during the same encounter she should be educated regarding the preference of the selected management option over the alternative options explaining the pros and cons of each.
- The establishment of consenting clinics for prior education of the patient.
- The intern house officers who will be taking consent should be properly trained and should possess adequate resources and knowledge.
- The patients should be thoroughly informed of the type of surgery, site of incision, mode of anesthesia and regarding subsequent complications of the selected surgical intervention leaving them adequate time to decide on their preference of intervention preferably before admitting for surgery.
- Advising the patients of other means of acquiring knowledge regarding their respective surgeries such as internet, books, magazines and other reading materials.
- Promotion of pictorial depiction of the surgical procedures when obtaining consent and arranging visual aids of explaining the procedures such as videos, handbooks, brochures/ leaflets.
- Periodic auditing and upgrading of the consenting process should be encouraged.
- Establishment of a uniform evaluation and consenting procedure based on the local guidelines and protocols.

Discussion

An ideal consent form as per RCOG Clinical Governance Advice, should be consisted of following aspects

- Name of proposed procedure
- The description of the proposed procedure
- Intended benefits
- Serious and frequently occurring risks
- Any extra procedures which may become necessary during the procedure
- The benefits and risks of any available alternative treatments, including no treatment
- Procedures which should not be carried out without patient's prior consent
- Preoperative information
- Anesthesia

As the first aspect of the consenting process, proposed surgical procedure should be precisely discussed with the patient. As an example, if consider abdominal hysterectomy it should be precisely mentioned as total or subtotal abdominal hysterectomy. Also, the decision regarding tubal excision, ovarian preservation or excision should pre decided and discussed with the patient.

Then the proposed surgical procedure should be described in step manner. Patient should be advised regarding the potential impact on sexual function, bladder function and psychology. The intended type of incision (midline or transverse) and route of surgery (abdominal, vaginal, or laparoscopic). If the plan is for a total hysterectomy, the patient should be informed that, occasionally, it may be necessary to limit the operation to a subtotal hysterectomy for technical reasons. If the ovaries are to be removed in a premenopausal woman, she should be informed that it would cause immediate surgical menopause and the long-term health implications should be discussed. If any other procedures are anticipated (for example ovarian cystectomy, surgery for incontinence) those must be discussed, and a separate consent should be obtained.

Patient should be advised that menstrual bleeding is guaranteed to be abolished by total hysterectomy and improvement of pelvic pain and premenstrual symptoms is not guaranteed.

Clinicians should make every effort to distinguish serious risks from those of frequently occurring and explain them to the patient. Risks may be quantified using the descriptors below.

Presenting information on risk		
Term	**Equivalent numerical ratio**	**Colloquial equivalent**
Very common	1/1 to 1/10	A person in family
Common	1/10 to 1/100	A person in street
Uncommon	1/100 to 1/1000	A person in village
Rare	1/1000 to 1/10000	A person in small town
Very rare	Less than 1/10000	A person in large town

The above descriptors are based on the RCOG Clinical Governance Advice, *Presenting Information on Risk*.[2] They are used throughout this document.

Serious risks of abdominal hysterectomy:

- Damage to the bladder and/or the ureter (7/1000) and/or long-term disturbance to the bladder function (uncommon)
- Damage to the bowel: 4/10 000 (rare)
- Hemorrhage requiring blood transfusion, 23/1 000 (common)
- Return to theatre because of bleeding/wound dehiscence, and so on: 7/1000 (uncommon)
- Pelvic abscess/infection: 2/1000 (uncommon)
- Venous thrombosis or pulmonary embolism, 4/1000 (uncommon)
- Risk of death within 6 weeks, 32/100 000 (rare).
- The overall risk of serious complications from abdominal hysterectomy is approximately 4/100
- (common)

The main causes of death are pulmonary embolism and cardiac disease following an abdominal hysterectomy.

Serious risks of Laparoscopy include:

- The overall risk of serious complications from diagnostic laparoscopy is approximately 2/1000 (uncommon). This includes damage to the bowel, bladder, ureters, uterus or major blood vessels which would require immediate repair by laparoscopy or laparotomy (open surgery is uncommon). However, up to 15% of bowel injuries might not be diagnosed at the time of laparoscopy.
- Failure to gain entry to the abdominal cavity and to complete the intended procedure.
- Hernia at site of entry (less than 1/100; uncommon).
- Thromboembolic complications (rare or very rare).
- Death: 3–8/100 000 (very rare) undergoing laparoscopy may die as a result of complications.

As frequent risks include:

- Wound infection, pain, bruising, delayed wound healing or keloid formation
- Numbness, tingling or burning sensation around the scar (the woman should be reassured that this is usually self-limiting)
- Frequency of micturition and urinary tract infection
- Ovarian failure.

Frequent risks of laparoscopy are usually mild and self-limiting. They may include:

- bruising
- shoulder-tip pain
- wound gaping
- Infection.

Extra procedures may necessitate during the procedure, such as

- Blood transfusion
- Repair of bladder, bowel or major blood vessel
- Oophorectomy for unsuspected disease.

Oophorectomy for unexpected conditions found at hysterectomy should not be performed without consent. All women undergoing hysterectomy should be informed that unexpected disease may be found in one or both ovaries and their wishes (to remove this or leave alone) should be documented.

Women should be informed about alternative treatment modalities other than hysterectomy in DUB such as ablation and pharmacological therapies with the option of no treatment but to wait and watch. Woman must be aware of the form of anesthesia and should be given an opportunity to discuss with the anesthetist before surgery.

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