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Informed Consent Prior to Elective Gynaecological Surgery in Two Reference Hospitals in Yaoundé, Cameroon: A Mixed Methods Study

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Abstract

Introduction: Informed consent is a process that enshrines respect for patients' autonomy, their dignity, and their rights to determine what happens to their own bodies. We set out to describe the surgical informed consent process and evaluate its quality in patients undergoing elective gynaecological surgeries in two University Teaching Hospitals in Yaounde, Cameroon. **Methods:** This was a cross-sectional, prospective study over 9 month period, from October 1st, 2018, to June 30th, 2019 at the Yaounde Gynaeco-Obstetric and Paediatric Hospital (YGOPH) and the Yaounde Central Hospital (YCH). By administering a modified Brezis questionnaire 48 hours after surgery, we obtained data which enabled us to evaluate and score the informed consent process and obtained written reports of patients' appreciation of key aspects of the informed consent process prior to surgery. We then called each participant 6 months after their surgery date to obtain information on the occurrence or not of post-operative complications. **Results:** We recruited 72 patients aged 24 to 68 years old (61 at YGOPH, 11 at YCH). The operating gynaecologist sought patient consent in 65.3% (49/72) of cases, while 61.1% (44/72) of the subjects would have loved to have more information on surgical risks; 69.4% (50/72) were satisfied with the consent process; and 56.9%

(41/72) could recall and repeat the information they received prior to surgery. While 37.5% (27/72) had poor quality (non-valid consent), 40.3% had good quality consent (valid). Consent administered by the gynaecologist (OR = 0.172; 95% CI = 0.060 - 0.049) was a strong determinant of valid consent. Also, patients with non-valid consent significantly reported more complications (OR = 4.469; 95% CI = 1.412 - 14.147) than those with valid consent. **Conclusion:** Informed consent prior to elective gynaecological surgeries in our study was poor. The timing of the consent process, as well as the person involved in the process affect the validity of the consent.

Keywords

Informed Consent, Elective Gynaecological Surgery, Yaounde

1. Introduction

Hippocratic recommendations reveal a startling ethical finding, as physicians in his day could "legally" not trust their patients to make intelligent health decisions, and were thus "legally" authorised to conceal information from them [1]. Centuries later, in addressing the Nazi abuses which consisted of medical trials on non-consenting humans, the 1949 Nuremberg Code insisted on the essential nature of uncoerced consent of the human subject, placing the burden of this responsibility upon every individual who initiates, directs or engages in research involving the human subject [2]. Furthermore, in 1964 the World Medical Association (WMA) via the Declaration of Helsinki provided non-negotiable guiding principles to physicians and other participants, insisting on the duty of the physician to promote the health of the people while protecting the life, privacy and dignity of the human person in all issues involving medical research [3]. In addition, the 1960s witnessed the establishment of the legal doctrine for informed consent [4], and since then manipulating a patient without their expressed consent is considered an act of assault almost worldwide [5].

However, informed consent as a legal tool has been hugely criticised by bioethicists who indict its failure to reflect the genuine and autonomous choices of patients in the physician-patient decision-making process [6]. This distinction between legally-valid versus ethically-sound constitutes the basis for the work by Faden and Beauchamp who sought to differentiate between consent that took into consideration patient autonomy and a model based on the respect of social or institutional rules [7].

Ethically-sound informed consent is thus defined as a patient granting their caregiver uncoerced and intentional authorisation to undertake a proposed medical intervention following substantial understanding on the patient's part concerning the said procedure [8]. Beauchamp and Childress in their work identified seven essential elements that fit into this definition. These are proven patient competence, patient voluntariness, thorough disclosure of material infor-

mation to the patient, including treatment alternatives, risks and benefits, a proposed treatment plan, adequate patient understanding of this information and plan, and a patient's decision in favour of the said plan and their subsequent authorisation for treatment to commence [8].

Obtaining patients' informed consent validly is therefore not the same thing as signing a consent form [9]; rather it is a process that enshrines respect for patients' autonomy, their dignity and their rights to self-determination [10]. For this process to be considered valid, it must meet a number of conditions including information disclosure, comprehensibility of information, voluntariness, decision-making capacity (including legal competency), consenting to the treatment, and an established physician-patient relationship [11].

Despite Epstein's publication [6] aimed at counteracting the defining work of Beauchamp and Childress, it is clear that informed consent still constitutes the essence of ethical healthcare delivery, by recognizing the rights of every right-thinking human being to make decisions regarding their own body, as well as providing a legal covering for both the caregiver and their patient.

Multiple studies worldwide have been conducted evaluating the quality of informed consent in medical care [11] [12]. In much of sub-Saharan Africa, culture and belief systems cause the patient to perceive doctors as all-knowing and therefore the unquestionable determinants of what needs to be done as per their health issues [13]. In Cameroon, however, we could not find any studies on this subject. We therefore sought to evaluate the quantity and quality of information given to patients prior to elective major gynaecological surgery and determine the validity of the surgical informed consent (SIC) process in 2 University Teaching Hospitals in Yaounde, Cameroon.

2. Methods

2.1. Study Design and Setting

We carried out a prospective, cross-sectional study over 9 months, in patients undergoing major elective gynaecological surgery in 2 University Teaching Hospitals in Yaounde: the Yaounde Gynaeco-Obstetric and Paediatric Hospital (YGOPH), and the Yaounde Central Hospital (YCH). These hospitals boast 11 and 10 Obstetrician-Gynaecologists respectively and provide medical and surgical reproductive health services to over a thousand women monthly. The YCH has 2 operating rooms used for both obstetric and gynaecological procedures, while the gynaecological department of the YGOPH shares the hospital's 4 operating rooms with the other surgical specialties of the hospital. While the YCH houses the central maternity, which is the busiest in Cameroon, the YGOPH has a minimally invasive laparoscopic surgery unit as well as breast surgery services for women with benign and malignant breast disease. Both units employ over 40 nurses and/or midwives with 10 - 15 obstetrics and gynaecology residents rotating through the units, as well as over 30 - 40 medical interns per period. Depending on the timing and urgency of surgery or the availability of the obstetrician-gynaecologist, SIC is performed either in the outpatient department or in

the admission wards. Also, obtaining the signed consent of the patients was carried out either by the operating Obstetrician-Gynaecologists, Obstetrics and Gynaecology residents in the unit or nurses in the wards prior to surgery.

2.2. Inclusion Criteria

We included all patients aged 21 years or more (legal right to consent by the law in Cameroon), seen 48 hours post-operatively and who consented to the study.

2.3. Exclusion Criteria

Patients with known cognitive or consciousness impairment, those who could neither communicates in English nor in French and those who withheld consent were excluded from the study.

2.4. Sample Size Determination and Sampling

We carried out a facility-based convenience, consecutive and exhaustive sampling of all patients who met the inclusion criteria for the study from October 1st, 2018, to June 30th, 2019.

2.5. Study Procedure and Data Collection

To avoid intervening in the consent process, we interviewed our patients 48 hours post-operatively either in the gynaecological wards or the reanimation units. We further called them 6 months after surgery to obtain information on the occurrence and the nature of any post-operative complications. The principal investigator administered a tested and modified version of the validated Brezis questionnaire used by Dogan *et al.* [14]. In addition to the aspects tested by Dogan et al, we included some open-ended questions to uniquely capture patients' experiences on some aspects of their surgical experience. The questionnaire was reviewed by 2 senior faculty members in Obstetrics and Gynaecology, and a senior faculty member in legal medicine, and their suggestions were used to revise the questionnaire. Next, we tested our questionnaire on 5 patients from either hospital in September 2018. Based on their responses, the questionnaire was further revised to clarify any ambiguities. We did not include the pretested patients in our study. All unclear questions were explained to the patients.

The questions focused on patients' recall of information about surgery-related risks, alternative treatment options, preferences about the decision process and overall satisfaction from the informed consent procedure. Other questions were included to acquire demographic data, educational status and the date and nature of the procedure. Finally, we observed the hospital files of these patients to verify for the presence and content of a consent form.

2.6. Operational Definitions

In this study, we evaluated both the quality and validity of the informed consent process using a Surgical Informed Consent Score. That we created by modifying

the Brezis questionnaire [10]. However, for the purposes of this work, the validity of informed consent refers to the extent to which the process respects the legal and/or institutional parameters guiding its administration. On the other hand, the quality of informed consent refers to its ethical soundness or in other words how "informed" and/or "autonomous" the patients' decision to surgery was.

1) Valid informed consent = Informed consent score ≥ 12/22
2) Non-valid informed consent = Informed consent score ≤ 11/22
3) Good quality informed consent = Informed consent score ≥ 16/22
4) Acceptable quality informed consent = Informed consent score = 12 - 15/22
5) Poor quality informed consent = Informed consent score ≤ 11/22

2.7. Data Analysis

We obtained our data using either the English or French versions of our validated structured questionnaires. Though this questionnaire had been validated and used previously [14] [15] we pre-tested them prior to use to reassess their validity and reliability. Throughout the study period, we screened our data to rule out wrong information and ensure coherence between different fields. Double occurrences and incomplete information were constantly refined.

To measure the quality of the SIC process, we assigned a score to each of the 9 components of the SIC process evaluated in our questionnaires. This enabled us to obtain an "Informed Consent Score" per client and thus classify the patients into two groups "valid" and "non-valid" for pre-operative consenting. A positive response scored either a 3 or a 2 depending on whether there was an intermediate response (3 set response) for example "I can remember/I cannot remember/I received no information" versus "Yes/No" (2 set response); whereas all negative responses scored a 0. Therefore, for the 9 components of surgical informed consent tested and scored in our questionnaire, 4 had a 3-set response for a potential maximum score of 12 while 5 had a 2 set response for a potential maximum score of 10, giving a total score of 22 on the questionnaire. We pre-determined scores ranging from 16 and above to be of good quality (fulfilled all the 9 SIC components scored), scores ranging from 12 - 15 of acceptable quality (fulfilled the minimum requirements for valid consent with a few irregularities), while scores below or equal to 11 signalled poor-quality consent. Likewise, all patients who scored 11 and below were classified as not having granted valid consent, while all patients who had a score of 12 and above were considered to having granted valid pre-operative consent. We carried out data analysis using the SPSS version 21 software. Graphs and **Figures 1-4** were elaborated using Excel v17.

We subjected our data to descriptive statistics and evaluated our findings for normality. We used the Chi-squared and Fischer tests to compare proportions and the Students t-test for differences in means and presented the data as proportions, means and standard deviations. The Odds ratio (OR) and confidence interval were calculated to measure the association between variables. We considered as statistically significant differences with p-value < 0.05.

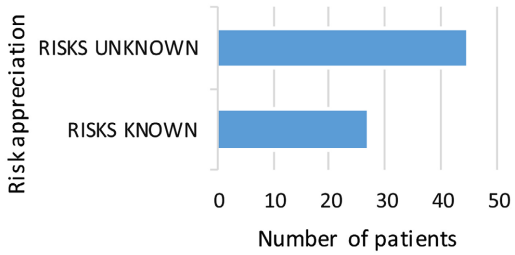

Figure 1. Distribution of patient surgical risk appreciation.

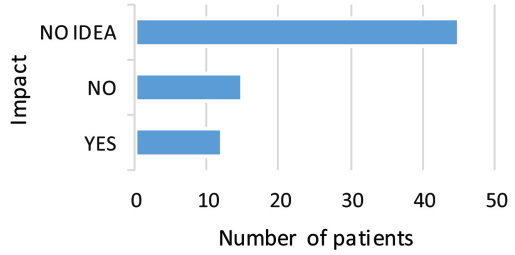

Figure 2. Distribution of risk-awareness impact.

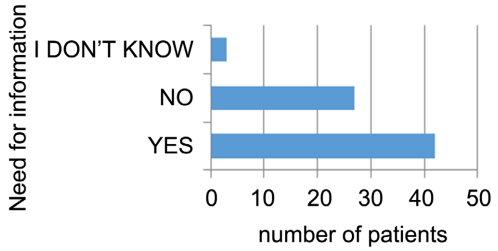

Figure 3. Distribution of client need for more information on surgical risks.

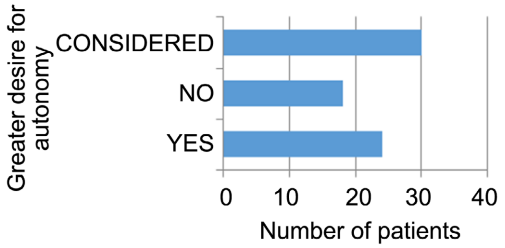

Figure 4. Distribution of patient desire for greater autonomy.

For open ended questions, we coded the responses into themes and performed a thematic analysis by identifying and analysing common ideas and patterns in the responses. We further computed these by assigning all positive items to one newly created variable representing each subtopic.

2.8. Ethical Framework

We obtained administrative permission for the study from the hospital authorities through their research offices. The ethics committee of the Faculty of Medicine and Biomedical Sciences provided ethical approval for the study as per local requirements (*Ethical Approval: N° 934/CIERSH/DM/2019*). The study re-

spected the ethical standards of the Declaration of Helsinki (World Medical Association 2004). All participants in this study provided written consent.

3. Results

In all, 85 patients met our inclusion criteria across both centres in 3 months. Of these, 4 were deceased, 2 withdrew consent and a further 7 lost to follow-up 6 months after surgery when we contacted them again to find out for post-operative complications. We therefore retained 72 participants (61 at YGOPH, 11 at YCH) for the study giving a retention rate of 84.7%.

3.1. Socio-Demographic Findings

The mean age of our participants was 41.57 years ± 10.41 years (range 24 years - 68 years). Amongst the participants, 65.3% were married, while 55.6% had either received or were currently enrolled in a tertiary level institution.

3.2. Clinical Characteristics

Surgery for uterine pathologies constituted 58.4% of all cases (27.8% hysterectomies, 30.6% myomectomies), with 36.1% undergoing cancer-related surgery. Also, mastectomies were performed in 19.4%, 11.1% underwent laparoscopic minimally invasive surgery in patients with infertility, 8.3% had adnexectomies and 2.8% had a vulvar procedure. At the 6 months post-operative encounter 23.6% of participants reported post-operative complications with 36.4% (4/11) of patients reporting complications at the YCH against 21.3% (13/61) at the YGOPH. Table 1 reveals the frequency of complications reported in each hospital.

Table 1. Frequency of post-operative complications across both hospitals.

Variables N = 17	Frequency (n)	Percentage (%)
Yaounde Central Hospital (N = 4)		
Chronic post-operative pain	1	5.9
Severe Anaemia	1	5.9
Septicaemia	1	5.9
Severe weight loss	1	5.9
Yaounde Gynaeco-Obstetric and Paediatric Hospital (N = 13)		
Chronic post-operative pain	2	11.8
Lymphoedema	2	11.8
Repeat surgery	2	11.8
Septicaemia	1	5.9
Severe weight loss	1	5.9
Surgical site sepsis	3	17.4
Wound dehiscence	2	11.8

3.3. Surgical Informed Consent Process

Table 2 details the different aspects of the consent process. There was no documentation of the surgical informed consent process at YCH, and none of the 11

Table 2. Details of the SIC process.

Variables N = 72	Frequency (n)	Percentage (%)
Person who administered consent		
Obstetrician/gynaecologist	47	65.3
Resident	12	16.6
Nurse	13	18.1
Read consent before signing		
Yes	59	81.9
No	6	8.4
Partially	7	9.7
Accompanied by		
Spouse	27	37.5
Relative/Friend	29	40.3
Nobody	16	22.2
Need for more explanation on surgical risks		
Yes	44	61.1
No	25	34.7
I am not sure	3	4.2
Comfortable asking questions		
A lot	55	76.4
A little	14	19.4
Not at all	3	4.2
Degree of satisfaction		
Satisfied	50	69.4
Somewhat satisfied	20	27.8
Not satisfied at all	2	2.8
Understanding of process tested		
Yes	52	72.2
No	18	25.0
I don't remember	2	2.8
Recall information received		
Yes	41	56.9
I can't remember	20	27.8
I didn't receive any explanation	11	15.3

patients seen there signed a consent form before surgery. Consent forms were an obligatory requirement at YGOPH, however they used single non-specific consent forms for both obstetric and gynaecological procedures, which did not document surgical risks, alternative treatments or surgical prognosis. Likewise, patient preferences, fears and decisions were not documented. The forms read:

"*I the undersigned Miss/Mrs.* _____ *ID Card Number* _____ *Address* _____ *Accept to undergo* _____ *A procedure for which I am duly informed of the nature and consequences by Dr.* _____ *I have been informed that this procedure which will be carried out under general anaesthesia/loco-regional anaesthesia/local anaesthesia will consist of*: _____ Patient signature _____ Physician signature _____ Date _____".

In our cohort, 77.8% signed consent forms (56/72), and all the patients who signed a consent form attested to have done so less than a week before surgery, with 62.5% (35/56) saying they signed the forms the night before surgery.

3.4. Quality and Validity of the SIC Process

In Table 3, we present the distribution of our study population by the validity and/or quality of the informed consent process. In line with this, 37.5% (27/72) were of poor quality, 22.2% (16/72) were of acceptable quality as they fulfilled the minimum requirements for valid consent with a few irregularities, and 40.3% (29/72) fulfilled all the 9 SIC components scored and thus of good quality.

Table 4 shows the significant positive association between past or ongoing university level studies and a valid consent process (p = 0.001) amongst our participants.

Likewise, we had statistically significant levels of valid consent amongst patients operated laparoscopically (p = 0.001) whereas patients who reported surgical complications 6 months after surgery had significant levels (p = 0.008) of poor-quality informed consent as presented in Table 5.

The distribution of the validity and quality of the surgical informed consent process as per its different aspects is detailed in Table 6. The quality of consent

Table 3. Distribution of the quality and validity of the informed-consent process.

Variables N = 72	Frequency (n)	Percentage (%)
Informed consent score (3 class distribution)		
Poor Quality	27	37.5
Acceptable	16	22.2
Good Quality	29	40.3
Informed consent score (2 class distribution)		
Non Valid Consent	27	37.5
Valid Consent	45	62.5

Table 4. Proportions of valid consent per socio-demographic variable (N = 72).

Variables	NV. Consent n = 27 n (%)	V. Consent n = 45 n (%)	Odds Ratio (CI at 95%)	p-Value
Age (years)				
[20 – 40]	7 (25.93)	25 (55.56)	0.280 (0.099 - 0.794)	0.014
[40 – 60]	14 (51.85)	20 (44.44)	1.346 (0.517 - 3.505)	0.542
[60 - 80]	6 (22.22)	0 (0.0)	*	0.001
Marital Status				
Single	7 (25.93)	14 (31.11)	0.775 (0.267 - 2.253)	0.639
Married	20 (74.07)	27 (55.56)	1.905 (0.668 - 5.428)	0.225
Widow	0 (0.0)	4 (8.89)	*	0.111
Educational Status				
Primary	10 (37.04)	4 (8.89)	*	0.003
Secondary	9 (33.33)	9 (20.0)	2.000 (0.677 - 5.909)	0.206
University	8 (29.63)	32 (71.11)	0.171 (0.060 - 0.488)	0.001
Employment Status				
Worker	15 (55.56)	35 (77.78)	0.357 (0.127 - 1.005)	0.480
Unemployed	8 (29.63)	8 (17.78)	*	0.242
Retired	3 (11.11)	1 (2.22)	5.500 (0.542 - 55.808)	0.111
Student	1 (3.70)	1 (2.22)	1.692 (0.101 - 28.219)	0.711

Table 5. Proportions of valid consent per surgery type and patients' clinical characteristics (N = 72).

Variables	NV. Consent n = 27 n (%)	V. Consent n = 45 n (%)	Odds Ratio (CI at 95%)	p-Value
Cancer related surgery				
Yes	10 (37.04)	16 (35.56)	1.066 (0.396 - 2.873)	0.899
No	17 (62.96)	29 (64.44)	*	*
Type of Surgery				
Adnexectomy	5 (18.52)	1 (2.22)	10.000 (1.100 - 90.901)	0.015
Hysterectomy	12 (44.44)	8 (17.78)	3.700 (1.260 - 10.864)	0.014
Mastectomy	2 (7.41)	12 (26.67)	0.220 (0.045 - 1.073)	0.046
Laparoscopy	0 (0.0)	8 (17.78)	*	0.001
Myomectomy	7 (25.93)	15 (33.33)	0.700 (0.242 - 2.022)	0.509
Others	1 (3.70)	1 (2.22)	1.692 (0.101 - 28.219)	0.711
Complications				
Yes	11 (40.74)	6 (13.33)	4.469 (1.412 - 14.147)	0.008
No	16 (59.26)	39 (86.67)	*	*

Table 6. Distribution of the validity of consent per aspect of the SIC process (N = 72).

Variables	NV. Consent n = 27 n (%)	V. Consent n = 45 n (%)	Odds Ratio (CI at 95%)	p-Value
Person who brought the consent				
Obstetrician/ Gynaecologist	11 (40.74)	36 (80.0)	*	0.001
Resident	5 (18.52)	7 (15.56)	1.234 (0.349 - 4.358)	0.744
Others	11 (40.74)	2 (4.44)	14.781 (2.948 - 74.115)	<0.001
Read consent before signing				
Yes	16 (59.26)	43 (95.56)	*	<0.001
No	5 (18.52)	1 (2.22)	10.000 (1.100 - 90.901)	0.015
Partially	6 (22.22)	1 (2.22)	12.571 (1.421 - 21.119)	0.006
Accompanying person				
Spouse	1 (3.70)	26 (57.78)	0.028 (0.004 - 0.226)	<0.001
Relative/Friend	13 (48.15)	16 (35.56)	1.683 (0.638 - 4.443)	0.292
Nobody	13 (48.15)	3 (6.67)	*	<0.001
More explanation of these risks				
Yes	17 (62.96)	27 (60.0)	1.133 (0.424 - 3.028)	0.803
No	9 (33.33)	16 (35.56)	0.906 (0.331 - 2.479)	0.848
I am not sure	1 (3.70)	2 (4.44)	*	0.879
Comfortable asking questions				
A lot	18 (66.67)	37 (82.22)	0.432 (0.143 - 1.308)	0.132
A little	6 (22.22)	8 (17.78)	1.321 (0.404 - 4.327)	0.645
Not at all	3 (11.11)	0 (0.0)	*	0.022
Degree of satisfaction on Consent				
Satisfied	14 (51.85)	36 (80.0)	0.268 (0.094 - 0.770)	0.012
Somewhat satisfied	11 (40.74)	9 (20.0)	2.750 (0.953 - 7.935)	0.057
Not satisfied at all	2 (7.41)	0 (0.0)	*	0.064
Recall information received				
Yes	9 (33.33)	32 (71.11)	0.203 (0.073 - 0.568)	0.002
I can't remember	7 (25.93)	13 (28.89)	*	0.786
I didn't receive any explanation	11 (40.74)	0 (0.0)	13.000 (3.227 - 52.376)	<0.001

was positively associated with the patients' obstetrician-gynaecologist administering consent ($p = 0.001$), or consent administered in the presence of their spouse ($p < 0.001$) and with those who read the consent form fully before sign-

ing it ($p < 0.001$). On the other hand, poor quality consent was significantly associated to consent being administered by non-medical staff ($p < 0.001$), patients undergoing the consent process unaccompanied ($p < 0.001$) and patients who said they did not recall whatsoever or who received no information regarding their surgery ($p < 0.001$).

3.5. Thematic Findings

We absolutely wanted to obtain patients' perspective of the informed consent process, especially their appreciation of surgery-related risks. This explains we provided open-ended questions for this aspect of care. Our results were as follows:

3.5.1. Talk to Us about Any Risks You Remember as Concerns Your Surgery

"No known risks" was the theme that grouped most of the responses given, as the majority revealed they will have preferred to be informed on these risks. Some patients however expressed that it was best not to know. Amongst the responses received we noted:

"*I don't know any because I was not informed that there were risks. I was led to think I could only have problems if I did not undergo surgery*" said a 44 years old patient post-hysterectomy. "*I do not know any. But I guess it is best that way because it would have potentially put fear in me if I knew any risks*" was gotten from a 37 years old patient following myomectomy for symptomatic fibroids.

3.5.2. Did Any Risks Prompt You to Consider Refusing Surgery?

For the patients who received information on surgical risks, similar proportions expressed the idea that they were willing to pursue surgery despite being informed on risks, as those that were tempted to turn down surgery. No patient operated upon for a cancer-related indication considered not having surgery. Recorded responses included amongst others.

"*I never considered turning down surgery although I was afraid, I just wanted the cancer out even if I knew there could be complications*" (52 years old patient operated for cervical cancer).

"*Accepting to undergo a myomectomy was challenging enough for me because of fear of the unknown. Further information on the risks made me refuse surgery for close to six months because I was scared to lose my uterus as I really want to have my own children*" (39 years old patient, uterine fibroids).

3.5.3. Would You Have Wanted More Information on These Risks?

Most of our participants had an affirmative response when asked if they needed more information on surgical risks. A minority however expressed the idea there was no need because the doctor knew best and/or they trusted their doctors completely. They said:

"*Yes, I believe I need to know exactly what I am agreeing to because it is my body we are talking about, so I too have a say*", (35 years old patient, laparo-

scopic adhesiolysis).

"*Yes, I did not know he will take out the whole breast. I do not think my husband will still love me. After losing my breast, it feels so much as if I have lost my womanhood*", (42 years old, breast cancer).

3.5.4. Would You Have Wanted to Be More Involved in the Treatment Decision?

While most of patients seemed to indicate that their opinions were taken into consideration prior to surgery, a desire for greater autonomy was a frequently evoked amongst the participants:

"*By virtue of my age, I was supposed to undergo a hysterectomy. But for me, I needed that hope that just maybe one day I might bear my own children. So, I insisted on a myomectomy and obtained just that*", (50 years old patient, post-myomectomy for/infertility).

"*I would have wanted my decision to count too because it is my body we are talking about here. I did not want this surgery. I almost feel as if he operated me to please my husband*"; (44 years old, post-total abdominal hysterectomy for uterine fibroids).

4. Discussion

We conducted a cross-sectional study to evaluate the Surgical Informed Consent process and determine the quality and/or validity of consent in patients undergoing elective major gynaecological surgery.

4.1. The SIC Process

As regards the contents of the consent forms in the YGOPH, there was no documented mention of surgical risks, potential complications, patient preferences and/or treatment alternatives where applicable, neither is there documented evidence of the patients' decision. Moreover, the available consent forms were not procedure specific. The absence of key components of ethically valid consent at the YGOPH not only strip the process of legal validity, but also lend substance to Beauchamp and Faden's second type of consent privileging institutional demands above true autonomous authorisation [7]. Yet many authors agree there exists a dilemma as to the scope and detail of information surgeons are expected to provide their patient [16]. Similarly, at the YCH, in addition to the complete absence of consent forms, there was no documentation of the informed consent process in all the patients' records. While consent is not only valid if written, this reveals a cultural reality whereby in our setting, patients still predominantly rely on their physician to make the health decisions almost exclusively, confirming that cultural differences manifest themselves in the practice of informed consent [16].

Various authors have revealed similar deficiencies worldwide. Lühnen *et al.* in their systematic review found out that there were huge gaps in the contents of the consent forms used both in and out of Germany and this especially in the

communication of risks [17]. Likewise in a setting similar to ours Teshome *et al.* [18] described the similar deficiencies in a teaching hospital in South Ethiopia, as well as Ashraf *et al.* who described sub-optimal implementation of Surgical Informed Consent in routine surgical practice in Pakistan [19]. These irregularities contrast findings by Abed *et al.* in New Mexico, USA [20] who describing a setting with high levels of litigation revealed that surgeons there were prone to provide details on surgical risks and treatment alternatives.

Next, in our cohort the patients' surgeon sought consent 65.3% of the time across both hospitals, while 62.5% of patients signed the consent form the night before surgery. The burden of responsibility falls on the practitioner, we could question the ethical and legal validity of consent in 34.7% of patients in whom consent was sought by either a resident in training or a nurse in the wards rather than the principal surgeon of the patients. Moreover, consent especially in the case of elective surgery could only be ethically valid if the patient's decision was voluntary, and this supposes sufficient time to think and decide. With most of our patients signing consent the night before, it questions the voluntary nature of their decision giving the impression of a decision obtained under duress.

In a similar setting to ours, Teshome *et al.* in South Ethiopia [18] reported that 70.4% of their patients signed consent immediately prior to surgery. This slightly higher value could be explained by the fact that they had a larger cohort of patients, and their study involved both emergency and elective surgeries, with slightly better statistics for patients operated electively. While Abolfotouh *et al.* [21] reported similar proportions of physicians at 60.5% seeking patient consent prior to invasive procedures in a tertiary care centre across multiple specialties in Saudi Arabia, Ochieng *et al.* in Uganda [22] in detailing best practices across 3 university teaching hospitals said only 48.8% of over 130 doctors across surgical specialties attested to routinely obtaining informed consent before surgery as most of the time consent was seemingly obtained by an individual other than the patient's physician again revealing significant gaps worldwide in the informed consent process.

Most of our patients (81.9%) said that they read the consent forms prior to signing them. While the majority (76.4%) said they were comfortable asking questions during the physician-patient interaction, 2.8% were out rightly dissatisfied with the SIC process. While this is similar to findings by Dogan *et al.* and Brezis *et al.* [14] [15], it somehow contradicts the fact that more than half (61%) would have wanted more explanations on surgical risks and as much as 52% of patients expressed the desire for greater autonomy in the decision-making process. These deficiencies could be explained by physician paternalism as patients have been conditioned socio-culturally in our setting to believe in the supreme and unquestionable authority of the doctor. It could also be explained by the fact that litigation rates remain very low in our setting, a fact which could comfort surgeons in their unwillingness to improve the informed consent process.

Data obtained from the open-ended questions reveals that contrary to assertions by many physicians, a significant number of patients are not deterred from

pursuing surgery by being informed adequately on surgical risks. These findings voiced through disappointed patients further confirm the finding that the reported highest source of patient dissatisfaction is patient perception of having received insufficient medical information about their treatment options and outcomes [23]. Ankuda *et al.* in the USA reported that only 13% of their patients exhibited deficiencies in knowledge on surgical risks and alternative treatment option [24] probably due to stricter legal dispositions and the ever existing risks of patients filing lawsuits in the USA.

Additionally, 43% of our patients could not repeat the explanations they had received when asked if they could repeat the explanations, they had received regarding their surgery either because they could not recall or had simply not received any information with 1 out of every 4 patients saying their physician did not verify if they understood the information received during the informed consent process.

Petrić *et al.* described a similar recall rate in a cohort of 100 women undergoing elective surgery [25], while Abed *et al.* similarly revealed that the surgeons they interviewed in New Mexico, USA rarely tested patients' understanding of the information received [20]. These findings could be explained by both physician paternalism as well as the fact that many patients in our setting are still naïve as per their health rights. Also, the somehow high information recall rate in our cohort (56.9%; 41/72) could be explained by the high levels of literacy in our patients with as many as 55.6% of our patients benefitting of tertiary level education. Multiple sources have associated literacy with better understanding and recall rates [11] [15] [26].

4.2. Quality and Validity of SIC

Our modification of the Brezis questionnaire enabled us to implement a scoring system towards establishing the validity and/or quality of the SIC process. With only 40.3% of our participants registering valid good quality consent, we could state that there is an urgent need to reinforce physicians' understanding and administration of informed consent in caregiving. We could equally infer that the patients' overwhelming acceptance of having granted consent in our cohort, did not necessarily reflect their informed and autonomous decisions.

We have similar findings to Abolfotouh *et al.* [21] who despite a difference in methodology, by using a similar tool found out that the percent mean score of quality of the informed consent was 50.97% ± 17.49%, denoting overall poor quality amongst their participants. Hosein *et al.* [26] in their survey of hospitalized Iranian patients also reported undesirably low levels of valid consent, and concluding that consent did not reflect the informed choices of the patients.

Probably because of higher understanding and better recall rates, the SIC process achieved better scores amongst our patients with University level education, compared to our patients with elementary education. Also, by surgery the fact that all 8 patients operated laparoscopically had good quality consent, with the highest scores on the modified Brezis questionnaire could be explained by

the fact that the sole surgeon with laparoscopic skills doubles as a professor of clinical medicine who had by experience and learning achieved a good mastery of the informed consent process, and above all he obtained patient consent to surgery himself.

In addition to educational status, information recall levels were found to have a good correlation with the validity and/or quality of consent obtained. Thus, all the patients who claimed they received no explanation about their surgery process had poor quality consent, as against about 3 in 4 valid consent procedures amongst patients who claimed they had received and understood explanations as concerns their surgery. Moreover, almost all who had valid consent attest to having completely read through the consent form, again granting credit to the role of better information. Dogan *et al.*, and Brezis *et al.* reported similar findings [14] [15].

Other prognostic factors for valid consent included consent administered directly by the patients' surgeon as against resident physicians or nurses). Leclercq *et al.* [27] also found out that Dutch surgery residents were less competent in administering informed consent compared to their consultants. A finding further corroborated by Hosein *et al.* [26]. In our study, we found that being accompanied by a spouse probably because of the comfort of having support and reassurance was more favourable for the validity of consent with almost all of the women accompanied by their spouses achieving either good or acceptable quality consent. Interestingly, patients with non-valid consent reported significantly higher rates of complications 6 months after surgery. This is most likely due to the inadequacies of information exchange between them and their caregivers, leading to probable unrealistic surgical expectations.

Overall, our values for non-valid consent are lower than those found by Teshome *et al.* in Southern Ethiopia [18] who findings revealed that as much as 45.8% of their cohort did not fulfil 6 of the 13 SIC components investigated by them. This could be because they worked with a larger cohort than ours (a total of 230 patients), but also because their study involved both elective and emergency surgeries with most of their patients undergoing emergency surgery. Our findings equally corroborate those by Petrić *et al.* [25] who concluded by saying that "handing a written document to a patient, without appropriate communication, is of itself worthless".

5. Limitations

Our study presented some limitations. First, we carried out our study in two tertiary health facilities. Because of the increased cost of care there, we were probably having access to patients who averagely are socio-economically more viable than the average Cameroonian patient. However, because we wanted to capture a good mix of patients with diverse major gynaecological surgical indications, we could only work in hospitals with the right human resource providing these services. Next, there was a bias in trying to evaluate patient recall especially as we did not examine to what extent the treating physician had attempted to convey

information since we did not take part, neither did we observe the surgical informed consent process for fear of influencing it. We attempted to mitigate this by interviewing patients in the immediate post-operative period at what point we assumed that recall of surgical information was still optimal. Furthermore, our sample size was small and could have been maximised by extending the study period. However, the study period was limited as it was carried out as part of an end of training dissertation. Interestingly, the open-ended questions showed saturation on multiple themes and therefore comforted the scientific team that their findings were quite revealing of the sentiments of patients undergoing major gynaecological surgery in these settings. Finally, we carried out an institution-based study meaning we cannot generalise the findings of our study to the overall surgical environment in Cameroon.

6. Conclusion

Based on our findings, we concluded the need to improve the pre-operative informed consent process, which presents huge deficiencies and is not governed by any standard protocols in our setting. Also, patients' understanding and recall of information are significant determinants of patients' ability to make informed decisions.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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Annexes

Modified brezis questionnaire

a) Socio-demographic data			
Patient code			
Age			
Address			
Marital status			
Educational level			
Employment status			
b) Informed-consent Questions (Modified Dr. Brezis Questionnaire)			
1) Nature of the surgery (Pre-operative diagnosis + Surgical procedure)	Known name (3)	Known nature (1)	Unknown (0)
2) Evaluation of the consent form in the patient's file by the principal investigator (content and signature)	Present signed (3)	Present unsigned (1)	Absent
3) Did you have enough time to think, seek advice and consult others before signing the form	Yes, well in advance (2)	No, or on the day of surgery (0)	
4) Who brought the form to you and asked you to sign it	Treating Ob/Gyn	Resident in Ob/Gyn	Other hospital staff (nurse, anaesthesiologist)
5) Did you read the consent form before signing it?	Yes	Partially	No
6) Why did you not read the consent form? (open-ended)			
7) Who accompanied you when you signed the consent form?	Spouse	Relative or Friend	Nobody
8) To what degree was the information you received about your procedure sufficient, clear and detailed?	It was sufficient, clear and detailed (3).	It was not sufficient, clear, and detailed (1).	I am not sure, or I received no explanation (0).
9) Did you receive an Explanation of the treatment risks?	Yes (2)	No (0)	
10) List any risks you remember as regards your surgery (qualitative)			
11) Did any risks prompt you to consider refusing surgery? (qualitative)			
12) Would you have wanted more explanation of these risks?	No	I am not sure	Yes
13) Did you receive an explanation about alternative options for this treatment? For example, were you told about other forms of therapy available	Yes (2)	No (0)	
14) From whom did you receive most of the explanations?	Consultant (treating) Ob/Gyn	Resident Ob/Gyn or Other hospital staff	I did not receive explanations

Continued

15) To what degree did you feel comfortable asking questions?	A lot	A little	Not at all
16) Who do you think made the final decision about the treatment?	Patient (2)	Patient and treating physician together (1)	Physician (0)
17) Would you have wanted to be more involved in the treatment decision? (qualitative)			
18) To what degree are you satisfied with the process of deciding on the treatment?	Satisfied	Somewhat satisfied	Not satisfied at all
19) Were you asked whether you understood the explanation?	Yes	I do not remember	No
20) Could you repeat the explanation now?	Yes	I cannot remember	Somewhat I did not receive any explanation
21) Do you know any expected benefits from your surgery?	Known (2)	Unknown (0)	
22) List these benefits (qualitative)			
23) Will there have been consequences if you refused surgery?	Known (2)	Unknown (0)	
24) List these consequences (qualitative)			