Original Article

Efficacy of a separate informed consent for anesthesia services: A prospective study from the Caribbean

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Abstract

Background and Aims: This study aimed to determine whether a separate written consent form improved the efficacy of the informed consent process for anesthesia in adult patients undergoing elective surgery at a tertiary care teaching hospital.

Material and Methods: We randomized patients into two groups prospectively. The first group (Group A) signed the hospital's standard "Consent for Operation" form only while the second group (Group B) signed a separate "Consent for Anesthesia" form additionally. Patients were interviewed postoperatively with an eight-item questionnaire with responses in a 5-point Likert scale. A composite "adequacy of consent index" was generated from the responses and analyzed.

Results: Two hundred patients (100 in each group) were studied. All patients indicated that the anesthesiologist(s) had their permission to proceed with their anesthesia care. The mean "adequacy of consent index score" in Group B was higher than that of Group A (30.6 ± 4.6 [standard deviation (SD)] vs. 27.9 ± 5.2 [SD]) ($P < 0.001$). The separate written consent had a positive impact on the patients' understanding of the nature and purpose of the intended anesthesia procedures ($P = 0.04$), satisfaction with the adequacy of information provided about common side effects ($P < 0.001$) and rare but serious complications ($P = 0.008$).

Conclusions: A separate written consent for anesthesia improved the efficacy of the informed consent process with respect to better information about the nature and purpose of anesthesia, common side effects, and rare but serious complications.

Key words: Anesthesia, informed consent, separate consent

Introduction

Informed consent is "a process of communication between a patient and physician that results in the patient's authorization or agreement to undergo a specific medical intervention."[1] For the clinician, this process is both an ethical obligation as well as a legal requirement.[2] There are three key elements of an appropriate informed consent process:[2]

The patient (or the surrogate) should have the capacity to decide; sufficient information should be provided on which to base that decision, and the decision reached should be free from coercion.

Professional guidelines in the specialty of anesthesia require that express informed consent should be obtained for any procedure that carries a material risk (a risk which a reasonable person in the patient's position would be likely to attach significance).[3,4] A Working Party of the Association of Anaesthetists of Great Britain and Ireland (AAGBI), revisited the issue of consent and anesthesia in 2006 and reiterated, among other things, that express verbal consent is sufficient for anesthesia provided that the anesthetist documents both the patient's decision as well as the discussions which led to the decision.[5] They emphasized that the process of informed consent was more important than a "signed form," which in itself may not increase the validity of the consent.

The role and usefulness of separate consent forms for anesthesia continue to be a subject of debate.[6] Proponents

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of separate written consent argue that from a liability standpoint a well-thought-out anesthesia-specific consent form is the method of documentation that offers the best level of protection in cases of malpractice litigation.[7] Apart from its value as documentary evidence, in theory, the presentation of a consent form may act as a stimulus for an active discussion of risks, thereby facilitating patient's unique and legitimate concerns.[8] A well-written consent document may also serve as a reminder to the anesthetist of the issues which need to be addressed to obtain an acceptable informed consent. Notably, a review of the medical literature does not identify any study which investigates the hypothesis that a requirement for signed consent for anesthesia may serve as a catalyst for an enhanced informed consent process.

The documentation of consent for anesthesia in majority of hospitals of Trinidad, relies on a simple clause in the surgical consent document which states that the patient consents to the operation "and to such general or other anesthetic and such further or alternative procedures as may be necessary." Similar documents are used in at least one major Jamaican Hospital.[9] These "consent for operation" documents are administered by a member of the surgical team (usually a house officer) and are often signed prior to any contact with the anesthetist. A discussion between the patient and their anesthetist regarding their anesthesia care may subsequently occur to varying degrees during the preoperative anesthetic visit but a record of this discussion is rarely made except in high-risk cases or sometimes where regional anesthesia is proposed. The reliance on a "catch-all" phrase regarding anesthesia on the surgical consent document places no apparent legal or institutional obligation on the anesthetist in this setting to engage in a proper informed consent discussion with the patient and it is a reasonable inference that if the anesthetist was required to obtain separate signed consent it would increase the likelihood that this discussion does occur and would also be documented adequately.

With this background, this study sought to compare the efficacy of a separate informed consent process for anesthesia services at our tertiary care teaching hospital and the factors which may influence the consent process.

Material and Methods

This prospective study was conducted on the pre- and postoperative wards of a tertiary care teaching hospital during a 3 month-period. Approval to conduct this study was received from the Ethics Committee of the University and from the Medical Director of the Hospital.

Adult patients undergoing elective surgery during the study period who consented to participate were eligible for inclusion in the study. Patients were excluded if:

- They were anesthetized/consented by the investigator.
- They were unable to communicate comfortably during the postoperative period for any reason (e.g., respiratory distress, confusion/disorientation, tracheal intubation etc.).
- They declined to participate.

All the subjects enrolled in the study were informed of the following:

- The nature and purpose of the study.
- That no identifying data would be recorded, and no communication would take place between the investigator and the attending anesthetist or surgeon with regards to the interview.
- That their care would be unaffected whether they agreed to participate or not.

Informed consent was obtained from patients to participate in the study. The subjects were allocated into two groups: Group A and Group B randomly by computer allocation. Group A included all patients who were required to sign the hospital's "Consent for Operation" form only as was the standard practice. Group B comprised of all patients who were required to sign a separate "Consent for Anesthesia" form [Appendix 1] in addition to the "Consent for Operation" form. The "Consent for Anesthesia" form was administered and countersigned by the attending anesthetist during the preoperative anesthetic visit. The anesthetists who participated in the study, anesthetized patients in both groups; the only difference being the separate consent form.

All the participating subjects were approached by the investigator during the postoperative period at the earliest time at which they were comfortable enough to participate, but not later than 4th postoperative day. The majority of the interviews lasted for <10 min. The type of anesthesia and the grade of the anesthetist obtaining consent were determined from the anesthetic record.

Questionnaire

A questionnaire was designed *de novo* for the purpose of this study. Demographic data recorded were age, gender, and level of education (classified as primary and below, secondary, and tertiary or above). Other case-specific data obtained were type of anesthesia, grade of anesthetist taking consent, and whether a "Consent for Anesthesia" form was signed.

Appendix 1

Consent form for anesthesia services

General Anesthesia	Spinal/Epidural Anesthesia/ Analgesia ± sedation	Peripheral Nerve Blockade ± sedation	Monitored Anesthesia Care/Sedation	Other
				.....
				.....

With respect to the proposed operation/procedure of _____, I _____ _____ hereby consent to the anesthesia service(s) checked above, to be provided to _____ (myself/my _____), the purpose, nature and risks of which have been explained to me by

Dr _____.

I also consent to such further procedures (e.g. invasive monitoring, blood transfusion, unplanned general anesthesia) as may be deemed necessary by my anesthetist during the course of my operation/procedure, except _____.

I acknowledge that I have been given the opportunity to ask questions.

Date: _____

Signed: _____ (Patient/Relative)

Witnessed by: _____ (Anesthetist obtaining consent)

The following eight elements of the informed consent process considered to be desirable by the Working Party of the AAGBI in their 2006 publication entitled "Consent and Anesthesia"[5] were investigated:

1. Permission.
2. Absence of coercion.
3. An appreciation of the nature and purpose of the proposed anesthetic procedures.
4. Patients satisfaction with information provided on common side effects of the proposed anesthetic procedures.
5. Patients satisfaction with information provided on rare but serious complications of the proposed anesthetic procedures.
6. Discussion of alternatives.
7. Provision of information about postoperative care and pain control.
8. Opportunity to ask questions.

Each of the above elements was listed as a statement on the questionnaire with each patient being asked to state their agreement with the statement on a 5-point Likert scale ranging from strongly disagree to strongly agree. A cumulative score for each patient's responses was calculated, with a maximum possible score of 40 and a minimum possible score of 5. This score was termed the "adequacy of consent index."

Statistical analysis

Data collected were coded and entered in Microsoft Excel™. Analysis was done using Statistical package for Social Sciences (SPSS) version-12 (SPSS Inc., Chicago, Illinois, USA). Mann-Whitney U-test was used to compare the adequacy of consent index between patient Groups A and B, as well as gender, level of education, or grade of anesthetist administering the consent process. Chi-square analysis was used to detect differences in responses between Group A and Group B for each of the eight individual informed consent issues addressed. The statistical significance was set at the level of $P < 0.05$.

Results

Seventy-eight males (39%) and 122 females (61%) consented to participate in the study. One hundred and sixty-five patients (82.5%) received general anesthesia, 29 (14.5%) had central neuraxial blocks, and 6 (3%) had peripheral nerve blocks. Overall patient age ranged from 18 to 87 with a mean of 44. The majority of the subjects had attended secondary school (55%), 29% achieved a level of education of primary and below and 16% achieved a tertiary level education. The grades of anesthetists involved in the consent process were House Officers in 72% of cases, Registrars in 21.5% and Consultants in 6.5%.

One hundred patients belonged to Group A having signed the hospital's "Consent for Operation" form only, as was the standard practice. Another hundred patients were included in Group B, who signed a separate "Consent for Anesthesia" form in addition to the "Consent for Operation" form. Demographics did not differ significantly between the two groups as shown in Table 1.

All patients (100%) indicated that their anesthetist(s) had their permission to proceed with their anesthesia care. Overall 97.5% indicated that they did not feel pressured or rushed into giving permission (99% in Group A; 96% in Group B). 84% of the Group A patients and 93% of the Group B patients agreed that they understood the nature and purpose of the intended anesthesia procedures. Notably, 60% of the Group A patients did not feel that they were adequately informed about common side effects compared to 27% of Group B patients. With respect to rare but serious side effects, 73% of Group A patients and 54% of Group B patients felt that information provided was inadequate. A summary of the responses to the eight-item questionnaire is given in Table 2.

The adequacy of consent index scores in Group A ranged from 16 to 39, with a mean of 27.9, standard deviation (SD) 5.2. In Group B, the adequacy of consent index score ranged from 17 to 38, with a mean of 30.6 (SD) 4.6. Mann–Whitney U-test showed a statistically significant improvement in adequacy of consent index scores when separate written consent for anesthesia was obtained ($P < 0.001$).

Table 1: Summary of population and group demographics

Variable	Group A common consent	Group B separate consent	Overall (%)
Age			
Mean	45.0	43.2	44.1
IQR	30.5-57.0	31.0-55.8	31.0-56.0
Male *n* (%)	38	40	78 (39)
Female *n* (%)	62	60	122 (61)
Educational level			
Primary or below	28	30	58 (29)
Secondary	55	55	110 (55)
Tertiary and above	17	15	32 (16)

IQR = Interquartile range

The comparison of the adequacy of consent index scores within the Group B patients with respect to gender, level of education and grade of anesthetist did not show any significant difference among subjects according to gender or level of education. The mean adequacy of consent index was higher among patients who were consented by a Registrar or SMO (32.2) compared to a House officer (30), but the *P* value was 0.05 (borderline at the set level of significance).

Chi-square analysis identified only three aspects of the informed consent process which were positively affected by the use of separate written consent for anesthesia. These were patients' perception of the adequacy of information provided about commonly occurring or expected side effects ($P < 0.001$), information about rare but serious complications of the proposed anesthetic procedures ($P = 0.008$) and the patients' understanding of the nature and purpose of the intended anesthetic procedures ($P = 0.04$). The results are summarized in Table 3.

There was almost total agreement among both groups that permission was given without undue pressure and that they had sufficient opportunity to ask questions.

Discussion

The primary finding of this study is that in our public hospital setting, the informed consent process may be better

Table 2: Responses to statements regarding the informed consent process

Issue in consent for anesthesia	Consent	Strongly disagree	Somewhat disagree	Neither agree nor disagree	Somewhat agree	Strongly agree
My anesthetist(s) had my permission to proceed with the anesthesia care that I received	Separate	0	0	0	0	100
	Common	0	0	0	0	100
I did not feel pressured or rushed into giving permission for my anesthesia care	Separate	0	4	0	4	92
	Common	1	0	0	5	94
I understood what procedures my anesthetist intended to do and why he/she intended to do them	Separate	1	6	0	48	45
	Common	2	13	1	41	43
I felt that I was adequately informed about commonly occurring or "expected" side effects of the proposed anesthetic procedures	Separate	20	7	0	35	38
	Common	42	15	3	25	15
I felt that I was adequately informed about rare but serious complications of the proposed anesthetic procedures	Separate	34	20	1	26	19
	Common	53	20	1	16	10
The possibility of alternative anesthetic techniques was discussed with me	Separate	62	5	0	5	28
	Common	72	2	0	10	16
Information was provided about what to expect after my operation including how my pain would be controlled	Separate	23	26	0	40	11
	Common	38	22	1	26	13
Sufficient opportunity was given to me to ask questions concerning my anesthesia care	Separate	2	1	1	2	94
	Common	2	0	0	19	79

Table 3: Comparison of issues

Issues in informed consent	Consent form	Agree	Did not agree	*P**
My anesthetist(s) had my permission to proceed with the anesthesia care that I received	Separate	100	0	NA
	Common	100	0	
I did not feel pressured or rushed into giving permission for my anesthesia care	Separate	96	4	*P*=0.37
	Common	99	1	
I understood what procedures my anesthetist intended to do and why he/she intended to do them	Separate	93	7	*P*=0.04
	Common	84	16	
I felt that I was adequately informed about commonly occurring or "expected" side effects of the proposed anesthetic procedures	Separate	73	27	*P*<0.001
	Common	40	60	
I felt that I was adequately informed about rare but serious complications of the proposed anesthetic procedures	Separate	45	55	*P*=0.008
	Common	26	74	
The possibility of alternative anesthetic techniques was discussed with me	Separate	33	67	*P*=0.35
	Common	26	74	
Information was provided about what to expect after my operation including how my pain would be controlled	Separate	51	49	*P*=0.12
	Common	39	61	
Sufficient opportunity was given to me to ask questions concerning my anesthesia care	Separate	96	4	*P*=0.68
	Common	98	2	

**Statistical significance by Chi-square analysis, NA = Not available*

when a separate written consent was obtained for anesthesia as estimated by the adequacy of consent index.

Anesthesia procedures are clearly different from surgical procedures in their nature, purpose, and risk profiles. It is therefore logical that if informed consent for anesthesia procedures is obtained independently, and further, if it is obtained by a clinician (anesthetist) capable of formulating and discussing the anesthesia care plan (vis-à-vis its' risks, benefits, and alternatives), the patient is likely to have a better information.[10]

The use and usefulness of consent forms have been contentious issues. The AAGBI has advised that a signed consent form is not necessary for anesthesia procedures because it felt that emphasis should be placed on the process of informed consent rather than on obtaining a signature on a form.[11] In addition, several studies have shown that "consent forms" are often too complex for the average patient to read and understand and, in fact, many patients sign consent forms without reading or understanding them.[11,12] Another criticism is that many consent forms appear to be constructed to protect hospitals and caregivers from liability rather than clarify information about procedures or aid patients in decision-making.[13] These authors have suggested that the legal appearance and content of these consent forms are likely to inhibit, if not counteract, the goals of informed consent by adding to the perception that institutional protection takes precedence over patient care.[13]

Despite these myriad concerns which question the value of consent forms, this study has demonstrated that the use of a consent form for anesthesia improved the adequacy of the informed consent process. It is quite likely that in this setting (where the institutional obligation for consent to anesthesia is fulfilled by a signature on the surgical consent document) a requirement to obtain separate written consent serves as an essential stimulus for a discussion between the anesthetist and the patient about the anesthesia care plan. This idea that a consent form may aid the consent process by acting as a prompt or a stimulus to an active discussion about treatment options has been supported by several authors.[14,15] Apart from the possible role as a catalyst to the process, the form itself may serve as a reminder or a checklist of the elements of the informed consent process which need to be addressed.[13,15]

Another probable reason why the use of separate written consent helped rather than hindered the informed consent process in this study may be that the "Consent for Anesthesia" form was kept very simple, excluding details about the anesthetic techniques and risks that may have made the form difficult to understand. The onus therefore remained on the anesthetist to provide the patient with the information necessary for the consent to be informed. This approach of not providing detailed information on the form itself reduces the chances of the anesthetist just giving the patient the form to read and sign and thereby using the form as a substitute for the process. The fact that the anesthetist necessarily remained the source of the information would have also hypothetically allowed the information to be tailored to the education level of the patient. This may explain why no statistically significant relationship was found between educational level and adequacy of consent.

Notwithstanding the fact that the use of separate written consent enhanced the overall adequacy of the informed consent process, several areas were identified where improvements are still needed. As much as 55% of patients who signed the

anesthetic consent form did not think that they were adequately informed about rare but serious complications of the proposed anesthetic procedures. Several other studies have detected similar inadequacies in risk disclosure.[16-18]

One justification used in the past for the withholding of information is the notion that patient apprehension caused by "frightening" information results in raised catecholamine levels which make it more difficult to anesthetize the patient.[19]

Stanley *et al*. demonstrated that patients' anxiety levels were unaltered by the provision of additional detailed verbal and/or written information.[20] Shimoda *et al*. went a step further and showed that patients who had anxiety about anesthesia before an operation indicated a greater need for detailed printed information compared with those without anxiety.[21] Furthermore, several other studies investigating patients' desire for information perioperatively have found that, in general, there is a desire for more rather than less information.[22-24] Some practitioners may withhold information because they feel that it may deter a patient from undergoing a beneficial procedure. The AAGBI in their 2006 publication titled "Consent and Anesthesia" argued in favor of the converse, that any information which might lead a patient to cancel or defer a procedure should be considered significant.[5]

Another major shortcoming identified in the informed consent process was the infrequency of discussion about alternatives to the proposed anesthetic procedures. Sixty-seven percent of patients who signed the consent for anesthesia form indicated that no discussion took place about the possibility of alternative anesthetic techniques. In our setting, with anesthetists often meet their patients on the day of surgery, hence the anesthetist primarily discusses what he/she intends to do, meeting the lower standard of legal acceptability but at the same time sacrificing the ideals of patient autonomy and shared decision making. This compromise is unfortunate because it has been shown that the preservation of patient autonomy is associated with improved patient satisfaction and more favorable medical outcomes.[25]

The issue of postoperative pain control was another area that was not satisfactorily discussed by the anesthetists who obtained consent, with approximately 55% of patients overall indicating dissatisfaction with the information provided. Barneschi *et al*. reported that the desire for information about pain in their study was particularly high (85%). This underscores the relevance of pain and analgesia as an issue in the informed consent process.[23]

Although the results suggest that the information provided to patients was not as complete as it should be, patients apparently opted not to utilize the opportunities that they were given to ask questions. Crawford-Sykes and Hambleton reported that although Jamaican patients expressed a desire for information concerning anesthesia and surgery, they did not regard it as their right.[26]

A study conducted in the UK revealed that nearly all women before obstetric anesthesia (82-94%) wished to know about common, less severe side effects, while a substantial majority (70-77%) also wished to know about rarer but more severe complications, such as permanent neurological deficit, meningitis, and high spinal block.[22] Our study established a better knowledge of this aspect of anesthesia when a separate consent form was used.

The significance of the findings of this study should be however interpreted within the context of the limitations of the study. First, the adequacy of consent index was devised and used for the first time in this study and therefore it was not previously validated. Although eight different essential aspects of the informed consent process were assessed with this instrument, there are several other aspects which were not included. The most important one is probably the extent to which the patient was allowed to share in the decision-making process.

With respect to information provided to the patient about material risks, patients were asked if they "felt" that they were adequately informed. One problem with this approach is that it is subjective in nature, and a patient who claims to be satisfied may find other risks relevant if they were made aware of them. An alternative approach taken by other researchers was to measure objectively patients' recall[12] and understanding of information provided.[27]

With respect to the methodology of this study, it can be argued that the introduction of a consent form for anesthesia on a trial basis, with the implication that there will be an assessment of the new measure, may have led anesthetists to artificially alter their practice, which could have introduced a "desirability bias." Although this consideration was a real possibility, many anesthetists were not made aware of any details of the planned evaluation.

Another possible limitation involves the timing of the assessment. It has been shown that patients are best informed immediately after signing the consent form and from then on there is a deterioration of the recall of information.[12] The consequence of this is that patients may have forgotten some of the details about what they were told by the time the interviews were conducted. The other option of administering the questionnaire after the informed consent process but before the surgery could quite possibly have the undesirable effect

of interference with the process of care. We felt that it was prudent to avoid this risk.

Nevertheless, it may be possible to recommend that the practice of obtaining separate written consent for anesthesia may be useful in selected settings.

We suggest that the consent form used should:

1. Be simply written without legal jargon.
2. Contain cues to the anesthetist regarding the issues to be covered.
3. Not lengthy and in itself provide the information but should keep the onus on the anesthetist to do so (thereby allowing the information to be tailored to the individual patient's needs and educational level, while at the same time reducing the risk that the form be substituted for the informed consent process), and
4. Contain ample space to document the information discussed.

Conclusion

This study shows that in a Caribbean setting, the introduction of separate written consent for anesthesia improved the overall adequacy of the informed consent process. Patients who were asked to sign a separate anesthesia-specific consent form were better informed about the nature and purpose of anesthesia, common side effects, and rare but serious complications.

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