Are Patients Comfortable Consenting to Clinical Anesthesia Research Trials on the Day of Surgery?

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Consent for clinical anesthesia research trials is often sought on the day of surgery when patients are most anxious and have little privacy or time for reflection. We conducted a retrospective survey of patients' perceptions and concerns regarding consent for clinical anesthesia trials on the day of surgery. Questionnaires were mailed to 175 patients who had participated in 1 of 6 negligible- or minimal-risk clinical anesthesia trials within the preceding year. Seventy-six patients responded (43%). Most patients (80%) reported that they understood the purpose of their trial, did not feel obligated (61%) or pressured (67%) to participate, and were satisfied (mean visual analog scale: 71 mm) with the recruitment and consent process on the day of surgery. Few patients (7%) believed that their well-being was put at risk because of their participation in the trial.

(Anesth Analg 2004;98:1106–10)

With the shift away from costly preoperative hospital admissions on the day before surgery, most surgical patients in North America present to the hospital on the day of surgery. Consent for clinical anesthesia research trials often occurs on the day of surgery because this is likely the time when the patient first encounters the anesthesiologist (1). However, the Canadian National Council on Bioethics in Human Research considers it inappropriate for patients to consent to clinical trials on the day of surgery (2) because the hospital can be regarded as a coercive environment and because the immediate preoperative setting prohibits adequate time for reflection. Moreover, consent for clinical anesthesia trials is often sought in a common area with little privacy and when the patient is most anxious (3). There is, nevertheless, little evidence to suggest patient discontent with the recruitment and consent process for clinical anesthesia trials on the day of surgery.

Our objective was to identify patients' perceptions and concerns regarding recruitment and consent for clinical anesthesia trials on the day of surgery. We hypothesized that patients who participated in trials that posed negligible or minimal potential risk were satisfied with the recruitment and consent process on the day of surgery.

Methods

The present study is a retrospective survey of all patients who had consented to participate in one of six clinical anesthesia trials within the preceding 12 mo at our institution. Recruitment and consent for participation in each of the six clinical trials occurred on the day of surgery in the preoperative common room holding area by one of six hospital-clothed research assistants. The clinical trials chosen for inclusion in the present study were continuing investigations in regional or ambulatory anesthesia and posed negligible or minimal potential risk as outlined in their respective consent forms (Table 1). All consent forms were two pages in length. After IRB approval, 175 patients were mailed a survey package consisting of an information letter, consent form, and questionnaire. The questionnaire was designed to investigate six areas of potential concern regarding the recruitment and consent process, namely, Comprehension, Situation (privacy/time), Obligation (pressure), Motivation, Compunction (regrets), and Satisfaction (Figure 1). Handwritten comments were solicited at the end of the questionnaire. Patients returned their completed questionnaire, along with the signed consent form, by post.

Accepted for publication October 28, 2003.

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DOI: 10.1213/01.ANE.0000106801.98537.25

0003-2999/04

Table 1.

Risk category	Title of clinical anesthesia research trial	Principal investigator	Type of surgery	IRB approval
Negligible	"Evaluation of postoperative complications and nursing workload in fast-tracking recovery process following ambulatory surgery." Intervention: Randomization to bypass phase I recovery.	F Chung	Various; ambulatory	15-02-2001
	"Development of an ultrasound-guided technique for brachial plexus blockade." Intervention: Ultrasound-guided localization of brachial plexus.	VWS Chan	Upper extremity	23-11-2001
	"Delayed effect of general anesthesia on cognitive function following ambulatory surgery." Intervention: Cognitive function questionnaire.	F Chung	Various; ambulatory	05-06-2002
Minimal	"Effect of small-dose bupivacaine-fentanyl spinal anesthesia on balance and ambulation following ambulatory surgery: a comparison with general anesthesia." Intervention: Randomization to low-dose spinal anesthesia vs. general anesthesia for serial postoperative gait testing.	S Yogendran	Lower extremity; ambulatory	23-03-1999
	"Effect of ketamine added to ropivacaine for interscalene brachial plexus block for shoulder surgery." Intervention: Randomization to perineural or systemic ketamine (0.5 mg kg^{-1}) adjunct vs. placebo.	CJL McCartney	Shoulder	12-06-2000
	"Intravenous lidocaine for postoperative pain in spinal surgery." Intervention: Randomization to intravenous lidocaine (1.5 mg kg^{-1} bolus; 2.0–3.0 mg min^{-1} infusion) adjunct vs. placebo.	VWS Chan	Spine	14-07-2000

Nonresponders were mailed a survey package as a reminder once again after 3 mo.

Results

Of the 175 questionnaires mailed, 76 were returned (first mailing: 58 respondents; second mailing: 18 respondents) to yield a 43% response rate. Respondent demographics appear in Table 2. The median score for each item in the questionnaire is listed in Figure 1. The majority of patients (80%) reported understanding the purpose of the clinical anesthesia trial for which they consented to participate. Most patients reported understanding the written consent form (76%) as well as the risks and benefits (71%) of the trial before agreeing to participate. Both the time and setting of recruitment and consent for the trial were reported as appropriate by most patients (68%). Most patients had enough time (62%) and privacy (62%) to consider their participation in the trial. A small number of patients felt anxious at the time of consent (21%), whereas a minority felt obligated (26%) or pressured (21%) to participate in the trial. Most patients were aware that participation in the trial was voluntary (87%) and that they could withdraw from the trial anytime without consequence (80%). A minority of patients would have liked to discuss the trial with someone else (32%), most often family (20%), before agreeing to participate. Motivation for participation included the perceived contribution to medical knowledge (84%) and future benefit for others (86%). Few regretted participating in the trial (8%); however, 5 patients (7%) believed that their well-being was put at risk because of their participation in the trial. Eight patients (11%) perceived suffering from one or more complications as a result of their participation in the trial. Complications listed by these patients included prolonged numbness after upper extremity nerve block (three patients); prolonged pain in the operative extremity (two patients); postoperative nausea and vomiting (one patient); urinary retention (one patient); dizziness (one patient); and anxiety (one patient). Most patients were satisfied with the consent process on the day of surgery (mean visual analog scale: 71 mm) and would participate in a similar trial again (65%). Forty-six patients included handwritten comments regarding the recruitment and consent process on

Instructions: Please indicate the appropriate number for each of the following statements.

1	2	3	4	5
Strongly disagree	*Somewhat disagree*	*Undecided*	*Somewhat agree*	*Strongly agree*

A. I am aware that I participated in an anesthesia research study.	*Median*: 5	*Range*: 1-5
B. I was asked to participate in the study at the appropriate time and place.	*Median*: 4.5	*Range*: 1-5
C. I was asked to participate in the study at the ideal time and place.	*Median*: 4	*Range*: 1-5
D. I felt anxious when I was asked to participate in the study.	*Median*: 2	*Range*: 1-5
E. I understood the purpose of the study before I agreed to participate.	*Median*: 4.5	*Range*: 1-5
F. I understood the benefits and risks of the study before I agreed to participate.	*Median*: 4	*Range*: 1-5
G. The study was well explained to me before I agreed to participate.	*Median*: 4	*Range*: 1-5
H. I had enough time to consider the study before I agreed to participate.	*Median*: 4	*Range*: 1-5
I. I had enough privacy to consider the study before I agreed to participate.	*Median*: 4	*Range*: 1-5
J. I read and understood the consent form before I agreed to participate.	*Median*: 4.5	*Range*: 1-5
K. I discussed the study with someone else before I agreed to participate.	*Median*: 1	*Range*: 1-5
L. I wished to discuss the study with someone else before I agreed to participate.	*Median*: 2	*Range*: 1-5

If you *somewhat agree* or *strongly agree*, then who: (please select all that apply)	n
☐ Surgeon	11 (14%)
☐ Another doctor	7 (9%)
☐ Nurse	5 (7%)
☐ Family member	15 (20%)
☐ Friend	1 (1%)
☐ Other	0

M. My participation in the study was voluntary.	*Median*: 5	*Range*: 1-5
N. I could have withdrawn from the study at any time without affecting my medical care.	*Median*: 5	*Range*: 1-5
O. I felt anxious about participating in the study.	*Median*: 2	*Range*: 1-5
P. I felt pressured to participate in the study.	*Median*: 1	*Range*: 1-5
Q. I felt obligated to participate in the study.	*Median*: 2	*Range*: 1-5
R. My medical care would be jeopardized if I did not participate in the study.	*Median*: 1	*Range*: 1-5
S. My participation in the study is important.	*Median*: 4	*Range*: 1-5
T. My participation in the study will benefit other patients in the future.	*Median*: 4	*Range*: 1-5
U. My participation in the study will contribute to medical knowledge.	*Median*: 5	*Range*: 1-5
V. I regret participating in the study.	*Median*: 1	*Range*: 1-5
W. The study put my health and/or well-being at risk.	*Median*: 1	*Range*: 1-4
X. I suffered from one or more complications as a result of my participation in the study.	*Median*: 1	*Range*: 1-5
Y. I would participate in another study similar to this one.	*Median*: 4	*Range*: 1-5

Z. Please mark an 'X' on the line below to indicate your satisfaction with the consent process for the study in which you were involved:

Not Satisfied _____ Very Satisfied

Mean VAS: 71 mm *SD*: 30 mm

Figure 1. Questionnaire. Results appear in bold. *n* = number of patients (with corresponding percentage of all study patients in parentheses); VAS = visual analog scale; and SD = standard deviation.

the day of surgery: 23 patients wrote positive feedback, whereas 19 patients wrote negative comments, specifically, 15 patients would have preferred recruitment and consent before the day of surgery, 4 patients were dissatisfied with the information/explanation provided at the time of recruitment and consent, and 2 patients suffered undue anxiety because of the recruitment and consent process. Finally, four patients described having poor recollection of the recruitment and consent process on the day of surgery.

Discussion

The present study is the first to retrospectively examine patients' perceptions and concerns regarding the recruitment and consent process for clinical anesthesia trials on the day of surgery. Our results suggest that patient recruitment and consent for negligible- or minimal-risk clinical anesthesia trials is appropriate on the day of surgery. In an American survey of 182 patients awaiting surgery on the same day, Mingus et

Table 2.

Patient demographics		*n* (%)
Sex	Male	39 (51)
	Female	37 (49)
Age	20–29 yr	8 (10)
	30–39 yr	14 (18)
	40–49 yr	22 (29)
	50–59 yr	16 (21)
	60–69 yr	13 (17)
	>70 yrs	3 (4)
Race	White	64 (84)
	Black	1 (1)
	Asian	3 (4)
	Native American	0
	Hispanic	0
	Other	8 (10)
Language spoken most often at home	English	69 (91)
	French	0
	Chinese	1 (1)
	Arabic	0
	Italian	0
	Spanish	0
	Portuguese	1 (1)
	Other	5 (7)
Highest level of education attained	Grade school	4 (5)
	High school	18 (24)
	Community or technical college	21 (28)
	University-undergraduate	22 (29)
	University-postgraduate	11 (14)
Current occupation	Laborer	6 (8)
	Sales and/or service	15 (20)
	Clerical	4 (5)
	Technical	2 (3)
	Tradesperson	4 (5)
	Manager	7 (9)
	Self-employed	6 (8)
	Professional	11 (14)
	Homemaker	5 (7)
	Retired	9 (12)
	Student	1 (1)
	Other	6 (8)

al. (4) concluded that all patients were capable of deciding whether to participate in a clinical anesthesia trial, most patients required only 20–30 minutes to read and understand the consent form, and most patients considered it acceptable to be recruited on the day of surgery. However, meaningful implications from the latter study are drawn with caution given that patients were not actually recruited for any clinical trial. Montgomery and Sneyd (5) surveyed 204 patients who had been recruited for one of six clinical anesthesia trials in the United Kingdom. They demonstrated that most patients were content with the consent process; however, no distinction was made between the risks inherent to each trial or between the time at which consent was obtained; that is, either on the evening before or the day of surgery. Finally, a recent German study by Treschan et al. (6) provides good evidence that patients are unwilling to consent to a clinical anesthesia trial if they feel pressured to participate or do not understand the risks involved. However, generalization of the authors' results is limited because subjects were recruited and consented for sham clinical trials as inpatients on the day before surgery.

Consent rates for clinical trials may reflect the relationship or interaction between the recruiter and the patient. Large consent rates may signify excess pressure from the recruiter, whereas small consent rates may indicate residual doubt or lack of trust on the part of the patient (7,8). To limit the influence of any one recruiter, patients included in the present study were drawn from six clinical trials, each with different research assistants charged with recruitment and consent.

Whereas the present study suggests that recruitment and consent for negligible- or minimal-risk clinical anesthesia trials is appropriate when performed

on the day of surgery, the ideal time for recruitment and consent to ensure patient autonomy remains controversial. Approaching patients to consent for clinical trials on the day before surgery does not necessarily translate into better understanding of the trial and less preoperative anxiety. Treschan et al. (6) demonstrated that 33% and 28% of patients did not understand the inherent pain and risk of injury, respectively, associated with participating in a sham clinical anesthesia trial when approached on the day before surgery. Similarly, when approached on the day before surgery, parents who were asked to consent to clinical anesthesia trials on behalf of their child did not read the consent form any more thoroughly and reported even more anxiety than those parents approached on the day of surgery (9). Preadmission telephone calls have been used in 19% of North American academic centers to inform and recruit patients for clinical anesthesia trials before the day of surgery (10); however, this method is controversial given the potential for a preadmission telephone call to exacerbate preoperative anxiety and undermine patient confidentiality (1). Finally, some institutions distribute an information letter to eligible patients well in advance of recruitment and consent on the day of surgery; the efficacy of an information letter has yet to be defined in the literature.

The implications of the present study may not extend to clinical anesthesia trials that pose moderate or substantial potential risk to the study patient. In such instances, recruitment and consent on the day of surgery may not be acceptable, and would be the subject of worthwhile future investigation. Moreover, the present study is limited by its retrospective design and dependence on patient recall. Future prospective investigation is required to capture valid measures of patient comprehension and preoperative anxiety, as well as reasons why patients may refuse to participate, when approached for negligible- or minimal-risk clinical anesthesia trials on the day of surgery. Finally, the incidence of complications associated with negligible- or minimal-risk clinical anesthesia trials is best discerned in a prospective manner because the complications reported by our study patients are nonspecific and questionably stem from the interventions examined.

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