Original Article

Evaluation of anesthesia informed consent in pediatric practice – An observation cohort study

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Abstract

Background and Aims: An informed consent requires active participation by both physicians and patients. It is the responsibility of the physician to give the complete disclosure of information in easy language for the parent to understand. An informed consent process can be a challenge especially for the anesthetists when time is a limiting factor for patient-anesthetist interaction especially in same day admission and day surgery. The aim of this study was to subjectively evaluate the understanding and recall of the informed consent by the parents.

Material and Methods: The validated survey was conducted over 10 weeks and was limited to one parent per child and to the parent who was directly involved in the consent process.

Results: Majority of parents rated positively for adequate disclosure of all items of information. Consent process done on day of surgery was found to be associated with lower parental rating in adequacy of disclosure of pain relief options. Seniority of anesthetists was associated with higher parental rating of adequacy of information regarding post operative plan, specific risk of child and overall consent process. Consent for minor surgeries, on day of surgery, did not significantly affect the parental performance in their recall of disclosed information but was associated with significant lower rating of adequacy of postoperative plan. Postoperative pain is among the areas for improvement especially in day surgery cases.

Conclusion: Consent taken on day of surgery was found to be associated with lower parental rating. Postoperative plan for pain required improvement especially in day surgery cases.

Keywords: Day care, informed consent, minor surgeries, pediatric anesthesia, prospective, survey

Introduction

An informed consent for a surgical procedure requires active participation by both physicians and patients. For giving consent for the concerned procedure, the patient/guardian not only has to understand but also retain the information given by the physician. It is the responsibility of the physician to give the full disclosure of information in simple and easy language to the patient/parent so that they are able to understand it.[1-3]

The disclosure of complete information prior to surgery is essential as there has been a clear shift from Bolam's reasonable doctor standard to a reasonable patient standard in medical law.[1,3-6] In pediatric anesthesia, the complexity of consent process is increased because the desire for perioperative information may vary for surrogate party – the parents or legal guardians,[4,7,8] although a majority of parents have been reported to desire a comprehensive detailed risk disclosure.[9-12]

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An informed consent process can be a challenge especially for the anesthetists when time is a limiting factor especially for same-day admission and day care surgery. For the anesthetists, this short anesthetist–parent/patient interaction and very often the first encounter[6] may not be enough. It is not unreasonable to question whether the timing of anesthesia counseling would increase the anxiety of parents and child and affect the recall.[12,13] Since trainees are involved in informed consent taking, concern also arises if their experience equips them with the competence to explain the procedures, its risks, and important information to the patient.[4,14-16]

Many earlier studies have shown that retention and understanding of information is variable and poor among patients despite authorizing the procedures.[17-19] The risks of anesthesia and complexity of the anesthesia plan are determined by the medical status of the patient, the type of surgery, and surgical techniques. Therefore, how much information disclosure is required to constitute a reasonable practice and how much is too much is a matter of debate.

There is limited work looking at how patients/parents perform in terms of understanding and recall of the different types or items of anesthesia information disclosed, and we believe knowledge of this will help toward improving the consent process. In this study, we intended to evaluate the parental recall of each item of perioperative information with the use of a written standardized anesthesia information document. Parental rating of the ease of understanding and overall rating of the informed consent process and adequacy of perioperative information given were secondary outcomes studied. We also evaluated the effect of seniority of the anesthesia care givers and consent timing for the process on the outcome of consenting.

Material and Methods

After Singhealth Singapore Research and Ethics committee approval, this cross-sectional observational study was carried out over 10 months in KK Womens' and Children's Hospital, Singapore.

Standardized consent process

In accordance with the hospital policy, informed consent was obtained as a separate entity from a child's parent or legal guardian, by the anesthetic team directly involved in the anesthesia care of the patients. To ensure uniformity of anesthesia information delivery, a written information sheet was given to parents as departmental policy. The content of the anesthetic information document included (1) the reason for preoperative fasting, (2) the side effects and complications of GA which are categorized into common and severe but rare, (3) options of pain management such as regional blocks and patient-controlled analgesia along with their risks and benefit, and (4) the invasive monitoring and its complications. This informed consent process was done in the same setting as preoperative assessment of the patient for surgery.

Recruitment process

Participants were parents of children undergoing elective surgery under anesthesia. All the anesthetists in the department participated voluntarily in the study. A designated research assistant confirmed that informed consent for anesthesia had been given before approaching the parents to screen for eligibility. The survey was limited to one parent, who was directly involved in consent process for the child. Exclusion criteria included non-English-speaking parents, emotionally upset parents, parents who had already participated in the study once during the study period, and evening cases. Previous GA experience either with the index child or another child was not considered to be an exclusion criterion if it took place before the survey period.

Parents were recruited in the operating theater holding area on the day of surgery. After written informed consent was obtained for the survey, parents were instructed to complete the forms in the waiting area of the operating theater. They were also instructed to fill up the survey form. Upon completion, the forms were returned anonymously to the receptionist in the operating theater. Anesthetist participants involved in consent taking were asked to complete corresponding survey and return it to the recovery unit of the operating theater. Both parental survey forms and anesthetist survey forms were then matched by the principal investigators.

Survey

To ensure the content validity and reliability of the survey, the parental survey form was developed by investigating anesthetists based on literature[20] and modified after evaluating the content and language. A panel of consultant pediatric anesthetists, pediatric nurse, and epidemiologist helped toward the modification of the original survey form. A pilot test was performed with sample parents using the modified survey to assess consistent reliability and to ensure that the respondents understood the questionnaire. Final refinement of the survey was done and used for the study.

Parental survey

The survey was designed to evaluate (i) subjectively the parental perception of the quality of the informed consent by assessing the adequacy of delivery of information covering various aspects of perioperative anesthetic care and (ii) objectively parental understanding of the information delivered by assessing their recall of the information covering various aspects of perioperative anesthetic care.

Table 1: Demographic characteristics

	Total no. of participants	%
Profile of parents		
Age (years)		
20-30	32	13.3
>31	209	86.7
Gender, M:F	75:166	31.1:68.9
Marital status		
Single	4	1.7
Married	226	93.8
Separated	11	4.6
Ethnicity		
Chinese	143	59.3
Malay	37	15.4
Indian	30	12.4
Others	31	12.9
Education		
Primary	1	0.4
Secondary	30	12.4
O levels	49	20.3
A level/polytechnic	26	10.8
Graduate	92	38.2
Postgraduate	43	17.8
Profile of child		
Age (mean±SD)	5.8±4.4	
Gender, M:F	140:101	40.8
History of previous general anesthesia		
Yes	98	59.2
No	142	90
Types of surgery		
Minor*	217	10
Major**	24	42.3
ASA status		
I:II:III	130:87:24	15.4
Level of urgency of surgery		
Elective:emergency	227:14	42.3
Admission status		
Inpatient	102	
Same-day admission	37	
Day surgery	102	
Anesthesia staff obtaining informed consent		
Trainees	140	58.1
Specialist	89	36.9
Consultant	12	5

*ICU=Intensive care unit. *Minor=Duration <2 h surgery; no intraoperative blood transfusion, invasive lines, not requiring ICU stay postoperative; **major=ENT, abdominal, thoracic (>2 h duration, requiring the blood transfusion, invasive lines, ICU stay)*

The following data were collected:

(A) *Demographic data* of the parents.

(B) *Subjective evaluation included* (i) parental rating of adequacy of information where respondents were instructed to indicate their response to each of the following items with a 3-point scale of 1 (yes), 2 (not sure), and 3 (no). The items included were of general risks and complications general anesthesia (GA), specific risks of anesthesia, anesthesia plan, information on types and options of pain relief, and postoperative plan. (ii) Parental rating of the ease of understanding of information and overall rating with a 4-point Likert scale from very easy to very difficult

(C) *Parental feedback on preference* regarding (i) timing and duration of informed consent and (ii) parental preference to be informed in case of a sick child

(D) *Free response on desired additional information*

(E) *Objective evaluation* included the following: (i) parents were asked to list two common side effects, two major complications of GA, and rationale for fasting. (ii) Parents were also instructed to indicate their knowledge about specific risk of GA, pain management, perioperative monitoring plan, and postoperative monitoring in intensive care unit (ICU) or high dependency.

Statistical analysis

Once collected, data were reported as descriptive statistics using SPSS16.0 software (SPSS Inc., Chicago, IL, USA). The data were analyzed using frequency tables and percentages for categorical variables. Descriptive statistics were conducted to determine the percentage of parental evaluation of the following: adequacy of perioperative anesthesia care information, adequacy of time spent in informed consent, correct response in recall for itemized perioperative anesthesia care, and ease of understanding of information. Association between categorical variables was analyzed using Chi-square and Fisher's exact test, as appropriate. Analysis of variance (ANOVA) test was used for association between continuous and categorical variables. Correlation between ordinal and continuous data was done using Spearmen's correlation. Data are presented as mean ± standard deviation (SD), *N* (%). Statistical significance was accepted at the 5% level ($P < 0.05$).

To determine any potential effect of grade of anesthetists and timing of informed consent on various variables of informed consent, anesthetists were divided into three grades which included trainee, nonconsultant specialist, and consultant. Timing of consent was subdivided into consent taken on the same day and 1 day before surgery. ANOVA or Chi-square was used to examine the impact of the two groups.

As this was an observational qualitative cross-sectional study, and the recruitment of participants was limited by logistics constraints, the sample size was not calculated.

Results

A total of 335 parents who fitted the inclusion criteria were approached over a 10-week period, out of which 59 parents

Table 2: Characteristics of the informed consent process

	No. of consents	%
Time at which informed anesthesia consent was obtained		
Few days before surgery	7	2.9
One day before surgery	77	32
On the day of surgery	157	65.1
Format of informed consent		
Verbal	95	39.7
Verbal + written	144	60.3

refused to participate. A total of 276 parental survey forms were distributed; 32 were disqualified as parents either did not complete the questions or failed to return the survey forms. Three doctors did not return their form, and therefore the forms of 241 of 335 recruited parents (71.94%) were analyzed [Figure 1].

The baseline characteristics of the parents, patients, and anesthetists who participated in the study are presented in Table 1. The details of the time at which the informed consent was obtained and the format of informed consent are given in Table 2. The results of subjective evaluation of adequacy of information are presented in Table 3.

Objective evaluation

Fifty-five parents (22.8%) were able to correctly recall and understand the reason for fasting, while 135 (56.0%) failed to do so. In all, 134 parents (55.6%) could list two common side effects of GA, while 53 (22%) could not. Twenty-four parents (10.0%) listed two major complications of GA, while 168 (69.7%) parents failed to do so. Higher level of parental education was associated with significantly better performance in parental understanding and recall of common side effects ($P = 0.012$). Higher American Society of Anesthesiologists (ASA) status of the child was associated with better rating of adequacy of postoperative plan ($P = 0.004$).

Effect of seniority

There was a significant difference in the subjective evaluation of consent process based on (i) parental rating of overall process ($P = 0.009$), (ii) rating of adequacy of postoperative plan ($P = 0.033$), and (iii) rating of adequacy of specific risk ($P = 0.033$) because of the level of seniority. About 18.7% ($n = 26$) of parents rated consent process as excellent, when consent was taken by trainees, whereas 38.2% ($n = 34$) parents rated consent process as excellent, 49.4% ($n = 44$) as good, and 11.2% ($n = 10$) as satisfactory when consent was taken by specialist. Around 16.7% ($n = 2$) of parents rated consent process as excellent, 75% ($n = 9$) as good, and 8.3% ($n = 1$) as satisfactory when consent was taken by consultant. There was no association between level of seniority and objective evaluation of parental understanding and recall of information disclosed.

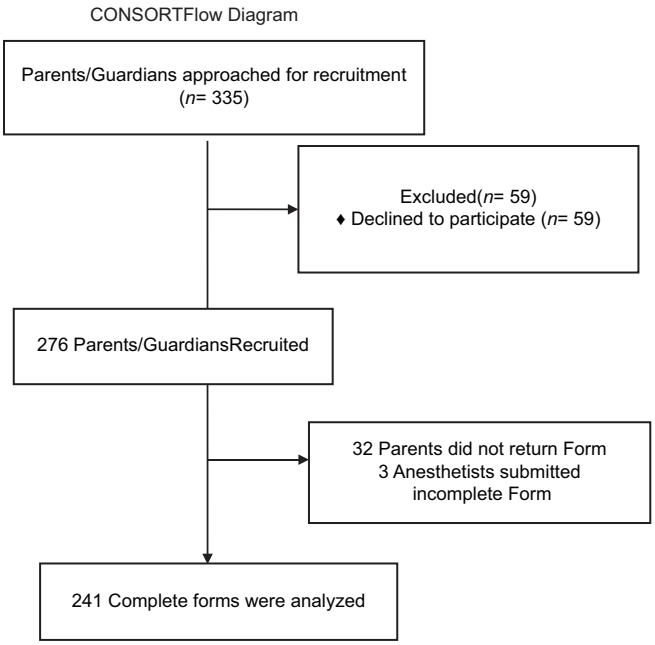

Figure 1: Consort Flow diagram

Effect of timing of consent process

Informed consent carried out on the day of surgery was associated with significantly lower parental rating of adequacy of disclosure of postoperative pain relief plan than when done on the day before surgery (61.54% day of surgery vs. 79.22% 1 day before surgery, $P = 0.046$). Timing of the informed consent was not a factor associated with better subjective ease of understanding of information or adequacy of disclosure of other items of perioperative information or parental recall and understanding of information disclosed. Subjective feeling of adequate duration of informed process is associated with better parental performance in understanding of common side effects ($P = 0.036$) and reason for fasting ($P = 0.042$). Table 4 demonstrates overall rating of consent process and adequacy of duration of consent process.

Parental preference

A majority of parents preferred informed consent to take place 1 day before ($n = 104$, 43.6%) compared to the day of surgery ($n = 56$, 23.2%) or days prior to surgery ($n = 65$, 27.0%). Parents had varied opinion, but 53.1% indicated that their preferred duration of informed consent process was 15 min. There was no association between ASA status of child and preference for information. About 88.4% wanted to know the risk of anesthesia in detail for their child even if he or she is in high-risk category.

Discussion

The primary aim of an informed consent process is to allow parents to make an informed decision and best choice that fits

Table 3: Subjective evaluation of quality of perioperative anesthesia information

a) Adequacy of perioperative anesthesia information	*n* (%)		
Items of perioperative care	**Adequate**	**Inadequate**	**Not sure**
GA-related general risks	202 (84.5)	19 (7.9)	17 (7.1)
Anesthesia plan	202 (84.2)	11 (4.6)	25 (10.2)
Specific risk for your child	181 (75.4)	30 (12.5)	28 (11.7)
Postoperative plan	162 (67.5)	32 (13.3)	44 (18.3)
Pain relief options	157 (65.1)	44 (18.3)	39 (16.2)
b) Parental rating of experience of other aspects	*n* (%)		
Items	**Yes**	**No**	**Unsure**
i) Ability to reach decision	227 (95.4)	-	11 (4.6)
ii) Easy to understand the information	217 (90.8)	21 (9.2)	-

GA=General anesthesia

Table 4: Rating of overall consent process and adequacy of duration of consent process by parents and anesthetists

	Parent's response, *n* (%)	**Anesthetists's response, *n* (%)**
Rating of overall consent		
Excellent	62 (25.8)	11 (4.6)
Good	127 (52.9)	164 (68.6)
Satisfactory	47 (19.6)	64 (26.8)
Poor	4 (1.7)	0 (0)
Rating of adequate duration for consent		
Yes	204 (85.0)	229 (97.0)
No	13 (5.4)	7 (3.0)
Not sure	47 (19.6)	0 (0.0)

the needs for the child. The secondary aim is to build rapport and allay anxiety by reassurance and addressing concerns. To achieve these goals, the challenge is to match effective delivery of perioperative information with the demand for information needs and comprehension ability of the recipients. The process of informed consent which often takes just prior to surgery, a stressful window for parents, especially with day care and same-day admission surgeries, can pose bigger question to understanding and recall of content of informed consent.

At the same time, the change in legal standards from peer-centric Bolam to "reasonable patient"-centric consent has generated interest and debate among medical community about the quality and quantity of information to be disclosed.[4,21,22] Opinions range from tailoring the disclosure to individual needs[23] to one where one should disclose any information related to procedure including the rare permanent severe injury.[12,24,25] Recent studies have reported wide variability in risk disclosure among anesthetists in Australia and New Zealand,[11,26-31] reinforcing the call for consensus among anesthetists.

The attention on informed consent process has resulted in global adoption of an anesthesia information document to standardize the quality and quantity of information delivered. The use of written information or information leaflet has been supported by various studies,[14,31-34] which showed improvement in knowledge imparted and patient's satisfaction as well as decreased the anxiety and resulted in better recall with its use.

Anesthesia information leaflet has been used by our department since early 2000s as part of our preanesthesia assessment. The information leaflet was physically incorporated into the anesthesia assessment document in 2012. Information leaflet may help in the efficient delivery of standard information. However, questions regarding who should take the consent, when should it be taken, how much information is to be disclosed, and how much do patients understand and recall still need to be answered.

Studies that evaluate recall of information in informed consent process are limited and mostly done in adult population[8,17] where written presentation of information was used. Tait *et al.*[20] assessed parental recall of 263 children on the knowledge of anesthesia plans, risks, benefits, pain management, and the side effects of pain treatment after consent was taken by surgeons and anesthetists. While Rosique *et al.*[17] found that a majority of patients had little or no recall of presented information, Gilles showed that patients fared worst in major risk (no recall in 80%) versus minor risk (37%) recall.

Our study highlights that subjectively most parents felt adequate anesthesia information was disclosed; however, it was not reflected in the results of their understanding and recall of perioperative anesthesia plans for their child (invasive monitoring during surgery, regional analgesia, postoperative plan). Three information items identified to fare poorly by a majority of parents were risk of anesthesia specific to the child, major complications of GA, and reasons for fasting. Our findings showed that despite parents' authorizing consent for anesthesia, only 25% could recall material information which reasonable patients would attach significance to, namely, the specific GA risk unique to their child as a result of child's medical condition or surgical-related anesthesia care. This finding questions the fundamental of the legal validity of the informed consent process.

Despite explanation, many parents fail to understand the potential risk of regurgitation and aspiration that comes with inadequate fasting. Situation of postponement or delay of surgery as a result of parental erring from fasting instruction was not uncommon in our practice.

The level of seniority of anesthetists made no significant difference in parental understanding of the consent. Although the duration of consent process did not have to be prolonged, a majority of parents felt 15 min is adequate for minor procedures. This is in keeping with the fact that an average adult can concentrate from 15 to 20 min at time.[35] Regardless of parental preference for earlier consent process, timing of informed consent has no significant effect on parental rating of adequacy of information or parental recall in our study except for postoperative plan.

The most commonly cited suggestions were use of visual format, simple nonmedical jargons, and repertoire of information and alternative plan of anesthesia. Studies have shown that 20%–55% of patients do not read the informed consent.[36,37]

There are some limitations in our study. We did not examine psychoemotional status of parents/guardians which can affect parental recall and rating of adequacy of information. Other factors positively influencing patient's recall include effective and empathetic communication and attitude of the physician.[8] The actual interaction between each parent and anesthetist during the consent process was not recorded or observed by investigators. The reliability of results of the study rests on the accuracy of the anesthetists' feedback on the actual material they disclosed to the parents. Bias maybe introduced from inaccurate completion of forms by doctors. To minimize this error, regular sessions were carried out during the survey period to remind all anesthetists the purpose of the survey and the importance of accurate documentation by all anesthetists. The anonymity of the anesthetists' feedback also helps reduce this error. Other important elements in the communication such as attitude (empathy, emotional support), language used, and nonverbal cues were not evaluated. Factors other than comprehension can significantly affect parental recall of information.[38] Parents were also predominantly female, and it is not clear whether gender can influence the results and therefore limit the validity though Martin showed that gender does not affect the level of parental desire of perioperative information. The majority of our sample population were children of ASA I and II status and scheduled for minor surgeries and was not representative of population I clinical practice. Perhaps future study should examine the impact of factors such as age, ASA status, and emergency nature of surgery on the consent form recall.

Observed discrepancy between high level of parental rating of understanding of ease of information and adequacy of information and the high rate of poor understanding and recall of information should be further evaluated. Actual comprehension and perception of ease of comprehension and provision of information are not compatible. A validated survey tool called the "Family satisfaction in the intensive care unit" (FS-ICU) exists to evaluate satisfaction on quality of information received and level of participation in decision-making.

We have not performed psychomotor assessment of our recruited parents but to minimize the bias, we excluded emotionally upset parents, children coming for cardiac surgeries, and neurosurgeries. All children requiring ICU postoperatively and blood transfusion were excluded from the study.

Conclusion

Actual recall of consent items by parents is inadequate despite positive rating for adequate disclosure of all items of information with the use of standardized information documentation. Consent taken on the day of surgery and inexperience of anesthetists were found to be associated with lower parental rating in adequacy of disclosure of pain relief options. Postoperative plan for pain required improvement especially in day care surgery among trainees.

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Conflicts of interest
There are no conflicts of interest.

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