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Is a pre-anaesthetic information form really useful?

THESE

préparée sous la direction du Professeur Nicolas Gilliard

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par

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Is a pre-anaesthetic information form really useful?

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«Is a pre-anesthetic information form really useful?»

Mise en perspective de l'étude

Comme pour tout acte médical, l'obtention du consentement libre et éclairé est nécessaire pour une anesthésie. Lors de la consultation préopératoire, le médecin-anesthésiste doit donc informer le patient des différentes techniques d'anesthésie et d'antalgie, de leurs avantages, et de leurs complications, ainsi que des éventuelles alternatives. La difficulté réside dans le contenu et la clarté de l'information dispensée afin que le patient signe un consentement appelé éclairé. L'information doit donc être complète, sans être exhaustive, et présentée dans un langage circonstancié, adapté au niveau socio-culturel du patient.

Différentes études conduites sur la qualité de l'information fournie avant une anesthésie ont démontré une réduction des scores d'anxiété¹ ou un gain d'information. Mais ces études étaient soit de nature observationnelle,^{2,3} soit prospectives non aveugles⁴ ou alors utilisaient un support vidéo⁵⁻⁷ qui augmentait le temps passé en salle d'attente.⁸ Par ailleurs, certains auteurs ont démontré qu'une information suffisante et l'implication du patient dans le processus décisionnel sont des critères importants de satisfaction.⁹

L'objectif de cette étude était d'évaluer si une feuille d'information remise à la consultation préopératoire permettait d'améliorer la perception de l'information, le gain d'information et le niveau de satisfaction.

Méthode

Cette étude prospective randomisée en simple aveugle a été conduite à l'hôpital Orthopédique du Centre Hospitalier Universitaire Vaudois. Deux cents patients prévus pour une chirurgie élective orthopédique ont été recrutés entre avril et juin 2008 et répartis en deux groupes selon une table de randomisation : un groupe recevait une feuille d'information 30 minutes avant la consultation préanesthésique, et l'autre pas. Les patients des deux groupes étaient ensuite examinés à la consultation préopératoire par un anesthésiste indépendant de l'étude, puis recevaient un questionnaire standardisé. Ce questionnaire, issu de questionnaires existants,^{8,10,11,12} et validé préalablement sur un échantillon de 50 patients, comportait 17 questions qui exploraient la perception de l'information (5 questions), le gain d'information (3 questions) et le niveau de satisfaction (9 questions). Parmi ces 17 questions, 3 étaient posées 24 h après l'intervention chirurgicale lors d'une visite dans la chambre ou lors d'un contact téléphonique. Les réponses étaient analysées et comparées entre les deux groupes.

Résultats

Cent huitante-cinq patients ont terminé l'étude. Le groupe qui a reçu la feuille d'information avait une meilleure perception de l'information (73% vs 63% dans le groupe de contrôle, $p = 0.002$), un gain d'information plus élevé (75% vs. 62% dans le groupe de contrôle, $p = 0.001$) et un niveau de satisfaction plus élevé (95% vs. 92% dans le groupe de contrôle, $p = 0.048$).

Discussion et conclusion

Cette étude a permis de démontrer que la remise d'une feuille d'information explicative avant la consultation préanesthésique était un moyen simple et bon marché pour

améliorer l'efficacité de cette consultation pour des interventions chirurgicales électives. Cette feuille, rédigée dans un langage compréhensible et dépourvue de termes scientifiques, faciliterait la discussion entre le patient et l'anesthésiste, et permettrait au premier d'être plus impliqué dans le processus décisionnel (choix de la stratégie anesthésique). Finalement, les patients avaient la possibilité de garder la feuille d'information, de la relire et d'en discuter avec leur entourage. Les limites de cette étude étaient l'impossibilité d'inclure les patients à leur insu dans un des deux groupes, et la possibilité que les patients aient mentionné la remise ou non de la feuille d'information à l'anesthésiste lors de la consultation.

En conclusion, cette étude a démontré qu'une feuille d'information remise avant une consultation préanesthésique permettait d'améliorer la perception de l'information, le gain d'information et le niveau de satisfaction des patients.

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Is a pre-anaesthetic information form really useful?

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Background: All patients should be fully informed about the risks and benefits of anaesthetic procedures before giving a written consent. Moreover, the satisfaction level may vary in proportion to the information given. We aimed to determine, in a single-blind randomized-controlled study, whether an information form given before the pre-anaesthetic consultation could improve perceived information, information gain and satisfaction level.

Methods: Two hundred patients ASA 1–3 scheduled for an elective orthopaedic surgery were randomized into two groups: a group that received an information form before the pre-anaesthetic consultation (IF group) and a control group (no information form). A standardized questionnaire was submitted after the pre-anaesthetic consultation and after the operation. This 17-item questionnaire explored perceived information (five items), information gain (three items) and satisfaction level (nine items). The

items of each topic were pooled and compared between groups.

Results: One hundred and eighty-five patients (92.5%) completed the study. The IF group had better perceived information (IF group 73% vs. control group 63%, $P = 0.002$), higher information gain (IF group 75% vs. control group 62%, $P = 0.001$) and a higher satisfaction level (IF group 95% vs. control group 92%, $P = 0.048$).

Conclusions: Our study suggests that an information form given before the pre-anaesthetic consultation enhances perceived information, information gain and satisfaction level.

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DURING the pre-anaesthetic consultation, the anaesthetist reads the patient's chart, takes the history, performs a medical examination, sometimes orders exams (laboratory test, ECG, X-ray), discusses the anaesthesia strategy with its risks and benefits, taking into account the patients' preferences or fears, and finally collects a written informed consent. To give a written informed consent, the patient should have, by then, all the necessary knowledge about the medical procedure. This raises the question of the quality of the information given. It is unfortunate, but the incidence of severe complications disclosed by regional anaesthetists and their fellows can be inconsistent with those found in the contemporary literature.¹ Additionally, receiving sufficient information and becoming involved in the decision-making process are major factors influencing patient satisfaction with anaesthesia care.²

This work was performed at Centre Hospitalier Universitaire Vaudois and University of Lausanne, Avenue du Bugnon 46, 1011 Lausanne, Switzerland.

The role of media, such as videos and printed information about anaesthesia care, has been reviewed in an extensive work by Lee et al.³ Their conclusion is that they reduce the anxiety level and enhance information gain. But, most of these studies used a video support,^{4–15} which can prolong the time spent by patients in the waiting room.⁴ Moreover, a study conducted in a paediatric setting found that most parents preferred the pre-operative information in the form of a pamphlet rather than a video.¹⁶ Various reports using printed information demonstrated that bringing written material to the consultation is considered helpful by patients^{17,18} and may increase the patient's knowledge of specific items such as the waiting time before driving a car¹⁹ or the post-operative pain management.²⁰ But these studies were either observational studies^{18,20} or non-blind prospective studies.¹⁹

Therefore, we decided to conduct a single-blind randomized-controlled trial that evaluated whether an information form given in a pre-anaesthetic consultation could improve perceived information, information gain and satisfaction level.

Methods

This study was reviewed and approved by the ethics committee of our institution. The study was conducted as a randomized, single-blind, prospective trial during a period of 12 weeks from April to June 2008 at the Orthopaedic Clinic of the University Hospital of Lausanne, in agreement with the revised recommendations of the CONSORT Statement.²¹ Inclusion in the study was proposed to all patients referred to a pre-operative consultation, scheduled a couple of weeks before elective orthopaedic surgery. The following exclusion criteria were applied: planned outpatient status, age under 16, inability to understand French, inability to give informed consent and lack of time to read the information form.

Information form

The information form is written in font size 11 on a recto-verso page and describes the types of anaesthesia (general, spinal, epidural, peripheral nerve block with neurostimulation) with their risks and benefits. It also depicts the pre-operative procedure in the operative room, and in the recovery room, the role of the anaesthetist and the pre-operative instructions like the NPO rule and medication. The information form was tested in 20 patients for comprehensibility, legibility and completeness. Finally, after last modifications, the final version was put into use (the appendix can be obtained by contacting the author).

Questionnaire

We chose questions on the basis of existing questionnaires and for most of them, validated by the literature.^{4,15,22,23} The chosen questions were translated into French, only with slightly modifications. They evaluated the perceived information, which is the patient perception of the given information, the information gained, which evaluates the objective transfer of knowledge from the anaesthetist to the patient, and the satisfaction level.

A pre-test was conducted on 50 patients to ensure that all questions were readily understood, without ambiguity, to maximize the reliability and validity of the questionnaire. Three questions were eliminated after the pre-test, leaving us with 17 questions and a shorter version questionnaire that fits on a recto-verso page. From this pre-test, power analysis ($\beta = 0.8$, $\alpha = 0.05$) indicated that a sample size of 80 patients per group would be sufficient to

detect a difference in questions related to perceived information and information gain.

The topic of perceived information was assessed with five questions, which covered categories such as discussion of the risks and benefits of general vs. locoregional anaesthesia (questions 4, 5, 6, 7) and management of post-operative pain (tablets, PCA, epidural or peripheral nerve catheter) (question 8). The information gained was explored with three questions (questions 13–15) regarding the qualification of the anaesthetist, the NPO rule and the mode of ventilation during a general anaesthesia procedure. Satisfaction level was evaluated with nine questions, covering categories such as the length of the consultation (question 1), the use of a comprehensive language by the anaesthetist (questions 2, 3, 9), the quantity and quality of the information (questions 10, 12) and finally the level of anxiety (question 11). Patients were asked two more questions in the post-operative period about the conformity between their experience of anaesthesia care and their expectancy (question 16), and finally, their global satisfaction with the anaesthesia care (question 17). Among these nine questions, three had a negative formulation (questions 3, 9, 12).

Responses to the questions of the perceived information and the satisfaction level were labelled 'completely agree', 'partly agree', 'partly disagree' and 'completely disagree', with a fifth possibility of 'no opinion'. Answers to the questions on the information gained consisted of four given possibilities, including the answer 'I don't know'. To compare items between groups, answers 'completely agree' and 'partly agree' were gathered, so that answers 'partly disagree', 'completely disagree' and 'no opinion' in order to obtain a 2×2 contingency table. For questions with a negative formulation (questions 3, 9, 12), we produced the 2×2 contingency table by collecting answers 'partly disagree' and 'completely disagree' in a group and 'partly agree', 'completely agree' and 'no opinion' in another group. For each topic, we pooled the questions and compared the results between groups after data analysis by item; for example, the topic of perceived information was globally evaluated by stacking the answers of questions 4–8.

Procedure

The study design is displayed in Fig. 1. At the pre-anaesthetic consultation, one of the authors (R. S.) explained the study procedure to the patients, asked them to participate and collected all the

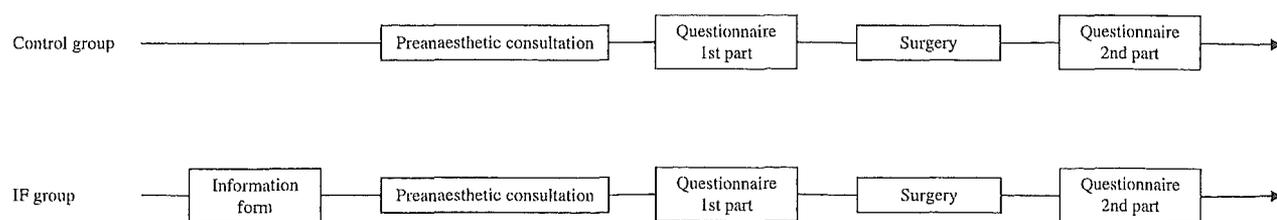


Fig. 1. Overview of the study structure and time points of data collection.

data. Those who agreed received a random numbered envelope containing either an information form (IF group) or a paper telling them they belonged to the control group, according to a computer-generated randomization list. Patients received the instruction to read the content of their envelope during their wait and not to share it with the anaesthetist. Residents with at least 2-year post-graduate formation conducted the pre-operative consultation with an unstructured interview and were unaware of the study. After the pre-operative consultation, patients answered the first two parts of the questionnaire in a separate room. The study investigator ensured that the questionnaire was completely filled in. Patients were finally asked to complete the last two questions of the questionnaire on the first post-operative day. During the entire procedure, the study investigator, the anaesthetists and the data analysts were blinded to patient's study group assignment.

Demographic and anaesthetic data including age, gender, education level, classification American Society of Anaesthetists (ASA), anaesthesia strategy and type of surgery were collected for each patient. Once the questionnaire was completed, data were returned anonymously.

Statistical analysis

Statistical analysis was performed using the JMP 7 statistical package (SAS Institute, Cary, NC). The student *t*-test was applied for continuous variables to compare the differences between groups. Categorical variables were analysed using the Fisher exact test for contingency tables 2×2 or by the Pearson test for larger contingency tables. The data are expressed as mean \pm SD. A bilateral *P* value < 0.05 was considered statistically significant.

Results

Of the 291 initially screened patients, 91 were excluded, 200 agreed and finally 185 patients

(92.5%) completed the entire study. There were 93 patients in the control group and 92 patients in the IF group. Figure 2 depicts the flow chart of the patients. Eight different residents performed the pre-anaesthetic consultation. As shown in Table 1, the majority of patients underwent shoulder, hip and knee arthroplasty. The average age was 54 ± 19 years and 85% of the study participants were ASA 1 and 2. There were no significant differences between both the study groups regarding age, gender, education level, ASA status, anaesthesia strategy and type of surgery (Table 2).

Perceived information scored higher in the IF group than in the control group (IF group 73% vs. control group 63%, $P < 0.01$). More specifically, the IF group had better perceived information regarding the benefits of general anaesthesia (IF group 79% vs. control group 66%, $P = 0.04$) and the risks of general anaesthesia (IF group 73% vs. control group 53%, $P < 0.01$). Similar results were not obtained, either with information about risks and the benefits of locoregional anaesthesia or with information about post-operative analgesia.

Patients who received the information form gave a higher percentage of correct answers in the information gain test than control patients (IF group 75% vs. control group 62%, $P < 0.01$). For example, patients of the IF group were more likely to answer correctly to the question of the mode of ventilation during general anaesthesia (IF group 70% vs. control group 43%, $P < 0.01$) and to the question of the reasons for fasting (IF group 85% vs. control group 63%, $P < 0.01$). Only 75% of the patients could say that the anaesthetist was a medical doctor, without a significant difference between both groups.

Satisfaction level was above 90% in both groups, with a significant difference in favour of the IF group (IF group 95% vs. control group 92%, $P = 0.04$). When considered separately, none of the single items showed a significant difference, although all items showed a trend towards higher scores in the IF group. Finally, 95% of the patients

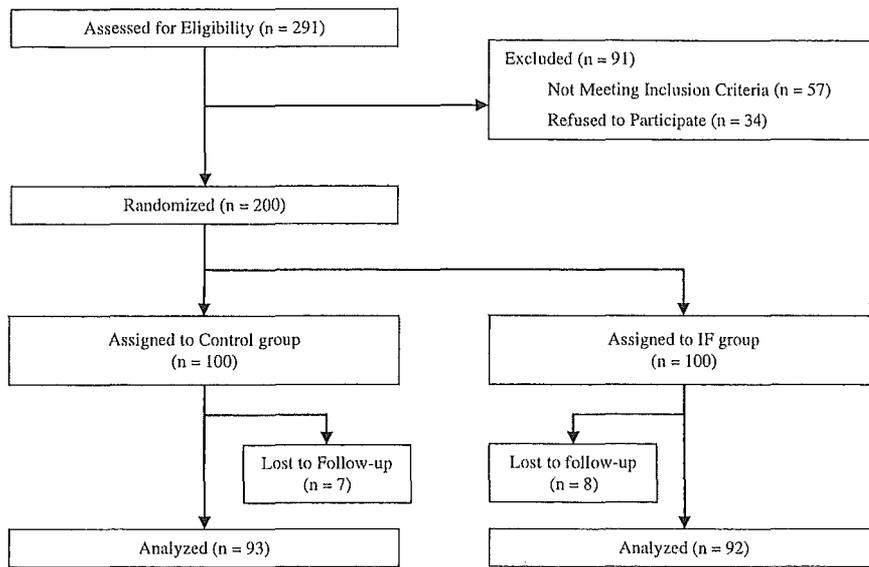


Fig. 2. Flow chart of patients. IF, information form.

Table 1
Patients' characteristics (n = 185).

	Control group (n = 93)	IF group (n = 92)
Age (mean ± SD) years	57 ± 18	52 ± 19
Male Gender [n (%)]	51 (55)	61 (66)
Education level [n (%)]		
Primary education	25 (27)	23 (25)
Apprenticeship	30 (32)	39 (42)
Secondary Education	23 (25)	22 (24)
University	15 (16)	8 (9)
ASA status [n (%)]		
ASA 1	21 (23)	25 (27)
ASA 2	55 (59)	56 (61)
ASA 3	17 (18)	11 (12)
Anaesthesia strategy [n (%)]		
General anaesthesia	53 (57)	61 (66)
Locoregional anaesthesia	40 (43)	31 (34)
Surgery [n (%)]		
Spine surgery	7 (7)	10 (11)
Shoulder surgery	11 (12)	9 (10)
Hip arthroplasty	17 (18)	22 (24)
Knee arthroplasty	16 (17)	13 (14)
Knee arthroscopy/ACL reconstruction	11 (12)	6 (7)
Foot surgery	21 (23)	14 (15)
Other surgery	10 (11)	18 (19)

Data are mean ± SD or n (%) (n = 185).
ASA, American Society of Anaesthetists; IF, information form;
ACL, anterior cruciate ligament.

stated that the procedure went as explained, without significant differences between both groups.

Discussion

This single-blind randomized-controlled trial was designed to assess the impact of a written

information form distributed before the pre-anaesthetic consultation. The group with the information form had better-perceived information, higher information gain and a higher satisfaction level. Thus, the results of this study suggest that a routine distribution of an information form may be a simple and inexpensive method to increase the efficiency of the pre-anaesthetic consultation for elective surgical patients.

Regarding the perceived information, Binhas et al.²⁰ demonstrated in a study on 287 patients that printed information could improve the information knowledge on post-operative pain treatment. We were unable to confirm this result in our study, although there was a trend in the IF group toward better information on post-operative analgesia. A possible explanation was that we only evaluated that item with one question, contrary to Binhas et al.,²⁰ who took four questions, thus increasing the accuracy of their study. Further, we were surprised to find a significant difference for questions on the risks and benefits of general anaesthesia and not for questions on the risks and benefits of locoregional anaesthesia. One explanation may be an unclear formulation of the paragraph concerning that topic in the information form, leading us to rewrite that section. Nevertheless, after pooling the questions, we found that the information form improves the perceived information.

The reports evaluating the impact of a video support on the information gain^{6,9,10,14} demonstrated a real benefit. We reach the same conclusion with our study using printed information only.

Table 2

Answers to the survey ($n = 185$).

Item	Control group ($n = 93$)	IF group ($n = 92$)	<i>P</i> value
Perceived information	63	73	<0.01
Benefits of general anaesthesia (question 4)	66	79	0.04
Risks of general anaesthesia (question 5)	53	73	<0.01
Benefits of locoregional anaesthesia (question 6)	68	68	1
Risks of locoregional anaesthesia (question 7)	54	60	0.46
Information on postoperative analgesia (question 8)	77	84	0.35
Information gain	62	75	<0.01
Formation of the anaesthetist (question 13)	78	71	0.24
Reasons of starvation (question 14)	63	85	<0.01
Mode of respiration (question 15)	43	70	<0.01
Satisfaction level	92	95	0.04
Sufficient time (question 1)	99	100	> 0.99
Explications clear (question 2)	99	99	> 0.99
Questions without answers (question 3)	83	89	0.29
Incomprehensible vocabulary (question 9)	85	87	0.83
Insufficient information (question 10)	98	100	0.50
Reassured after the consultation (question 11)	90	92	0.79
Unsatisfied about the given information (question 12)	88	91	0.63
Development of intervention as planned (question 16)	94	96	0.75
Global satisfaction (question 17)	95	98	0.44

Results to the questions of perceived information and satisfaction level topics are expressed in the percentage of answers 'completely agree' and 'partly agree', except for questions with a negative formulation (questions 3, 9, 12), whose results are expressed in the percentage of answers 'completely disagree' and 'partly disagree'. Results of the questions of the information gain are expressed in the percentage of correct answers.

IF, information form.

Question 15 (mode of ventilation) revealed the greatest differences between groups (correct answer: 70% IF group vs 43% control group). This is of importance, as up to a fourth of patients who had the information form could not understand the mode of respiration during general anaesthesia, raising the question of an effective informed consent. The results are worse than those of Snyder-Ramos et al.,¹⁴ who concluded that 97% of the patients of the video group gave the correct answer. However, our findings demonstrate that printed information could further improve the information gained, which is consistent with other studies.^{19,20}

There are several reasons why an information form can improve perceived information and the information gained. First, the form is written in an everyday language, free from scientific or medical terms. Secondly, the information form triggers interaction with the anaesthetist and facilitates discussion,²⁰ increasing the involvement of the patient in her/his own treatment. Finally, patients can keep the form, can read it again and discuss it with their family. For all these reasons, an information form can increase effective communication. This is important, as it can help guard against malpractice litigation²⁴ and contribute to patient satisfaction with the anaesthesia care provided.^{2,25}

Although the overall degree of satisfaction is high in both groups, we demonstrated that the information form significantly improves this parameter. This is consistent with the findings of a previous study using a video support and a multiple-item questionnaire,¹⁴ contrary to other studies using a single-item rating.^{19,26} Indeed, a single global question cannot accurately measure the complexity of satisfaction.²⁷ Surveys of patient satisfaction regularly produce high scores (>80% satisfied or very satisfied) but may not reflect the true nature of the anaesthesia care.^{28,29} For example, patients may be merely expressing their appreciation and gratitude to the providers who 'got them through' or patients may be unwilling to criticize their doctors and nurses, due to a fear of jeopardizing any future care. Therefore, the underpresentation of the true level of dissatisfaction might remain as a systematic error. Nevertheless, our findings suggest that an information form plays a major role in patient satisfaction.

This study has several limitations that should be mentioned. For obvious reasons, it was not possible to blind patients regarding the study group. Moreover, even if patients were requested not to tell the anaesthetist whether they had had the information form or not, we cannot exclude that they might not

have respected this instruction. Therefore, some anaesthetists might have been unblind during the pre-anaesthetic consultation, and would have given more information as they usually gave if they had been unaware of the study. Unfortunately, we are unable to detect the number of unintentionally unblind anaesthetists. As we already mentioned, the information form could improve the interview by bringing patients to participate actively and asking more questions, but we did not measure the time spent at the consultation for patients in the IF group vs. the control group.

Fifteen patients abandoned the study. But as the number of patients who gave up the study is similar in both the groups, we believe that this factor played a limited role. Finally, this study was not designed to assess the effect of an information form on the anxiety level.

In conclusion, this study assessed the impact of a written information form presented to the patient before the pre-anaesthetic consultation. We were able to demonstrate that it leads to better perceived information, better information gain and to a higher degree of satisfaction.

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