Major Article

Informed consent for strabismus surgery: the importance of patient information sheets

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PURPOSE To analyze the additive effect of supplementing verbal consent with written patient information sheets in optimizing patients' and families' understanding of strabismus surgery.

METHODS A prospective randomized study was conducted with 28 patients for strabismus surgery randomized into two groups: group 1 with standardized oral informed consent, and group 2 with standardized oral consent and a written information sheet. A confidential questionnaire with 13 questions was completed by patients and families before surgery.

RESULTS A total of 7 adults and 21 children were included in the study. The mean score (number of correct answers) for group 1 was 4.14 ± 1.99; for group 2, 5.79 ± 2.12 ($P = 0.044$), indicating that patients and families in group 2 understood their strabismus surgery better than those in group 1. Areas needing more emphasis during the consent process were identified, including risk of under- or overcorrection or repeat surgery and use of eyedrops postoperatively.

CONCLUSIONS In this study, patient information sheets seemed to help patients and families better understand information about their surgery. Patient recall of information provided is poorly reliable and must be considered in decision making for medicolegal cases. (J AAPOS 2018; ■:1-3)

A major change in the practice of medicine over the past decades is the transition involving patients in a process of shared decision making.[1] Patients must be given information about their disease, management options, and the risks or side effects of treatment to enable them to make informed choices. The process of informed consent includes the following five elements: voluntarism, capacity, disclosure, understanding, and decision.[2] For patients to effectively exercise their right to informed consent, provision of adequate information in an appropriate manner is necessary.[1] An optimally informed patient will have more realistic expectations regarding a surgical procedure and its associated risks. Preoperative information may be provided either verbally or through patient information sheets.

Strabismus is a complex disorder with myriad presentations, and different management options, including surgery, may exist for the same condition. There are different incision styles, a choice of muscles which can be targeted surgically, various tables for calculating the amount of surgery needed, and different muscle reattachment techniques. There is also a risk of diverse side effects, such as over- or undercorrection and diplopia. Therefore, it is imperative that patients understand the management plan before the surgery is undertaken. Another important factor to consider is patient recall. Even with standardized verbal and written consent process, how reliable is patient recall? This is particularly important from the medicolegal view point. The goal of the current study was to analyze the additive effect of supplementing verbal informed consent with written patient information sheets in optimizing patients' and families' understanding surgical management of strabismus.

Subjects and Methods

Patients scheduled for strabismus surgery at Auckland Eye, a tertiary eye care center in Auckland, New Zealand, from January 8, 2009, to January 10, 2010, were prospectively enrolled. The study was approved by the Clinical Management Committee of Auckland Eye and was completed in accordance with the tenets of the Declaration of Helsinki. Patients were randomized into two groups using a table of random numbers. Group 1 consisted of patients with standardized oral informed consent with some variations related to their particular surgery. Group 2 patients had a standardized oral consent (with variations according

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to their particular surgery) and a written strabismus information sheet (see eAppendix A) with additional information specific to the patient. Verbal information was provided to all patients and families by the same clinician. The information sheet was given to patients and families to take home after they were provided with verbal information at the clinic. Patients and families were asked to read the information sheet completely. They were free to use additional sources of information (including the Internet) if they wanted to. In case of more than one family member being present for the discussion, only one was asked to participate in the study, although information was provided to all members.

A confidential questionnaire, with questions to gauge patients' and families' understanding of aspects of surgery, was completed by all patients or families (when the patient was a child) on the day of surgery and before the surgical consent form was signed (see eAppendix B). Thus patients and families went through the process of verbal consent and took information sheets home and answered questionnaires on the day of surgery; that is, recall was delayed. Each participant was asked 13 questions. The answers to all questions but the first were scored, with the participant receiving one point for each correct answer. No points were scored for "not sure" answers, wrong answers, and unanswered questions. Thus, each participant received a score out of 12. Patient and family responses were evaluated to determine differences (if any) between groups. The results were analyzed by appropriate statistical tests using SPSS software. A P value < 0.05 was considered statistically significant. Patients and families were given an opportunity to clear any doubts/questions/concerns about their surgical procedure arising after answering the questionnaire before signing the consent form for surgery. Group 1 participants were given full access to the information sheets after the questionnaire was answered.

The language used for the purpose of verbal information and discussion with patients and families was English. The information sheets were also in English. Only patients/families comfortable with English as the language of discussion were included in the study. Also, only patients who had not undergone any previous strabismus surgery were included.

Results

A total of 28 patients were evaluated, 14 in each group (eTable 1). There were 7 adults and 21 children (4 adults in group 1 and 3 adults in group 2). The mean age for adults in group 1 was 45.75 ± 22.78 years; for children, 5.7 ± 3.20 years. The mean age for adult patients in group 2 was 35.00 ± 21.80 years; for children, 5.27 ± 2.72 years. There were 6 male patients in group 1; 8 in group 2.

The mean score for all participants was 4.14 ± 1.99 for group 1 and 5.79 ± 2.12 for group 2 ($P = 0.044$ [unpaired t test]). There was 1 unanswered question by one participant and 2 unanswered questions by 1 participant in group 1. There was 1 unanswered question by one participant and 3 unanswered questions by one participant in group 2. The mean of "not sure" answers was 3.14 ± 3.03 in group 1 and 1.57 ± 1.74 in group 2 ($P = 0.105$). The mean of wrong answers was 4.57 ± 1.95 in group 1 and 4.36 ± 1.86 in group 2 ($P = 0.769$). See eTable 2.

Discussion

Verbal information is useful if provided in a manner intelligible to the hearer and at a pace at which the recipient can understand it thoroughly.[3] Verbal information also allows the hearer to gain additional insight from the provider's facial expressions, tone of voice, emphasis on various points, pauses, and body language (such as a nod, smile, or hand gestures). It also allows the recipient to interrupt the information giver when she does not understand or requires clarification on some point. The information provider can also gain instantaneous (verbal and nonverbal) feedback from the recipient and therefore gauge her understanding and interest.

A patient information leaflet allows the recipient to take in information at her own pace, and it serves as a reference tool.[3] It allows the recipient to review various details repeatedly if needed and also serves as a record to substantiate the information that has been provided verbally. It also allows one to provide greater volumes of information without the constraints of clinician time. Patient information leaflets might therefore be a valuable component of informed consent. Our study aimed to analyze the additive effect of supplementing oral consent with a written information sheet.

The mean score for correctly answered questions in group 2 was significantly better ($P < 0.05$) than group 1, suggesting that group 2 participants understood the various facets of their strabismus surgery better than those in group 1. The mean of unsure answers in group 2 was also lower than in group 1, but this did not reach statistical significance, probably because of the small sample size of the study. All questions (except question 9) were answered correctly by more participants in group 2 than in group 1, though again, statistical significance was not reached.

Apart from one participant in group 1 who did not answer the question, all participants in both groups answered yes to question 1, thus affirming that they had an adequate understanding of the impending surgery. This is noteworthy given that the mean score of all participants in group 1 was only about 4.1 (about one-third) and in group 2 only 5.8 (about one-half).

It is reassuring to note that all participants in both groups had an adequate understanding of which eye was scheduled for surgery. This is one point that all clinicians would like to make clear to their patients, irrespective of how that information is provided.

On analysis of individual questions, it appears that there was a larger difference in correct answers between groups for questions 5 (stability of surgical results), 7 (undercorrection), 8 (overcorrection), 10 (repeat surgery), and 13 (loss of vision). Strabismus is a complex disorder with varied presentations and surgical options. Tailoring the choice of muscle(s) to operate on and the surgical