

THE EFFECTIVENESS OF PATIENT VERBALIZATION ON INFORMED CONSENT

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OBJECTIVE: To determine if preoperative patient verbalization of the risks and benefits of anterior cruciate ligament (ACL) reconstruction enhances understanding of the risks and benefits of that procedure.

DESIGN: A randomized clinical trial.

SETTING: A referral-based outpatient sport medicine clinic.

SUBJECTS: Twenty patients from the general population with clinically diagnosed ACL tears requiring elective reconstruction surgery were randomly assigned to 2 groups. Twelve patients who made up a control group received a standard surgical consultation, consisting of knee models, diagrams, open dialogue and informed consent to surgery. Eight patients in the experimental group were exposed to the same surgical consultation and were required to accurately verbalize the associated risks and benefits before operation. One month after informed consent was obtained, patients answered 3 questions about the risks and benefits of ACL reconstruction.

INTERVENTION: ACL reconstruction.

MAIN OUTCOME MEASURES: A 3-question questionnaire, addressing 2 risks and 1 benefit of ACL reconstruction.

MAIN RESULTS: Patients in the experimental group were able to answer all 3 questions correctly. In the control group, 4 patients answered all 3 questions correctly, but 1 patient answered all 3 questions incorrectly, and 7 patients answered 1 question incorrectly. There was a statistically significant difference ($p = 0.03$) between the control group and the experimental group.

CONCLUSION: Patients who verbalized the risks and benefits during their surgical consultation demonstrated a significantly greater understanding of the risks and benefits of an ACL reconstruction procedure.

OBJECTIF : Déterminer si la verbalisation par le patient, avant l'intervention, des risques et des avantages de la reconstruction du ligament croisé antérieur (LCA) l'aide à mieux comprendre les risques et les avantages de l'intervention.

CONCEPTION : Étude clinique randomisée.

CONTEXTE : Clinique de médecine sportive externe sur présentation.

SUJETS : Vingt patients de la population générale victimes de déchirements du LCA diagnostiqués sur le plan clinique et qu'il fallait reconstruire par une chirurgie électorale ont été répartis au hasard en deux groupes. Douze patients qui constituaient un groupe témoin ont reçu une consultation chirurgicale normale comportant des modèles du genou, des schémas, un dialogue ouvert et un consentement éclairé à l'intervention chirurgicale. Huit patients du groupe expérimental ont été exposés à la même consultation chirurgicale et ont dû verbaliser avec précision les risques et les avantages connexes avant l'intervention. Un mois après avoir donné leur consentement éclairé, les patients ont répondu à trois questions sur les risques et les avantages de la reconstruction du LCA.

INTERVENTION : Reconstruction du LCA.

PRINCIPALES MESURES DES RÉSULTATS : Questionnaire comportant trois questions, dont deux portaient sur

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le risque et une sur l'avantage de la reconstruction du LCA.

PRINCIPAUX RÉSULTATS : Les patients du groupe expérimental ont pu répondre aux trois questions correctement. Quatre patients du groupe témoin ont répondu aux trois questions correctement, mais un a répondu aux trois questions incorrectement et sept ont répondu à une question incorrectement. Il y avait une différence significative sur le plan statistique ($p = 0,03$) entre le groupe témoin et le groupe expérimental.

CONCLUSION : Les patients qui ont verbalisé les risques et les avantages au cours de leur consultation chirurgicale ont démontré qu'ils comprenaient beaucoup mieux les risques et les avantages d'une intervention de reconstruction du LCA.

Informed consent has now become an integral part of the physician-patient relationship. However, several factors may interfere with physicians' ability to communicate with their patients. Lack of time during a consultation, lack of medical knowledge on the part of some patients, and distractions such as anxiety, pain and fear of the unknown tend to be highly associated with the inability of patients to learn and retain information.¹ Furthermore, different consultation styles may affect patients differently. The patient-centred approach, a style whereby patients are permitted to express their concerns, was reported to enhance the overall interaction between patients and physicians.² In direct contrast to the patient-centred approach is the autocratic style whereby physicians maintain tight control over interviews and allow minimal opportunity for patients to interject. This style has been reported to decrease understanding²

Recently, efforts have been made to enhance communication between physicians and their patients.²⁻⁷ Despite receiving necessary information regarding the risks and benefits of procedures, patients continue to demonstrate poor understanding of common bedside procedures.⁸ This suggests the need for certain criteria when obtaining informed consent. It has been suggested that the consent-giver must have adequate decision-making capacity, a good understanding of the procedures and the risks and benefits associated with these procedures, and must freely authorize the procedures.⁸

Despite previous work on enhanc-

ing patient understanding, there are no studies specifically connecting learning styles to informed consent. Recent educational literature supports the use of auditory, visual and kinetic stimuli to enhance learning and understanding. In this study, the effectiveness of patient verbalization as a learning style to enhance understanding has been investigated. The purpose of this study was to determine if accurate patient feedback will enhance preoperative understanding of associated risks and benefits of an anterior cruciate ligament (ACL) reconstruction.

PATIENTS AND METHODS

The study comprised patients having ACL deficiency who required elective reconstruction. Patients were acquired from a referral-based, outpatient, sport medicine clinic. They indicated their willingness to participate in this study after carefully reading an explanatory hand-out and providing written consent. Twenty patients with a diagnosis of ACL-deficient knees were randomly assigned to either a control group or an experimental group. The randomization process was intended to balance any significant differences in knowledge between the subjects in the 2 groups.

The control group (12 patients) received a standard surgical consultation, consisting of knee models, diagrams, open dialogue and informed consent to surgery. Three steps were involved. First, the surgeon (C.F.) constructed a diagram of the knee joint, indicated the bones, the muscles, the ligaments and the menisci

and explained the function of each structure. In doing so, the surgeon explained the medical problem of the ACL deficiency. Second, he described the condition of the joint, the rationale for reconstructive surgery and the associated risks and benefits of such a procedure. A 3-dimensional model was used so that the patient could appreciate the general anatomy and the basic mechanics of the knee joint simultaneously. Third, during the consultations, the patients had the opportunity to hold and manipulate the knee model. This demonstrates the use of kinetics in the learning process. After the surgical consultation was completed, the patients in the control group were required to provide informed consent.

Those in the experimental group (8 patients) were exposed to the same surgical consultation as the control group. However, immediately after the surgical consultation process described, they were required to accurately verbalize the associated risks and benefits of the procedure back to the surgeon. Patients repeated, to the same consulting surgeon (C.F.), using their own words, the risks and benefits of an ACL reconstruction. Any patients making errors during their verbalization of the risks and benefits were corrected until their verbalization was accurate. Upon completion of the consultation, the patients then provided informed consent. It is important to reiterate that the patients in the control group were not asked to repeat the risks and benefits of the surgery back to the surgeon.

One month after informed consent,

patients answered a 3-question questionnaire designed to measure patient understanding of the risks and benefits of ACL reconstruction (Fig. 1). The period of 1 month was an arbitrary but standardized period; the length of time was based mainly on the surgeon's waiting list. The questionnaire was read by the principal author (V.W.) to each patient in both the control and the experimental groups. The first question addressed the relative operative risks associated with the procedure. The correct response to this question was (c) numbness. The correct response to the second question, which also addressed operative risks was (b) 1%. The final question addressed the operative benefits of the surgery. The correct response to this

question was (c) 80%. The principle investigator (V.W.) repeated the responses to the patients for correctness and then recorded the responses. The control versus experimental data were analysed statistically by the Wilcoxon rank sum test, a two-sided analysis and Fisher's exact test, with an alpha level of $p < 0.05$.

RESULTS

In the control group, 1 patient failed to make any correct responses, 7 patients answered 2 out of 3 questions correctly and 4 patients answered all 3 questions correctly. In the experimental group all 8 patients answered every question correctly (Table I).

When we analysed the responses more specifically in the control group we found that different patients misunderstood different questions. Of 7 patients, 1 erred on the positive side with respect to the outcome of the surgery. This patient understood that the operation would restore knee stability to 100%. Two patients erred in their understanding of infection. One patient believed that the risk of infection was very low (0.001%) and another thought it was reasonably high (20%). Four patients made a similar error when questioned about their understanding of the most likely surgical risk factor — all 4 selected knee stiffness.

A statistically significant difference ($p < 0.03$) existed between the control

and the experimental groups, using a non-parametric analysis, the Wilcoxon rank sum test (Table II). This was supported by a significant difference of $p = 0.015$ by Fisher's exact test.

DISCUSSION

Our study suggests that patient verbalization did enhance understanding of the risks and benefits of ACL reconstruction surgery in a small series of patients. All those who were asked to repeat the risks and benefits of the procedure at the time of their consultation answered the questionnaire correctly 1 month later. In the control group, however, the fact that 1 patient could not answer any of the 3 questions correctly and 7 patients answered only 2 of the 3 questions correctly suggests that the more traditional consultation style is significantly more likely to lead to a misunderstanding of some of the surgical complications.

A closer look at how these misunderstandings may have influenced patient's perceptions of outcomes reveals some interesting factors. From the first question we were interested in determining what the patient understood to be the most likely surgical risk factor: stiffness, bleeding, numbness or death. The fact that 4 patients answered this question incorrectly suggests that patients may not have a clear understanding of the correct de-

Questionnaire on the Anterior Cruciate Ligament Reconstruction Procedure

1. Several risk factors are associated with an ACL reconstruction procedure (i.e., anterior knee pain, swelling, bleeding problems, etc.). From the list below, can you indicate one risk factor that is most likely to occur?

- (a) stiffness
- (b) bleeding
- (c) numbness
- (d) death

2. Infection is a risk factor associated with an ACL reconstruction surgical procedure. What percentage of people may experience deep joint infection with this procedure?

- (a) 50%
- (b) 1%
- (c) 0.01%
- (d) 20%

3. Your ACL-deficient knee will never be completely normal with reconstruction surgery. What is the percent chance that an ACL reconstruction surgical procedure will improve the stability of your injured knee?

- (a) 40%
- (b) 60%
- (c) 80%
- (d) 100%

FIG. 1. Questions asked on a preoperative questionnaire about the risks and benefits of anterior cruciate ligament reconstruction

Table I

Responses to Three-Question Questionnaire by Patients in Control and Verbalization Groups

No. of questions answered correctly	Group		Totals
	Control, n = 12	Verbalization, n = 8	
0	1	0	1
1	0	0	0
2	7	0	7
3	4	8	12

finitions of some medical terminology and confused immobility with stiffness. Through the second question we were interested in the patient's understanding of risk of deep joint infection associated with ACL reconstruction. A large range of potential responses was given but the correct response was 1%. The 2 patients who responded incorrectly to this question selected either 0.001% or 20%. Some surgeons would prefer their patients to think that there is a high risk of infection. We know that 1% of all patients will experience infection for no apparent reason. If patients are erring on the side of low risk (0.001%) and an infection occurs, they may place blame on the surgeon. Alternatively, if patients indicate that there is a high probab-

ity of infection occurring by selecting 20%, they are demonstrating that infection is a very real consequence of surgery. These patients may be less likely to place blame on their surgeons.

The final question addressed the operative benefits of surgery, specifically the chances of the injured knee becoming more stable as a result of an ACL reconstruction procedure. In this study, 1 patient chose 100%, which suggests that some patients maintain the perception that ACL reconstruction surgery will recreate normal knee stability. Clearly, this is not the case. ACL reconstruction has a very good chance of improving but not normalizing knee stability. This type of response implies that patients

may be overly optimistic about the ACL procedure, a perception that can be very dangerous if surgeons are unable to produce results that meet the expectations of their patients. Patients may consider poor surgical outcomes to be the fault of the surgeon and may initiate medicolegal action.

The inability of surgeons to keep their patients well informed does have legal implications. In 1980, the Supreme Court of Canada made a ruling that "physicians must disclose what a reasonable or prudent patient would want to know about the particulars of their management plans. In addition, they are required to answer questions posed by the patients. Failure to do so, may constitute negligence."⁹ This could have strong implications in that some physicians might have the impression that simple disclosure of information to patients is sufficient for understanding the material being presented. Sulmasy and colleagues⁸ suggested otherwise. Disclosure alone may not ensure understanding and, therefore, may not be sufficient for adequate informed consent. Traditional medical training teaches physicians to inform patients. Only recently, however, are specific communication strategies being incorporated into medical school curricula to enhance physicians' skills in the area of communication. Effective communication, leading to an increased level of understanding, may reduce the litigation that physicians encounter in their practices.

The fact that 4 patients in the control group answered all 3 questions correctly suggests that patient verbalization is not essential to achieve a reasonable level of understanding. The normal consultation protocol employed by the surgeon seemed to be effective for about one-third of the patients in this series. The use of optic (diagrams), auditory (open dialogue)

Table II

Rank, Group and Correct Responses to Questionnaire

Observation, no. correct responses	Group	Rank	Rank, adjusted
0	C1	1	1
2	C2	2	5
2	C3	3	5
2	C4	4	5
2	C5	5	5
2	C6	6	5
2	C7	7	5
2	C8	8	5
3	C9	9	14.5
3	C10	10	14.5
3	C11	11	14.5
3	C12	12	14.5
3	V1	13	14.5
3	V2	14	14.5
3	V3	15	14.5
3	V4	16	14.5
3	V5	17	14.5
3	V6	18	14.5
3	V7	19	14.5
3	V8	20	14.5

C = control, V = verbalization

and kinetic (knee models) stimuli were the learning tools used during the consultations for both the experimental and the control groups. These stimuli were sufficient for some patients to perform flawlessly on the questionnaire. However, it fails to explain why the two-thirds of patients in the control group did not answer all the questions correctly.

Some patients appeared to have difficulty in understanding the information disclosed to them during their surgical consultation because the patients in the control group were not required to accurately verbalize the risks and benefits of the surgery. There was no immediate feedback to these patients, but rather the assumption was made that disclosed information implied understanding. Also, several external factors may have affected performance. The capacity for patients to learn, understand and process information may have been compromised by distractions such as anxiety, fear and pain.¹ Subjectively, however, patients who appeared to be well educated, less anxious and more aware of their knee problem, appeared to score higher on the questionnaire. It might have been more appropriate to assess the patient's understanding in a more relaxed environment. The fact that the questionnaires were read before surgery may have provoked an anxiety response in some patients.

It is important to consider the limitations and strengths associated with this study. First, by having the questionnaire in a multiple-choice format, recall rather than understanding may have been measured. It is an assumption in this study that by answering the questions correctly, patients understood the content of the responses. Second, the groups were small and the randomization was not equal. However, these facts did not prevent the demonstration of a statistically significant difference. Fi-

nally, the intonation in the researcher's voice while reading the questionnaire to the patients may have inadvertently influenced patient response.

Several strengths balanced these limitations. First, the investigation was controlled in that it involved a single surgeon who carried out the same surgical consultation with each patient. The only variable between control and experimental groups was patient verbalization. Second, this study was prospective in that all of the patients were exposed to the same surgical diagrams, knee models and discussion points focussing on the complications of ACL reconstruction surgery. All patients were required to give consent before surgery, and each patient answered the questionnaire before surgery. This ensured that the patients did not use the experience of the surgery to facilitate their performance on the questionnaire.

Based on the results of this study, we recommend the use of patient verbalization to enhance patient understanding of surgical procedures. One potential criticism of implementing this tool into a clinical setting is the time needed to effectively communicate to patients. Some surgeons may claim not to have the time to communicate with their patients. Perhaps the use of pretests may facilitate surgical consultations. These tests have been suggested to be useful tools in screening patient knowledge.⁹ It was not in the scope of this study to assess such pretests, but it would be interesting to compare the effectiveness and efficiency of such tests to that of the verbalization method used in this study. Other studies could involve the use of non-verbal communication with respect to how patients perceive the quality of time that their physicians spend during consultation and the associated impact on learning and understanding.

Despite the positive nature of tra-

ditional physician-patient interactions, most patients continue to lack complete understanding of complications surrounding their medical conditions. We do not really know which method of interaction is best for facilitating understanding. But, we do know that keeping patients informed will be very important in the 1990s and beyond. In this study, under the conditions described, data demonstrate that patient verbalization performed during a consultation can enhance patient understanding.

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