

Patients' Point of View on Informed Consent: A Prospective Study of Carpal Tunnel Surgery

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Abstract

Patients' perception of consent form (CF) is not well known and many patients tend to view the CF as an administrative act.

As part of a prospective study, a questionnaire was sent to 188 consecutive patients within 1 month after carpal tunnel release. Questions focused on patients' recall about risks, benefits, alternative options, preferences about the decision process and global satisfaction with CF. Patient's understanding of the legal consequences of the CF was analysed.

Risk's recall rate was 59%. CF reduced preoperative anxiety in 65% and the influence in patients' decision was relevant in 55% of cases. Patients have limited understanding of the legal consequences of the consensus and 29% of patients believed that primary function was to protect the hospital. Ten percent believed that CF expunges patients' right to compensation in case of claims.

Patient involvement in medical decision-making is a key aspect of patient centred care. A substantial uncertainty exists about legal implication of CF, leading to potential discord.

In ethical terms the role of consent to treatment is to safeguard and respect patient autonomy¹⁻⁵ and in Switzerland consent is formally required for any invasive procedure.

Patients' perception of informed consent, and globally, of the consent process is not well known and our experience suggests that many patients tend to view consent as a routine act, neglecting the role of the decision making instrument serving their interests. Many patients may feel frightened by the consent form (CF) and uncertain about the implications of signing it. In our unit, consent is a process of mutual exchange of information and it is obtained by combining verbal and written information.

For further improvement of the informed consent procedure it is crucial to understand patients' attitude and the

emotional impact of the information given preoperatively. The aim of the study was to assess the patient's satisfaction with the preoperative information using a questionnaire designed in collaboration with the Hospital Quality Service.

Materials and Methods

The study was conducted prospectively in the Hand Surgery Unit in 2009 among patients with unilateral carpal tunnel syndrome, confirmed with electrodiagnostic testing, and resistant to conservative treatment (splint and/or cortisone injection) during at least 3 months. The written consent form was standardized, provided by the surgeon, and approved by the hospital. It includes 1 standard drawing of the procedure.

Two preoperative standard visits were planned. The first visit took place 6 weeks preoperatively. The written CF was read with the patient and explained by the surgeon in the office in a process-oriented approach ("ask-tell-ask"). The CF was then given to the patient and the patient was allowed to contact the surgeon for any additional questions. Patients are requested to return the signed CF at least 2 days preoperatively. A second preoperative visit was done just before surgery, at which time the surgeon ensured that the preoperative information was sufficient and understandable.

Within 1 month after their operation, letters were sent to 188 consecutive patients who had undergone elective open carpal tunnel release in regional anaesthesia, inviting them to participate in a survey. The study group included 129 women, and the mean age was 67.2 (range, 21-97 years). The questionnaire was established by qualitative research of previous questionnaires⁶⁻¹⁰ by the Hospital Quality Service. The questions focused on patients' recollection of information concerning risks and benefits and alternative options, preferences about the decision process, and global satisfaction with the informed consent procedure. Qualitative comments volunteered by patients were recorded as notes.

Results

The standard allocated time for a carpal tunnel preoperative visit was 20 minutes. The effective mean time for the first appointment was 18 minutes (range, 13-21 minutes). The immediate preoperative visit lasted 8 minutes (range, 5-12 minutes).

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Three of 188 patients (2%) called the surgeon to get more information about the operation after the first visit. Three others underwent the consent process and subsequently declined the operation. These patients postponed the surgical procedure for personal reasons, but had surgery 5, 7, and 11 months later, respectively, because of persistent symptoms. None of the patients changed their mind about the operation during the second preoperative visit.

All patients had rapid wound healing with no significant complications and returned to normal activities within 5 weeks. At the final 3-month follow-up, 90% of patients had significant or complete resolution of paresthesia.

None of the patients required additional surgery and pillar pain was seen in 21% of the patients. Overall, 137 out of 188 patients replied to the anonymous questionnaire (response rate 73%).

“Alarming, we observed that there was substantial uncertainty about the legal implications of signing the [consent form] ... our series indicated that approximately one-third of the patients thought the primary function of the form was to protect the hospital.”

Quality of Information

Information from verbal questions was rated as of excellent or good quality by 65% and 35% of patients, respectively. Written information was rated as of excellent or good quality by 47% and 53% of patients, respectively. None of the patients rated either verbal and written information as fair or poor.

Scope of Consent

For 79% of the patients, the CF clearly explained carpal tunnel syndrome, as well as what was going to happen before and after the operation (72% and 66%, respectively). One month after the surgical procedure, risks of the procedure were remembered by 59% of the patients and facts about alternative procedures by 36%.

Emotional Impact

The CF reduced preoperative anxiety in 65% of the patients. Furthermore, it did not affect the patient's emotional status in 30% of the patients, and frightened 5% of the patients.

Need for Additional Information

Overall, 87% of the patients did not require more information about the operation, 9% looked for complementary information on the Internet, and 5% looked for a second opinion.

Relevance of the CF in Patients' Therapeutic Choice

Although 45% of the patients were convinced by the general practitioner to go ahead with the operation, the hand surgeon influenced 67% of these during the verbal explanation of the operation. The influence of the CF in patients' decision was rated as relevant by 55% of the patients, helpful in 15%, and of no influence by 30% of the patients.

Value and Function of the CF

Overall, 36% of patients reported that signing the CF was important and helpful in their final decision. Many patients (76%) understood that there are risks involved in having surgery but only 43% knew that the CF was legally required to have the surgery. Almost 1 in 3 patients (29%) were convinced that the CF was mainly meant to protect the hospital and the surgeon, and 10% of the patients believed that the CF invalidated patients' rights to compensation in case of claims. Two percent of patients saw it just as another piece of paper in a ritualistic-bureaucratic process.

Discussion

Patient involvement in a medical decision, even in routine acts,⁴ is a key aspect of patient-centred care.¹⁻¹² There is a growing body of literature that supports the view that the majority of patients prefer to be involved in a clinical decision affecting their health.^{4,10-17} Patient involvement is justified by the ethical principle of autonomy,¹⁻⁵ and the role of consent to treatment is meant to safeguard this autonomy.¹⁻⁵ Consent may be defined as the voluntary permission of the patient to receive treatment based on their understanding of the procedure and inherent risks in addition to its likely success and alternatives.

This study sought to define standards for the quality of informed consent, since the consent process is extremely variable and country-dependent in terms of legal requirements and cultural differences. Alarming, we observed that there was substantial uncertainty about the legal implications of signing the CF. Similar to previous studies,^{9,18} our series indicated that approximately one-third of the patients thought the primary function of the form was to protect the hospital, while 10% thought that signing the CF undermined their rights to compensation. A lack of awareness of the scope of the CF may influence the rapport of trust between patient and surgeon. This could lead to an asymmetrical relationship, a source of potential discord, even the existence of a straightforward relationship between rights knowledge and ability to exercise these rights was not demonstrated between the patient and surgeon.¹⁹

Legal authorities have attempted to provide some guidance by suggesting that it is the physician's duty to disclose risk increases with the magnitude of the risk. This could lead to patients underestimating the potential risks of carpal tunnel surgery, neglecting the informative aspects of this procedure, and wrongly consider them as insignificant. Indeed, Kahn and Giddins²⁰ demonstrated that claims are clustered to a few common conditions such as carpal tunnel surgery, compared with complex hand surgery. Professional standards do not provide explicit guidelines regarding the disclosure of risks, but as-

sert that it is the doctor's duty to disclose what a reasonably prudent physician with the same background, training, and experience would have disclosed to the patient in the same or similar circumstances.

Informed consent is a legal requirement for all invasive procedures in Switzerland, and the surgeon has a legal duty to provide information in a complete and comprehensible way. In our unit, consent is a process of mutual exchange of information and is obtained by combining verbal and written information in a process-oriented approach ("ask-tell-ask") that promotes tailored conversation in a time efficient model,^{15,16} favoring qualitative rather than quantitative aspects of the information given preoperatively. Written information is based on the proposed guidelines of Goubier and colleagues.²¹

The results of our study confirm that preoperative information satisfied the patient's expectations, clearly explaining the surgical procedure and enabling them to, in-turn, explain it to family and friends. Compared with the study by Reynolds and colleagues²² demonstrating that approximately half of patients awaiting physical examination or treatment are unhappy with the amount of information received, our study showed that patients' satisfaction rate with the preoperative information provided was very high. This difference may be due to patient selection bias and the type of surgery evaluated in our study.

It is somewhat disconcerting that 21% of patients did not understand what carpal tunnel syndrome was preoperatively, or what was going to happen before, during, and after surgery. This might be considered as a failure of the informed consent, but in our opinion, it suggests that highly symptomatic patients may be resigned to undergo surgery, disappointed by the ineffectiveness of the conservative treatment, and therefore less likely to pay attention to the CF. As reported by Lavelle-Jones and colleagues,⁶ advanced age and low educational level affect quality of the informed consent and information recall. This could explain the results in our study, which was performed in a rural region.

One month after the surgical procedure, only 59% of our patients could recall the risks of the operation, while only 36% remembered an alternative to the surgical procedure. Information recall in the context of informed consent has been reported as poor by many authors in different settings^{6,23-26} varying from 18% to 81% for surveys conducted on the same day as the provision of the information. It was not the aim of the study to analyze the ability to recall preoperative information, but our data suggest that it would be very dangerous to consider an implicit acceptance when performing the second contralateral decompression in a patient with bilateral carpal tunnel syndrome.

Interestingly, despite supposed omissions in the informed consent, most patients viewed the explanation as of good to excellent quality. Too long of an interval between medical consultation and surgery impairs information recall,⁶ particularly in elderly patients.⁶ Waiting lists should be kept as short as possible as the decay of information retention may be relevant in litigation, when patients are expected to recall information they received many months previously. Failure to recall

may occur because of medical omission or patients' inability to understand, assimilate, or recollect information. Using a written CF seems to have a minor impact on recollection,⁶ while printed information leaflets have been demonstrated to influence information retention.²⁷ A retrospective survey of 200 patients showed that those who had received written leaflets were significantly more satisfied with the information, compared with patients who did not receive leaflets.²⁸

We could not analyze whether the severity of the median neuropathy affects recall, but it is likely that patients subjectively more symptomatic—which does not necessarily mean with more severe objective findings—will accept the surgical procedure more easily. The anonymous nature of the questionnaire makes it impossible to correlate medical comorbidities with recall of the consent process and details. Another study²⁹ has shown that diagnosis can influence a patient's preference to participate in medical decision-making; patients reporting to be in better health tended to play an active role in treatment decision making. Mei-Ling and colleagues³⁰ observed that patients with fewer hospital and surgical experiences participated more fully in the medical decision-making process. These patients might be unfamiliar with situations related to surgery, which compelled them to actively participate in the informed CF.

Literature suggests that in a general practice, patients might be equally satisfied by seeing an unknown doctor as by a known one.³¹ We believe that, in the CF process, it is important that preoperative information is provided by the operating surgeon. With this strategy, only 9% of patients in our unit sought additional information on the Internet.

This data should be analyzed with prudence because our patients are elderly and of rural origin, and the literature suggests that more than 80% of adults use the Internet to get medical information.³² The apparent and supposed harmlessness associated with carpal tunnel surgery may influence the findings in our study, and challenge the completeness of the information in comparison with patients armed with printouts from the Internet. Benefits of the Internet include higher-level discussions, increased patient engagement, and more effective shared decision-making.³³ Disadvantages include the need to rectify wrong, uncontrolled, or incomplete information. Since this study, the website of our unit has been updated with preoperative information.

In our patients, the CF had a positive effect on the self-assessed anxiety level. Our study analyses the practice of informed consent after the performance of the surgical procedure and this must be considered as an important point in the analysis of our results particularly in term of anxiety. The emotional impact of the CF before and after surgery is different, and it could be suggested that after the procedure anxiety decreases independently from the quality of the consent process.

Kerrigan and colleagues³⁴ demonstrated that in elective inguinal hernia repair, a very detailed account of what might go wrong does not increase patient anxiety. Stanley and colleagues³⁵ studied whether the provision of more extensive

information altered patient anxiety levels, and found that it was unaltered by an increase in the information they were given. Whether this applies to more complex surgery remains to be seen, and at times of stress, many patients do not absorb information. In a series by Lavelle-Jones and colleagues,⁶ 69% of patients admitted to not reading the CF; in our series, only 2% of the patients did not read the CF. In the series by Lavelle-Jones and colleagues,⁶ patients underwent major surgery (eg, thoracic, vascular, abdominal) and it is not known to what extent they had the choice of refusing nonsurgical alternatives. It is possible that the patients perceived the CF merely as an administrative procedure. Excessive worry about the surgery is possible, particularly in major surgeries; this may influence the retention of information.

It has been shown that increasing overhead costs and paperwork make it more difficult to spend quality time with patients.³⁶ We did not measure the time spent on the consent explanations, CF was perceived as a relevant decisional tool. The recorded time of visit is only indicative of the time spent in CF explanations, as it is impossible to exclude that during this time the patient was questioned on issues not directly related to the surgical procedure. Visit length may differ between doctors and procedures, therefore our data cannot be generalised. The skill of the surgeon in using time well, rather than simply how long the visit lasts, is in our opinion the more important factor in the outcome of the consent process.

In a series of Braddock and colleagues,¹⁵ the extent of informed decision-making only had a modest impact on the duration of the consultation. The informed consent process is more rigorous among patients undergoing complicated surgical procedures and possibly over the course of several preoperative encounters with a different impact on the duration of the process.

Family plays a significant role in healthcare decisions, especially in Asian culture, even if the patient is cognitively capable.³⁰ We could not analyse this influence because in our practice, in our sociocultural environment and for this type of apparently harmless procedure the majority of the patients prefer to participate alone in the surgical decision making. Only patients who perceived their surgery to be more important expected and demanded family participation.

Since patients' preference in family involvement in the CF process is variable, the patient should be the first one to be informed and the family can then join the process according to the patient's desire. Alternatively, as patients take the CF home, we cannot exclude family involvement in the decision-making process. Family can act as a protective buffer between patients and healthcare professionals, and it may help the patient in understanding the information, but this could not be determined in our study.

A limitation to our study is represented by the selection bias of patients who are addressed to our surgical unit by the general practitioner after exhaustion of conservative measures. General practitioners have a relevant role in counselling patients about surgical procedures and they can be a useful source of information thanks to their longstanding patient-physician

relationship.

Many patients, who have undergone conservative treatment or had additional tests, will have several conversations with their general practitioner and the neurologist. Nonsurgical doctors therefore already provide information about the surgical procedure. It is difficult to determine whether the informed consent process performed by the operating surgeon as well as the patient's emotional impact of the CF is influenced by what patients are told by other doctors. Carpal tunnel surgery has generally a high satisfaction rate and this may positively influence the postoperative patient's perception of the preoperative information; the anonymous nature of our questionnaire makes further analysis impossible.

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