Informed Consent in Oral Surgery: The Value of Written Information

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Objective: To evaluate the efficacy of the written explanation given to patients when obtaining informed consent for oral surgery, taking the surgical extraction of the impacted mandibular third molar as the clinical model for this study.

Patients and Methods: This study included 87 patients requiring surgical extraction of an impacted lower third molar. Residents of the Oral Surgery Department explained verbally and in writing 7 possible complications that could arise as a result of the operation, after which informed consent was obtained from the patient. These complications were as follows: altered sensation of the homolateral lower lip and chin; altered sensation of the tongue; swelling; trismus; pain; allergies; and infection. The patients completed a Corah anxiety test on the same day, as well as a preoperative questionnaire about their level of understanding of the informed consent. Seven days after the operation, the patients returned to have their stitches removed and for a postoperative interview.

Results: A total of 87 patients participated in the study. Of these, 64% (n = 56) had understood the objective of the informed consent. All but 1 (1%) of the patients remembered having been informed of the possible risks before the operation. Changes in sensation of homolateral lower lip and chin (98%, n = 85) and of the tongue (86%, n = 75) were among the complications most recalled by the patients. Ninety-six percent of patients (n = 84) preferred to be informed preoperatively, and 71% (n = 61) described the signs and symptoms to be exactly as explained by the residents.

Conclusions: Patients do not remember the majority of the information they receive before giving informed consent. Paresthesia of the lower lip and chin on the operated side and of the tongue are among the most recalled complications. This may be due to the seriousness of this complication, to the effect it can have on the patients’ daily life, and to the possibility that it may be irreversible.

Obtaining informed consent implies, among other factors, explaining to the patient the nature and purpose of the treatment, its results and associated risks, as well as any possible alternative treatments.1

To obtain informed consent from a patient for medical or dental treatment, the following 3 conditions must be fulfilled: 1) the patient’s ability to make a sensible decision: is the patient able to give consent? 2) has the informed consent been given voluntarily? and 3) has the patient been adequately informed before the operation?2

Article 10.5 of the Spanish General Law of Public Health states that all users of the various public administrations have the right “to be given, in comprehensible terms, to themselves and their families or relatives, complete and continuous information, both

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Patients and Methods

Eighty-seven patients from those requiring surgical removal of an impacted lower third molar at the Oral Surgery Department of the Dental Clinic of the University of Barcelona between January and April 2005 were selected for the study. The study protocol was approved by the Institutional Review Board of the Dental School of the University of Barcelona (Ethical Committee of Clinical Investigation).

On the first visit, a previously trained resident explained verbally to the patients in an orderly manner 7 specific risks associated with the surgery. Next the patients were given an information sheet describing the same 7 complications, in nontechnical language, to aid their understanding (Table 1). The following 7 complications were explained:

1. Dysesthesia of the lower lip and chin on the operated side: the explanation was given using nontechnical terminology, being described as either temporary or permanent tingling, tickling, or numbness of the area.

2. Dysesthesia of the tongue using the above terminology.

3. Edema, described as swelling and inflammation of the cheek.

4. Trismus described as temporary difficulty and limited mouth opening.

5. Pain.

6. Allergic reaction to local anesthetic, or medication administered before, during, or after the operation.

7. Postoperative infections.

Once the patients had comprehended and indicated that they understood the possible risks set out on the written form, they were asked to sign the same to that effect. The patients also signed the standard informed consent form, containing the same explanations.

Subsequently, the patients completed a short questionnaire about their perception and level of understanding of informed consent, together with various demographic data (name, age, gender, and education), and then took an anxiety test (Corah Anxiety Scale).2
Seven days after surgery, the patients returned for suture removal and a postoperative interview with the same resident as on the first occasion.

The session began by asking if the patients remembered being informed about the risks inherent in this surgery, and recording those recalled (open questioning). If the patients had no recollection of being informed, or could not remember the 7 possible complications during open questioning, they were asked in detail if they remembered being informed about each of the 7 risks individually (directed questioning). All the answers were noted in a specifically designed questionnaire (Table 2).

The results were analyzed using the Statistical Package for the Social Sciences (SPSS version 12.0; SPSS, Chicago, IL).

Results

Eighty-seven patients (41 men and 46 women) (100%, n = 87) took part in the survey; all agreed to attend a postoperative interview. The mean age was 25.9 yr, with a standard deviation (SD) of 5.6 yr. The anxiety level of the sample, measured using the Corah Scale, was 9.7 (SD = 3.3) in the men and 10.7 (SD = 3.6) in the women (range 5 to 20).

Regarding education, 24% (n = 20) of patients had completed primary education; 49% (n = 42) had secondary education or professional training; 11% (n = 9) had a diploma; and 17% (n = 14) had a degree. Two patients did not reply to this section.

When asked “Do you know what informed consent is?” 64% of patients (n = 56) replied affirmatively, while 36% (n = 31) did not know its function. Two patients (4%) who replied affirmatively did not write down any function when asked to do so. The replies...
of those patients who answered affirmatively are shown in Fig 1.

Figure 2 compares understanding of the function of informed consent with patient education. When asked “Do you believe you have the right to refuse surgery?” 84% (n = 73) of patients replied affirmatively, while 16% (n = 14) thought that they could not refuse to be operated on. Figure 3 shows the level of patient education compared with the answer to this last question.

The results from the interview conducted 7 days after surgery were as follows. Apart from 1 patient (1%, n = 1), all remembered at least 1 postoperative complication (99%, n = 86). Figure 3 shows the complications most remembered by the patients. Paresthesia of the inferior alveolar nerve (98%, n = 85) and of the lingual nerve (86%, n = 75) were the most often remembered complications.

When the patients were asked for their opinion on receiving information preoperatively on the possible complications associated with the surgery, 59% (n = 51) thought it was necessary; 30% (n = 26) reported feeling more afraid; 7% of those surveyed (n = 6) believed they were more nervous; 3% (n = 3) commented that it was a way of determining the incidence of postoperative complications; and 1% (n = 1) considered it was a form of legal protection for the oral surgeons.

Finally, when the patients were asked if the postoperative signs and symptoms had been as described before surgery, 71% (n = 61) replied that their postoperative period had been similar to that explained before surgery. Sixteen percent (n = 14) reported having had a better recovery than they themselves had imagined or had been explained to them; 11% (n = 10) said they had experienced a worse recovery than they had expected or had been explained, while 2% of patients (n = 2) reported a longer than expected postoperative period.

Discussion

From a legal point of view, the most important risks associated with the extraction of an impacted third molar are damage to the inferior alveolar nerve and the lingual nerve. As can be seen in various studies,1,2 and as shown by the results of this study, lingual paresthesia and paresthesia of the homolateral lower lip and chin are the complications most recalled by patients. This may be due to the important qualitative changes they can cause to the patients’ quality of life, and to the possibility of leaving irreversible sequelae.

Health professionals should provide their patients with the maximum possible information about the treatment to be undertaken, alternative treatment options, and their possible complications.4 However, Layton5 showed that the exclusive use of verbal communication to inform a patient about complications in surgical removal of impacted third molars was inadequate and insufficient.

The use of verbal communication together with written information significantly improves the understanding of information received preoperatively by the patient.5 In addition, a greater degree of satisfaction was observed in those patients who had been informed verbally and in writing.5 In the present study, all patients were informed in this way, and only 1 was unable to recall any complication from those about which they had read and been informed.

Mohamed-Tahir et al6 carried out an observational study, using questionnaires and interviews, to determine whether parents of children who were to undergo surgery using general anaesthetic fully understood the proposed treatment. These authors observed that 40% of written consent forms elicited from parents or legal guardians were not valid as the treatment plan had not been properly understood, even when subjects had been adequately informed beforehand.

Although preoperative examination and diagnosis of a patient are unable to foresee all the complications
of a surgical operation, as commented above, it must be ascertained that the patient understands the treatment to be undertaken together with its possible complications. However, as can be seen in some studies, this basic obligation of all clinics is not fulfilled in most cases. In a survey carried out to determine the level of compliance with patients’ rights by dentists, 50% of participants responded that either their dentist never asked for their consent to carry out dental treatment or they were not informed about the risks of the dental treatment. In another study it was found that 66.3% of oral surgeons stated that they verbally explained the possibility of nerve damage during extraction of an impacted lower third molar; 29.7% routinely gave their patients written information about this possible complication, and 4% stated that they gave neither verbal nor written information about possible nerve damage.

Currently, litigation affecting the dental profession is increasing slowly but steadily. A considerable proportion of lawsuits are due to lack of understanding between surgeon and patient, and not to errors in treatment. Surgeons frequently focus on the legal requirements of informed consent and neglect to explain the possible complications after surgery. By contrast, patients tend not to ask about possible complications. A review of state and federal civil lawsuits in the US between 1987 and 2000 on lingual nerve damage found that 52% of claimants had not been properly informed, and that 46% of lawsuits were related to dental extraction.

The patient’s right to refuse treatment is provided for in Article 10.9 of the Spanish General Law of Public Health. A patient only loses this right “when urgency does not allow delay due to the possibility of causing irreversible damage or where there is a danger of death.” However, in the present study, 16% of patients (n = 14) were unaware they could refuse surgery. This may be because many patients on attending the first interview and signing the informed consent feel in some way “obliged” to be operated on. Not knowing the right to refuse surgery was associated with lack of higher education, because, of these 14 patients, 13 (93%) had only completed primary or secondary education or vocational training.

In a study that aimed to examine the level of communication between dentist and patient, and to determine the degree of satisfaction with the dental treatment performed, it was observed that those patients who decided on the treatment option for themselves were significantly more satisfied with the patient-dentist communication than those patients for whom the dentist decided the treatment. Further, patient satisfaction was directly related to the dentist’s communicative behavior. In the present study, 96% of patients (n = 84) were in favor of being given information before undergoing surgery, and 70% (n = 61) stated they had been adequately informed.

By contrast, due to patient overload in oral surgery departments in this country, obtaining informed consent is often reduced to a routine activity, and probably the patient (tired of waiting) very often does not pay the necessary attention.

From a medicolegal point of view, the most important risks associated with extraction of an impacted third molar best remembered by a patient are paresthesia of the homolateral lower lip and chin and the tongue.

Although many patients agree with being informed of possible risks caused by surgical removal of a third molar, a majority do not recall much of the information they are given during the informed consent process. Most patients stated that the postoperative signs and symptoms were exactly as described by the residents before surgery.

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