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Patient Recall in the Informed Consent Process

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Patient Recall in the Informed-Consent Process

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ABSTRACT

Introduction: **Informed consent is extremely important in healthcare practice. It is a frequently discussed topic in medical ethics. Research shows that when patients sign a consent form, in many cases, they do not understand or recall the information that was presented to them. The authors attempted to determine how much information patients retain.**

Methods: **This is a prospective, double-blind, pilot study of patients presenting to the Oral and Maxillofacial Surgery Outpatient Clinic of the Brooklyn Hospital Center (TBHC) for the extraction of wisdom teeth. Patients postoperatively completed a ten-question data collection tool inquiring about substantive information provided to them in the preoperative informed-consent process. The number of correct answers were compared at two points in time.**

Results: **One hundred and eight patients were interviewed at one week and one month after surgery. Our patients demonstrated a statistically significant (<0.005) decrease in their understanding and recall of the information in questions 3 through 10 on the questionnaire. The number of correct responses was not dependent upon age. Three questions were associated with educational level. Overall, there was a definite decrease in the retention of vital information within a short time period.**

Conclusion: **The study supports the need for new approaches to the informed-consent process.**

Although the concept of informed consent is critical to quality patient care,[1] its successful application is still an issue in medicine and, as a result, it is thoroughly discussed in medical ethics.[2] Importantly, informed-consent issues are consistently the cause of medical malpractice claims filed against healthcare practitioners.[2]

The law of informed consent requires the medical practitioner "to make a reasonable disclosure to the patient regarding the nature, probable consequences and dangers of the proposed treatment" and that "any surgical operation without the patient's consent could be considered assault."[1] The American Association of Oral and Maxillofacial Surgeons also has outlined policies regarding informed consent.

One of the challenges is that informed consent is complicated by constraints, such as patient comprehension, patient use

of disclosed information, recall and patient autonomy.[3] For instance, Hutson and Blaha conducted a study of patients undergoing elective orthopedic surgery.[4] They found that 70% of the patients could not recall the risks and 60% could not recall the benefits associated with their surgery six months later.[4] Unfortunately, research has also shown that patients, in court during medical malpractice cases, deny that information was provided to them during the informed-consent process.[1]

This led the authors to raise the two following questions: 1) how much of the information provided to the patient during the informed-consent process is actually retained after one week; and 2) how much of the same information provided to the patient during the informed consent process is actually retained by them after four weeks. This study was designed to answer these questions. Retention of information was tested one week and four weeks after surgery. The authors hypothesized that patients do not recall the information that is provided to them during the informed-consent process and that as time passes, retention and recall of information decreases.

Methods

A prospective, double-blind pilot study was designed. Patients aged 18 to 65 years presented to the Oral and Maxillofacial Surgery Clinic of the Brooklyn Hospital Center (TBHC) for third molar surgery between September 2018 and March 2019. This study received approval from TBHC's Internal Hospital's Review Board [IRB Number is 16-018]. All authors read and adhered to the guidelines of the Helsinki Declaration. Consent was received from each patient to be included in this study.

Data Collection

Data was obtained by patients filling out a questionnaire one week and one month after the treatment appointment. In order to ensure standardization, the patients were interviewed at exactly 7 days and 28 days after their procedure. Some interviews were collected over the phone. The patients were not told the correct answers following the first time they took the test. To be included in the study sample, patients had to be 18 years of age or older; require third molar surgery and present to the clinic for treatment; be able to consent for themselves (no mental impairment); understand, write and read English; have an oral surgery resident consult on their care; and have a complete record generated. Patients were excluded if they were under the age of 18, had incomplete data sets or were prisoners at the state or federal level.

The oral and maxillofacial surgery residents of TBHC had prior knowledge that a study on the recall of the informed-consent process was being conducted. The verbal information was standardized. Initially, a script was written by the primary author and subsequently provided to the residents. The residents were asked to review the script for any suggestions and/or questions. One

week later, the team met and reviewed the script. The written consent form that was given to the patients to sign was provided to the department by the hospital. Lastly, the residents were instructed to contact the primary author regarding each third molar surgery they performed.

In order to be able to appropriately answer the questionnaire, it was required that each study participant needed maxillary and mandibular wisdom teeth extractions. One hundred percent of the original 108 patients completed the follow-up questionnaire one week and one month after the procedure. Informed consent was provided to the patient at the consultation appointment and again at the treatment appointment by the same provider. All patients were booked for their surgery two weeks after the consultation appointment. The informed-consent process involved the script and a verbal discussion with the patient.

Each participant was asked to complete a questionnaire consisting of 10 questions. The questionnaire was written by the primary author, an oral and maxillofacial surgery resident with knowledge of the procedure. The test included questions regarding the procedure and complications.

Variables

The primary predictor variable is the time between the consent and completion of the questionnaire. The primary outcome variable is the number of correct answers. The secondary predictor variables are age, gender and educational background.

Analysis

Results were analyzed by a physician with a degree in statistics. The analyst was provided with the raw data with no access to the patients and the questionnaire.

First, a McNemar test was run to see if there was any change in the patient recall from week one to week four. Next, a chi square test was run to determine if age and educational level affect the change of recall from week one to week four. The groups were split into those under the age of 50 and those over the age of 50. Educational level was split into those who had not graduated from high school and those who had. A logistic regression test was then run to see if there was a correlation between education level and a change in patient recall from week one to week four. Last, an odds ratio was run to determine a higher level of education affecting the likelihood of people not changing their answers from week one to week four compared to those who did change their answer.

Power of the Study

Alpha was taken as 0.05 and beta was taken as 0.08. When assuming these two thresholds, the sample size needed to perform this study was 85 patients.

Results

One hundred and eight patients completed two questionnaires at 7 days and 28 days after their surgery. An informed-consent discussion occurred the day of the consultation and two weeks later, on the day of surgery. The demographics of the patients are provided in Table 1. The average age was 38 years, with a range of 18 to 62 years. There were 23.5% male participants.

TABLE 1

Demographics and Percentage of Correct Answers

Men	23.50%
Age	38
Number of correct responses (One-week follow-up)	63.61%
Number of correct responses (One-month follow-up)	27.13%

Table 2 presents a breakdown of the number of correct responses per question at the 7-day follow-up and 28-day follow-up. There was a statistically significant decrease in the number of correct answers for 8 out of the 10 questions. Table 3 presents the interaction between the covariates (age and education level)

TABLE 2

Percentage Responding Correctly by Question Type

Questions	One-Week Follow-Up	One-Month Follow-up	P value
Oral Antral Communication is fluid coming out of the nose when one drinks something	100%	71.40%	N/A
Nerve Injury is damage to the nerve that gives sensation to lips and chin	100%	53.80%	N/A
Nerve injury will affect the ability to feel sensation on lips and chin	76.90%	15.30%	<0.001
Swelling after the procedure will become worse on the second day after the surgery	76.40%	35.30%	<0.001
Dry socket will occur from spitting after the procedure	38.50%	7.70%	<0.001
Dry socket can cause pain going up to the ear	23.10%	7.70%	0.001
All wisdom teeth do not need to be taken out	23.10%	7.70%	0.003
Wisdom tooth extraction can result in loss of the ability to taste food and in loss of sensation in the tongue	41.20%	23.50%	0.009
Infection after surgery can occur	76.90%	35.30%	<0.001
During the procedure, one may feel some pressure	76.90%	15.30%	<0.001

and time. Patient recall of questions 2, 6 and 9 (nerve injury, dry socket and infection) were statistically significant for educational level.

Discussion

Interpretation of Results

The primary aim of the study was to determine if there is a decrease in recall of the informed-consent process over a short period of time. The secondary aim of the study was to determine if the recall is affected by the age, gender and educational background of the patient.

Our study showed that there is a definite decrease in the retention of vital information within a short time period. Our patients demonstrated a statistically significant decrease in the recall of questions 3 through 10. This decrease in retention, we surmise, would increase if measured after a longer length of time. One would expect to have a significant amount of forgetfulness over a longer period of time. Even on a short-term basis, there is a loss of recall. This is noteworthy and counterintuitive.

It has also been suggested that understanding and retention of information can be influenced by the age and education level of an individual.[1,12] For this reason, age and education level were evaluated as a secondary predictor value.

Our results demonstrated that education level influenced the number of correct answers in 3 out of the 10 questions. One question was about the innervation of the trigeminal nerve to the lower lip and chin. This can be a difficult piece of information to retain. The last question spoke of treating a postoperative infection with antibiotics alone. From the author's clinical experience,

TABLE 3

Interaction of Covariates with Time

Questions	Covariate (Age) interaction with change in recall	Covariate (Educational Level) interaction with change in recall
Oral Antral Communication is fluid coming out of the nose when one drinks something	0.634	0.072
Nerve Injury is damage to the nerve that gives sensation to lips and chin	0.329	<0.001
Nerve injury will affect the ability to feel sensation on lips and chin	0.628	0.177
Swelling after the procedure will become worse on the second day after the surgery	0.289	N/A
Dry socket will occur from spitting after the procedure	0.731	0.959
Dry socket can cause pain going up to the ear	0.336	0.049
All wisdom teeth do not need to be taken out	0.634	0.634
Wisdom tooth extraction can result in loss of the ability to taste food and in loss of sensation in the tongue	0.124	0.602
Infection after surgery can occur	0.448	0.001
During the procedure, one may feel some pressure	0.359	0.359

Figure 1: Data Collection Tool (one week after surgery)

1. Oral Antral Communication is:
   a) Fluid coming out of the nose when I drink something
   b) Damage to the filling on my tooth
   c) A hole in my gums
   d) I do not remember hearing this information during my informed consent

2. Nerve Injury
   a) Will affect my ability to speak and eat
   b) Is damage to the nerve that gives sensation to my lips and chin
   c) Will affect my ability to smile
   d) I do not remember hearing this information during my informed consent

3. Nerve injury
   a) Will affect my muscle movement
   b) Will affect my ability to feel sensation on my lips and chin
   c) Will definitely not occur
   d) I do not remember hearing this information during my informed consent

4. Swelling after the procedure
   a) Is not normal
   b) Should only last for one day
   c) Will become worse on the second day after the surgery
   d) I do not remember hearing this information during my informed consent

5. Dry socket
   a) Happens to everyone
   b) Will occur from spitting after the procedure
   c) Will get better if I take pain medication
   d) I do not remember hearing this information during my informed consent

6. Dry socket
   a) Can cause pain going up to the ear
   b) Will get resolved if I take pain medication
   c) Is an infection in my mouth
   d) I do not remember hearing this information during my informed consent

7. All wisdom teeth
   a) Must be taken out
   b) Do not need to be taken out
   c) I do not remember hearing this information during my informed consent

8. Wisdom tooth extraction
   a) Can result in loss of the ability to taste food
   b) Can result in loss of sensation in the tongue
   c) Can affect the muscles of the face
   d) A and B
   e) I do not remember hearing this information during my informed consent

9. Infection after surgery:
   a) Smoking after the procedure will not cause an infection
   b) It is possible to get an infection after surgery
   c) Antibiotics will 100% prevent an infection after surgery
   d) I do not remember hearing this information during my informed consent

10. During the procedure
    a) One will feel nothing
    b) One may feel some pressure
    c) I do not remember hearing this information during my informed consent

most patients believe that an infection can be treated with antibiotics. Perhaps patients of a higher education level understood that infections may not always be treated with antibiotics alone. Our results also demonstrated that there was no effect of age on the patient recall. Our study only had 15 patients above the age of 50 and 6 patients above the age of 60. This may have been the reason for no difference.

Overall, the results of this study support the additional need for a reformulation of the current informed-consent process. This modification could be a more extensive discussion of the information. Subsequently, a test-and-feedback approach could be used to confirm understanding and recall.

Review of Literature on Informed-Consent Process and Recall

As per a paper by McClean et al., currently, there is no standard protocol or curriculum to teach informed consent.[5] Additionally, less than half the residency programs across Canada do not formally evaluate their residents' informed-consent skills.[5] Observation of the residents in the residency program revealed that residents failed to inform patients of the most serious risks associated with procedures.[5] The theory is that the residents may be unaware of serious and uncommon risks, or they may experience anxiety discussing these risks with patients due to the fear that the patients will refuse the procedure.[5] Residents may worry that the patient's refusal to consent for treatment will be seen as a failure on their part to accomplish the task at hand.[5] Instead, residents could see the patient's refusal as an exercise of their autonomy.[5]

Crepeau et al. evaluated 98 patients who underwent elective orthopedic surgery.[6] The patient had a discussion with the surgeon about the risks and benefits of the procedures, followed by a reading of the consent form.[6] Next, they were administered a test to determine the recall of the information they had just been provided.[6] The patients were administered the same test at the first postoperative visit.[6] The patients recalled 70.7% of the information immediately after the first test and 59.5% of the information after the first preoperative visit.[6] The recall immediately after the informed-consent process was surprisingly low even though, as per the authors, the discussion was lengthy and the informed-consent form was detailed.[6] Additionally, the length of time between the informed-consent process and the first preoperative visit was a maximum of two weeks.[6]

The aforementioned Hudson and Blaha also studied patients undergoing elective orthopedic surgery.[4] Thirty-eight patients underwent total joint replacement.[4] Each patient was asked to respond to a questionnaire.[4] Informed consent was not presented for signature until the patient was able to respond correctly to all questions.[4] Six months later, each patient was given the same questionnaire to respond to.[4] After six months, 3% of the patients recalled that they could have had damage to a nerve or artery, and 25% of the patients recalled that they could have had an infection.[4]

Figure 1: Data Collection Tool (one month after surgery)

11. Oral Antral Communication is:
    e) Fluid coming out of the nose when I drink something
    f) Damage to the filling on my tooth
    g) A hole in my gums
    h) I do not remember hearing this information during my informed consent

12. Nerve Injury
    e) Will affect my ability to speak and eat
    f) Is damage to the nerve that gives sensation to my lips and chin
    g) Will affect my ability to smile
    h) I do not remember hearing this information during my informed consent

13. Nerve injury
    e) Will affect my muscle movement
    f) Will affect my ability to feel sensation on my lips and chin
    g) Will definitely not occur
    h) I do not remember hearing this information during my informed consent

14. Swelling after the procedure
    e) Is not normal
    f) Should only last for one day
    g) Will become worse on the second day after the surgery
    h) I do not remember hearing this information during my informed consent

15. Dry socket
    e) Happens to everyone
    f) Will occur from spitting after the procedure
    g) Will get better if I take pain medication
    h) I do not remember hearing this information during my informed consent

16. Dry socket
    e) Can cause pain going up to the ear
    f) Will get resolved if I take pain medication
    g) Is an infection in my mouth
    h) I do not remember hearing this information during my informed consent

17. All wisdom teeth
    d) Must be taken out
    e) Do not need to be taken out
    f) I do not remember hearing this information during my informed consent

18. Wisdom tooth extraction
    f) Can result in loss of the ability to taste food
    g) Can result in loss of sensation in the tongue
    h) Can affect the muscles of the face
    i) A and B
    j) I do not remember hearing this information during my informed consent

19. Infection after surgery:
    e) Smoking after the procedure will not cause an infection
    f) It is possible to get an infection after surgery
    g) Antibiotics will 100% prevent an infection after surgery
    h) I do not remember hearing this information during my informed consent

20. During the procedure
    d) One will feel nothing
    e) One may feel some pressure
    f) I do not remember hearing this information during my informed consent

Krupp at al. conducted a study on 104 patients who were to undergo intracranial or spinal surgery.[8] The questionnaire was administered within two hours after the informed-consent process, the day before the surgery.[8] Eighteen percent of the patients were able to recall the risks associated with their surgery.[8] The low recall rate was attributed to the proximity of the surgery.[8] Perhaps patients pay less attention during the informed-consent process when their surgery is imminent and they are overwhelmed by emotions; therefore, their recall rate is affected negatively.[8]

Last, Godwin conducted an informed-consent study on 38 patients undergoing reduction mammoplasty.[9] The patients had three discussions regarding their surgery prior to the surgery.[9] They spoke with a consultant in the outpatient clinic, with a junior doctor in the preoperative area and, finally, with their surgeon just prior to the surgery.[9] The patients had a retention of 25% six days after the surgery regarding the facts associated with their surgery.[9] It is hypothesized that because the recall test was conducted postoperatively, cognitive dissonance may have occurred, and recall may have decreased as a result.[9]

Review of Literature on Interventions to Improve Patient's Understanding and Recall of Informed-consent Process

Of 12 video intervention trials, 3 trials have documented an improvement in understanding.[10] Of note, most of the participants in these video intervention trials had a mental disability.[9] Hence, this intervention may be useful for that population.[10] Last, two trials reported an increase in retention of information.[10]

A video-intervention study published in the Journal of Oral and Maxillofacial Surgery demonstrated that patients were able to recall information correctly at an initial and follow-up interview.[1] The initial interview was immediately after the informed-consent process.[1] The follow-up interview was between 18 to 35 days later.[1] It is important to note that patients were able to correctly answer questions about difficult complications such as nerve injury.[1] However, there was a decrease in the retention of information as more time passed.[1]

Another possible intervention involves enhancing the informed-consent form.[10] This includes making the form shorter, making it easier to understand, adding images and using larger font size.[10] Out of 15 studies, 6 demonstrated improvement in understanding.[10]

Extended discussion between qualified persons and patients demonstrated an increase in understanding in three out of five trials.[10] Given this information, a person-to-person conversation may be the best way to improve informed-consent understanding and, by extension, recall.[10] This is likely the case, as extended interaction with another individual gives the patient an opportunity to ask questions and clarify information.[10]

The test-and-feedback approach reported increased understanding and recall in five out of five trials.[10] Each study in this category used the same questions to quantify recall as was used in

the intervention itself.[10] This is a methodological flaw, because an improvement in recall reflects rote memorization rather than a true increase in understanding and recall.[10]

The effect of age and education on understanding and recall was also studied. Twelve studies demonstrated that patients with advanced education levels had higher comprehension and recall.[10] The National Literacy Survey showed that 48% of adults in America are challenged in literacy.[11] Spanish speakers had even more difficulty.[11] Last, there were five studies that enrolled participants over the age of 50.[10] They showed that increased age was associated with decreased understanding.[10]

Recommendations

Based on the research, altering the standard consent form and adding an additional discussion with a qualified personnel may be an effective way to improve the understanding and recall of the informed-consent process.[10] The process can also be divided into two steps.[11] During the first step, the patient and a trusted advisor could be provided with information.[11] During the second step, the patient could sign the consent form.[11] If multiple meetings are not feasible, the use of touch-screen technology can be employed.[10] A feedback intervention could be introduced into the process to help patients comprehend.[10] And if the resources are limited, specific groups must be aided, including the less educated, the mentally disabled and the elderly.[10]

Last, a study by Bhattacharya et al., with a unique recommendation to improve the informed-consent process, will be described. Bhattacharyya et al. reported that the risk of medical malpractice may be reduced if the surgeon performs the informed consent in his or her office as opposed to in the preoperative holding area.[12] In the surgeon's office, the surgeon and patient are able to have a more interactive discussion that may be more challenging to have on a hospital floor or in the preoperative holding area.[12]

Limitations

While 8 out of the 10 questions showed a statistically significant decrease in recall in information provided during the informed consent, it is essential to remember that this data may be affected by patient measurement variations in the outcome variable. That is to say that a statistically significant decrease could be because

patients may have been less focused during the second questionnaire and more likely to answer incorrectly.

Additionally, although each resident was provided with a script and standardized written consent form, depending on the questions and concerns of the patient, the verbal discussion between the provider and patient could vary. The communication skills of the resident delivering the information would affect the quality of the patient understanding and, potentially, patient recall. Research has shown that younger doctors tend to use more medical jargon than more experienced clinicians. In our study, the informed consent varied from noncategorical interns to PGY-6 level residents.

Next, the questionnaire has not been formally validated as a precise and accurate tool to assess patient comprehension and recall, hence subjecting this study to measurement bias. Another limitation in the study was that the questionnaire did not distinguish between an inability to understand the consent process versus the inability to recall the consent process. In order to maintain standardization with the time intervals, the interview to determine recall was often conducted on the phone. The patient may have had a hard time understanding the provider or could have been distracted, leading to more incorrect results.

Last, patients may have come to the procedure with different levels of knowledge and comprehension based on their research, discussion with friends and family, and previous experience (for example, previous extraction of tooth).

This study was also affected by recall bias and reporting bias. A patient who had an adverse reaction to the surgery may be more likely to remember that nerve injury can occur and an infection is possible after a wisdom tooth extraction.

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