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Use of a simplified consent form to facilitate patient understanding of informed consent for laparoscopic cholecystectomy

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Abstract: Background. Surgical informed consent forms can be complicated for patients to read and understand. We created a consent form with key information presented in bulleted texts and diagrams combined in a graphical format to facilitate the understanding of information during the verbal consent discussion.

Methods. This prospective, randomized study involved 70 adult patients awaiting cholecystectomy for gallstones. Consent was obtained after standard verbal explanation using either a graphically formatted (study group, n=33) or a standard text document (control group, n=37). Comprehension was evaluated with a 9-item multiple-choice questionnaire administered before surgery and factors affecting comprehension were analyzed.

Results. Comparison of questionnaire scores showed no effect of age, sex, time between consent and surgery, or document format on understanding of informed consent. Educational level was the only predictor of comprehension.

Conclusions. Simplified surgical consent documents meet the goals of health literacy and informed consent. Educational level appears to be a strong predictor of understanding.

Keywords: Informed consent; Laparoscopic cholecystectomy

1 Introduction

Informed consent refers to a voluntary decision and an authorization by a patient that a health care provider can proceed with diagnostic or therapeutic interventions as planned during the consent discussion. An integral component of the consent process, the consent discussion, is structured around the essential points of the procedure, associated side effects, reasonably predictable risks, benefits, and outcomes, as well as other treatment options [1].

Informed consent is now ethically and legally ensconced as the right of patients to receive adequate information to make decisions about proposed treatment and currently available alternative options in medical care [2]. This is a relatively recent concept in some areas of medicine, and reflects the gradual shift away from the paternalistic approach predominant up until the early 1960s when doctors believed that, by virtue of their superior medical knowledge, they could disregard patients' choices and preferences or act against them if they ran counter to clinical indications. Surveys assessing health literacy in adults have found, however, that many people

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have a poor grasp of basic health concepts, medical information and instructions.

Other studies have shown that patients often have trouble to follow an explanation of diagnostic and therapeutic procedures discussed during the consent consultation [3] and are able to recall little of what was explained [4]. Because surgical informed consent forms are complex for patients to read and understand, we created a two-page consent document with key information presented in bulleted texts and diagrams combined in a graphical format to facilitate understanding during the verbal consent process for laparoscopic cholecystectomy. Factors potentially affecting comprehension, as assessed with a feedback questionnaire, were analyzed.

2 Material and methods

2.1 Study sample

In this prospective randomized study, 100 consecutive patients awaiting elective laparoscopic cholecystectomy for gallstones on a day surgery basis were enrolled between 1 April 2013 and 1 April 2015. Exclusion criteria were: incapacity to read and understand the informed consent form unaided, emergency surgery, need for other surgical procedures in addition to elective laparoscopic cholecystectomy, refusal to participate in the study, non-Italian speakers or patients noted to have difficulty understanding or communicating in Italian, severe mental disorders, and incapacity to provide adequate informed consent. A single physician and member of the medical team collected the consent forms from all enrolled patients before hospital admission for surgery.

Of these 100 patients, 18 were excluded because they had undergone emergency surgery during the time between informed consent collection and the scheduled date of elective surgery; 12 others were excluded because they met one of the exclusion criteria listed above. The 70 remaining patients were assigned to one of two groups according to a computer-generated sequence (available at www.randomization.com). Of these 70 participants, 33 (47%) were men and 37 were women (52.9%). The median age was 55 years (range, 24-80); 37 (52.9%) patients were below and 33 (47.1%) were above the median age. The study group included 33 (47.1%) patients and the control group 37 (52.9%). The demographic characteristics were similar in both groups (Table 1).

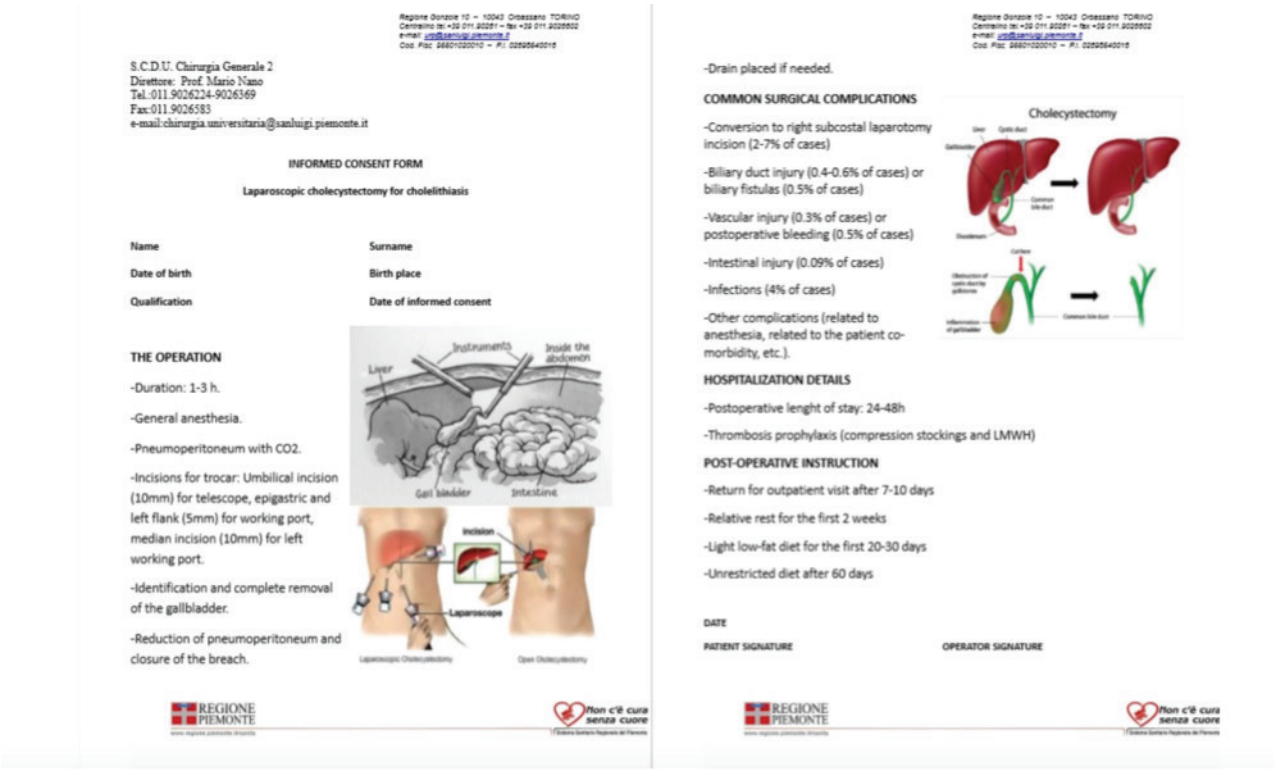
2.2 Informed consent discussion

The informed consent discussion during surgical preadmission assessment covered the essential points regarding the pathology and its natural history, clinical course and common complications associated with gallstones, the reason for laparoscopic surgery and related risks and benefits, details about the surgical procedure, the potential surgical risks and reasonably predictable complications, the postoperative course, the diet to be followed during the first month after surgery, and aftercare of the surgical wound. Consent was obtained after the exposure to standard verbal explanation with either a simplified informed consent form (study group) or a standard text document (control group) routinely used in our unit for this purpose. The simplified consent form featured a clear layout and visual design elements, including ample margins and white space, short bulleted lists with topic headings, both medical and lay terms, anatomical diagrams and figures with descriptions and captions, and institutional logo (Fig. 1). Neither informed consent form has been tested for readability standards.

2.3 Feedback questionnaire

Comprehension was evaluated with a non-validated, 9-item multiple-choice questionnaire administered the day before surgery. The self-report multiple-choice questionnaire (each of the 9 questions had only one correct answer from 2-4 choices) examined understanding of informed consent regarding the operation itself (questions 1 to 4), potential surgical complications (questions 5 and 6), and length of hospital stay and postoperative care instructions (questions 7 to 9). An additional final question (item 10 had only a yes/no response) investigated patient satisfaction with the clarity of the presentation and the amount of information given (Fig. 2). Physicians that obtained the consent forms also collected completed questionnaires.

Patient age, sex, educational level, time between consent and questionnaire collection, and questionnaire scores were entered into a database for analysis. Eleven (15.7%) patients had completed elementary school, 24 (34.3%) middle school, 10 (14.3%) technical-vocational school, 19 (27.1) high school, and 6 (8.6%) college level education. The average time between consent and collection of the feedback questionnaire was 23.4 days (median 12 days, range 0 to 152); the time interval was less than 15 days for 39 (55.7%) patients and more than 16 days for the remaining 31 (44.3%).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INFORMED CONSENT FORM

Laparoscopic cholecystectomy for cholelithiasis

Name Surname

Date of birth Birth place

Qualification Date of informed consent

THE OPERATION

-Duration: 1-3 h.

-General anesthesia.

-Pneumoperitoneum with CO2.

-Incisions for trocar: Umbilical incision (10mm) for telescope, epigastric and left flank (5mm) for working port, median incision (10mm) for left working port.

-Identification and complete removal of the gallbladder.

-Reduction of pneumoperitoneum and closure of the breach.

Instruments
Liver
Inside the abdomen
Gall bladder
Intestine
Incision
Laparoscope
Laparoscopic Cholecystectomy
Open Cholecystectomy

REGIONE PIEMONTE
Non c'è cura senza cuore

-Drain placed if needed.

COMMON SURGICAL COMPLICATIONS

-Conversion to right subcostal laparotomy incision (2-7% of cases)

-Biliary duct injury (0.4-0.6% of cases) or biliary fistulas (0.5% of cases)

-Vascular injury (0.3% of cases) or postoperative bleeding (0.5% of cases)

-Intestinal injury (0.09% of cases)

-Infections (4% of cases)

-Other complications (related to anesthesia, related to the patient co-morbidity, etc.).

Cholecystectomy

HOSPITALIZATION DETAILS

-Postoperative lenght of stay: 24-48h

-Thrombosis prophylaxis (compression stockings and LMWH)

POST-OPERATIVE INSTRUCTION

-Return for outpatient visit after 7-10 days

-Relative rest for the first 2 weeks

-Light low-fat diet for the first 20-30 days

-Unrestricted diet after 60 days

DATE

PATIENT SIGNATURE OPERATOR SIGNATURE

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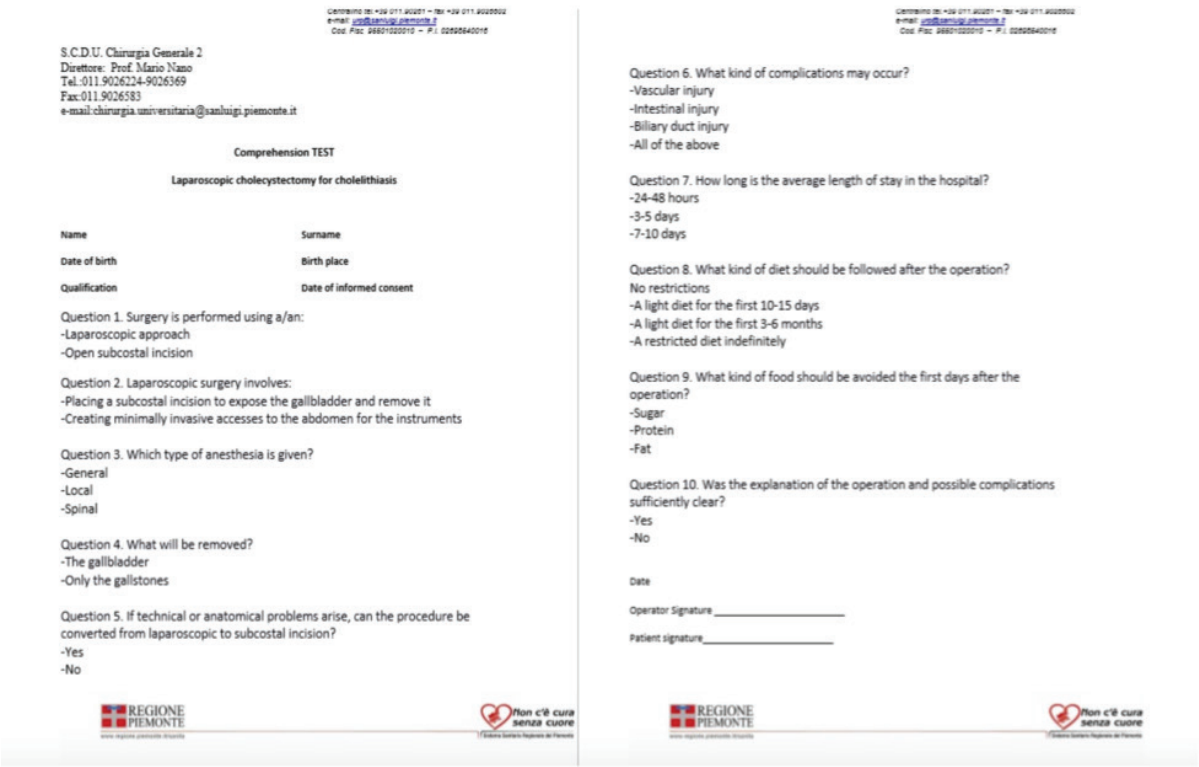
Figure 1: Simplified informed consent form

Table 1: Patient characteristics.

Characteristic	Number of patients (n=70)	Study Group (n=33)	Control Group (n=37)
Sex			
Male, n° (%)	33 (47.1)	15 (45.4)	18 (48.6)
Female n° (%)	37 (52.9)	18 (54.6)	19 (51.4)
Age – average (yrs)	54	54	55
Median	55	55	55
Range	24-80	24-78	35-80
≤55	37 (52.9)	16 (48.5)	21 (56.7)
>56	33 (47.1)	17 (51.5)	16 (43.3)
Educational level			
Elementary n° (%)	11 (15.7)	4 (12.1)	7 (18.9)
Middle school, n° (%)	24 (34.3)	11 (33.3)	13 (35.1)
Technical-vocational, n° (%)	10 (14.3)	5 (15.1)	5 (13.5)
High school, n° (%)	19 (27.1)	11 (33.3)	8 (21.6)
College, n° (%)	6 (8.6)	2 (6.2)	4 (10.8)
Time between consent and surgery (days)			
Average	23.4	23.4	22.9
Median	12	12	12
Range	0-152	0-152	0-115
Δ Time ≤ 15 , n° (%)	39 (55.7)	19 (57.6)	20 (54.1)
Δ Time > 16 , n° (%)	31 (44.3)	14 (42.4)	17 (45.9)



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Comprehension TEST

Laparoscopic cholecystectomy for cholelithiasis

Name Surname

Date of birth Birth place

Qualification Date of informed consent

Question 1. Surgery is performed using a/an:
-Laparoscopic approach
-Open subcostal incision

Question 2. Laparoscopic surgery involves:
-Placing a subcostal incision to expose the gallbladder and remove it
-Creating minimally invasive accesses to the abdomen for the instruments

Question 3. Which type of anesthesia is given?
-General
-Local
-Spinal

Question 4. What will be removed?
-The gallbladder
-Only the gallstones

Question 5. If technical or anatomical problems arise, can the procedure be converted from laparoscopic to subcostal incision?
-Yes
-No

Question 6. What kind of complications may occur?
-Vascular injury
-Intestinal injury
-Biliary duct injury
-All of the above

Question 7. How long is the average length of stay in the hospital?
-24-48 hours
-3-5 days
-7-10 days

Question 8. What kind of diet should be followed after the operation?
No restrictions
-A light diet for the first 10-15 days
-A light diet for the first 3-6 months
-A restricted diet indefinitely

Question 9. What kind of food should be avoided the first days after the operation?
-Sugar
-Protein
-Fat

Question 10. Was the explanation of the operation and possible complications sufficiently clear?
-Yes
-No

Date

Operator Signature _____

Patient signature_____

REGIONE PIEMONTE — Non c'è cura senza cuore

Figure 2: Feedback questionnaire

2.4 Statistical analysis

Univariate descriptive analysis was applied to categorical and continuous variables, followed by bivariate descriptive analysis of the categorical variables, interferential analysis of the categorical variables (two-sided Monte Carlo and Fisher's exact test), and a multivariate binary logistic regression model (odds ratio with 95% confidence intervals). Statistical significance was set at $P \leq 0.05$.

3 Results

The correct response rate was 100% on all 9 questionnaire items for 20 out of 70 patients: 11/33 (33.3%) in the study group and 9/37 (24.3%) in the control group; 23 responded incorrectly to 1 item (11 [33.3%] in the study group vs. 12 [32.4%] in the control group); 17 responded incorrectly to 2 items (7 [21.2%] in the study group vs. 10 [27.1%] in the control group); 8 responded incorrectly to 3 items (3 [9.1%] in the study group vs. 5 [13.5%] in the control group); 2 responded incorrectly to 4 items (1 [3.1%] in the study group vs. 1 [2.7%] in the control group). The percentage of correct responses to the first 5 items investigating understanding of the operation was generally high in both groups: 97% and 100% to item 1, 96.9% and 97.3% to item 2, 93.9% and 94.6% to item 3, 93.9% and 100% to item 4, and 90.9% and 100% to item 5 in the study and the control group, respectively.

By comparison, the correct response rate was lowest for item 6 (probability of surgical complications), with 57.6% and 62.1% in the study and the control group, respectively, responding incorrectly. The correct response rate improved on items 7 to 9 (length of hospital stay and postoperative care instructions): 78.8% vs. 67.6%, 90.9% vs. 75.7%, and 100% vs. 89.2% in the study and the control group, respectively. All patients stated that they were satisfied with the way they were informed and the clarity of the information provided irrespective of whether they had been exposed to verbal consent with the standard text or with the simplified graphically enhanced document (Table 2).

Univariate and bivariate analysis of the categorical variables (age, sex, educational level, time between consent and surgery) showed that none of these were statistically significant as a predictor of understanding consent nor did exposure to the standard text or graphically formatted consent document predict better understanding (Table 3). Multivariate binary logistic regression (odds ratio with 95% confidence intervals) of these variables showed that, independent of type of exposure,

Table 2: Feedback questionnaire items and number and percentage of patients who responded correctly or incorrectly.

	N° of patients (n=70)	Study Group (n=33)	Control Group (n=37)
Question 1. Surgery is performed using a/an: Laparoscopic approach Open subcostal incision			
Correct, n(%)	69 (98.6)	32 (97)	37 (100)
Incorrect, n° (%)	1 (1.4)	1 (3)	0 (0)
Question 2. Laparoscopic surgery involves: Placing a subcostal incision to expose the gallbladder and remove it Creating minimally invasive accesses to the abdomen for the instruments			
Correct, n° (%)	68 (97.1)	32 (96.9)	36 (97.3)
Incorrect, n° (%)	2 (2.9)	1 (3.1)	1 (2.7)
Question 3. Which type of anesthesia is given? General Local Spinal			
Correct, n° (%)	66 (94.3)	31 (93.9)	35 (94.6)
Incorrect, n° (%)	4 (5.7)	2 (6.1)	2 (5.4)
Question 4. What will be removed? The gallbladder Only the gallstones			
Correct, n° (%)	68 (97.1)	31 (93.9)	37 (100)
Incorrect, n° (%)	2 (2.9)	2(6.1)	0 (0)
Question 5. If technical or anatomical problems arise, can the procedure be converted from laparoscopic to subcostal incision? Yes No			
Correct, n° (%)	67 (95.7)	30 (90.9)	37 (100)
Incorrect, n° (%)	3 (4.3)	3 (9.1)	0 (0)
Question 6. What kind of complications may occur? Vascular injury Intestinal injury Biliary duct injury All of the above			
Correct, n° (%)	28 (40.0)	14 (42.4)	14 (37.8)
Incorrect, n° (%)	42 (60.0)	19 (57.6)	23 (62.1)
Question 7. How long is the average length of stay in the hospital? 24-48 hours 3-5 days 7-10 days			
Correct, n° (%)	51 (72.9)	26 (78.8)	25 (67.6)
Incorrect, n° (%)	19 (27.1)	7 (21.2)	12 (32.4)
Question 8. What kind of diet should be followed after the operation? No restrictions A light diet for the first 10-15 days A light diet for the first 3-6 months A restricted diet indefinitely			
Correct, n° (%)	58 (82.9)	30 (90.9)	28 (75.7)
Incorrect, n° (%)	12 (17.1)	3 (9.1)	9 (24.3)

Table 2: Feedback questionnaire items and number and percentage of patients who responded correctly or incorrectly.

Question 9. What kind of food should be avoided the first days after the operation? Sugar Protein Fat			
Correct, n° (%)	66 (94.3)	33 (100)	33 (89.2)
Incorrect, n° (%)	4 (5.7)	0 (0)	4 (10.8)
Question 10. Was the explanation of the operation and possible complications sufficiently clear?			
Yes	70 (100.0)	33 (100)	37 (100)
No	0 (0.0)	0 (0)	0 (0)
Number of errors			
0, n° (%)	20 (28.6)	11 (33.3)	9 (24.3)
1, n° (%)	23 (32.9)	11 (33.3)	12 (32.4)
2, n° (%)	17 (24.3)	7 (21.2)	10 (27.1)
3, n° (%)	8 (11.4)	3 (9.1)	5 (13.5)
4, n° (%)	2 (2.9)	1 (3.1)	1 (2.7)

Table 3: Results of interferential analysis of the categorical variables (two-sided Monte Carlo and Fisher's exact test).

Characteristic	Number of patients n=70 (%)	Study Group n=33 (%)	Control Group n=37 (%)	Univariate Analysis Chi-Square Tests p-value
Gender				0.381
Male	33 (47.1)	15 (45.4)	18 (48.6)	
Female	37 (52.9)	18 (54.6)	19 (51.4)	
Age (yrs)				0.260
≤55	37 (52.9)	16 (48.5)	21 (56.7)	
>56	33 (47.1)	17 (51.5)	16 (43.3)	
Educational level				0.285
Elementary	11 (15.7)	4 (12.1)	7 (18.9)	
Middle school	24 (34.3)	11 (33.3)	13 (35.1)	
Technical-vocational	10 (14.3)	5 (15.1)	5 (13.5)	
High school	19 (27.1)	11 (33.3)	8 (21.6)	
College	6 (8.6)	2 (6.2)	4 (10.8)	
Time between consent and surgery (days)				0.567
Δ Time ≤ 15	39 (55.7)	19 (57.6)	20 (54.1)	
Δ Time > 16	31 (44.3)	14 (42.4)	17 (45.9)	
Type of consent	70 (100)	33(100)	37(100)	0.905

Table 4: Results of multivariate binary logistic regression analysis comparing the factors affecting the probability of making errors: 0 errors (20 patients) vs. ≥1 error (50 patients).

Variable	Odds Ratio (95% confidence interval)	P value
Age (yrs) >56 vs. ≤ 55	1.58 (0.4-6.22)	0.515
Study group vs. Control group	0.71 (0.22-2.27)	0.560
Female vs. Male	0.46 (0.14-1.52)	0.203
Δ Time between consent and feedback questionnaire (days) >16 vs. ≤15	0.79 (0.25-2.56)	0.698
Educational level		0.048
Middle vs. Elementary	0.5 (0.05-5.08)	0.558
Technical-vocational vs. Elementary	0.4 (0.03-5.25)	0.485
High vs. Elementary	0.09 (0.01-0.85)	0.035
College vs. Elementary	0.1 (0.01-1.35)	0.043

educational level had a statistically significant effect on reducing the risk of responding incorrectly by the patients in both groups who had completed high school or college ($P = 0.035$ and $P = 0.043$, respectively) (Table 4).

4 Discussion

Like the trust that underlies the doctor-patient relationship, informed consent can be viewed as both an event and a process [5]. It begins with the preoperative encounter and continues through to the postoperative evaluation of treatment outcomes and patient satisfaction.

In a questionnaire study, Akkad et al. [6] found, however, that patients often had a limited understanding of the legal implications of signing an informed consent form and that they did not recognize the fact that informed consent works in their interest: 46% stated that informed consent serves to protect the doctor's interest. The authors concluded that the current informed consent process is inadequate and its ethical validity and credibility are questionable.

Health literacy surveys have underlined the need to provide medical information in plain language in order to bridge the knowledge gap between doctor and patient. Kusec et al. [7] reported that the complexity of presenting concepts could be graded according to patient characteristics by aiming for a balanced choice between medical and lay terms adjusted to the patient's educational level, for example. By the same token, not all patients have a desire of being fully informed about clinical aspects, therapy, common complications, and treatment outcomes.

Degerliyurt et al. [8] found a wide variability in the amount of information about therapy and potential complications that patients want to know: 57% of the patients in their study stated they wanted to be fully informed about all the complications associated with their surgical treatment, 33% wanted to know only the most common complications, and 10% did not want to be informed. Despite these discrepancies, the authors recommended that patients receive a standard informed consent form.

In a systematic review of the literature, Falagas et al. [9] found that less than one third of the studies they reviewed reported that patients had adequately understood of the components of the informed consent process. Although the majority of the patients felt that the amount of information they had received was adequate, the actual degree of understanding was suboptimal.

There are now various methods and strategies to simplify consent forms and improve comprehension with the aid of especially designed written or multimedia material being used during the informed consent process in clinical trials. The general agreement is that the use of such materials may increase patient understanding of informed consent [10-16]. Multimedia presentations have been effectively implemented in education to increase learning, interest, memory, comprehension, and satisfaction. Hung et al. [17] reported that the use of multimedia disclosure of informed consent does not significantly increase hospital costs. Not all authors agree that multimedia use necessarily improves patients' informed consent understanding, however. Clark et al. [18] reported that PowerPoint presentations illustrating laparoscopic cholecystectomy did not increase the degree of patient understanding. Other authors have suggested that a consent discussion follow-

ing a checklist of essential concepts is sufficient to obtain good understanding of consent [19] or that repeat back of concepts and repetition of the points not clearly understood can also help to improve understanding [20]. What has been consistently shown is that an increased understanding of the surgical procedure can increase satisfaction with treatment received and reduce perioperative anxiety [21-24] despite of the inherent difficulties of surgical procedures [25-44].

In our study, comparison of feedback questionnaire scores revealed no statistically significant difference in informed consent understanding between the two groups. This finding contrasts with previously published data [10-16]. We agree with Clark et al. [18] and Kondziolka [19] who demonstrated that the addition of educational material to the standard verbal consent process does not improve patient understanding of the risks and benefits associated with surgery. Like Falagas et al. [8], we noted that although the majority of patients felt that the amount of information received was adequate, their actual understanding was low: only 28.6% of the patients responded correctly to all 9 questionnaire items, though both groups stated they were satisfied with the clarity with which the information was presented.

Laparoscopic surgery seems to give greater difficulties in intervention explanation perhaps because of technology that can not be understood by all types of patients . [45-57]. Further to this, since the literature is scarce on the effects of simplifying informed consent forms in the clinical setting, we analyzed several variables that might correlate with patient understanding. Age, sex, and time between consent and questionnaire administration were not found to be statistically significant predictors of increased understanding. The only factor that had a statistically significant effect on reducing the risk of responding incorrectly to a questionnaire item was educational level ($P = 0.048$ on multivariate analysis). This was particularly evident for the patients with a high school ($P = 0.035$ on multivariate analysis) or college education ($P = 0.043$ on multivariate analysis) in both groups. This finding is in line with observations by Kusec et al. [7] and suggests that the complexity of medical information can be appropriately graded in patients with a higher educational level.

That said, we believe that, irrespective of exposure to a standard verbal consent procedures or to a consent process with a simplified, graphically formatted consent document, understanding informed consent is influenced by a patient's health literacy. Voluntariness and interest in their health condition may help patients retain the concepts discussed with their surgeon during the consent process and prompt them to ask for the information they feel is important when faced with decisions about their health.

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