

## EVALUATION OF PATIENT FEEDBACK FOLLOWING LAPAROSCOPIC CHOLECYSTECTOMY BASED ON INFORMATION DESCRIBED IN THE INFORMED CONSENT FORM DEVELOPED BY THE ASSOCIATION OF POLISH SURGEONS

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The cholecystectomy procedure is the most routinely performed intervention in general surgery. The current international gold standard is via the laparoscopic approach. It is a safe, minimally-invasive procedure; however, it is associated with complications in 1% of cases.

**The aim of the study** was to analyze patient feedback, by means of a survey, to determine how much knowledge patients possessed about their disease state and proposed surgical intervention, based primarily on information contained within the informed consent form developed by the Association of Polish Surgeons.

**Material and methods.** This study involved the participation of 51 patients who underwent laparoscopic cholecystectomy, indicated by a diagnosis of gallstones, in the years 2014 and 2015.

**Results.** Despite having signed the informed consent form, there was considerable variation among the responses given to the survey by the 51 patients in this study. Some patients' responses were tangential to the questions asked; many patients did not respond to any of the sub points.

**Conclusions.** Given that this study is based on a small sample size of patients, it must be presumed that the process by which the patient declares his or her informed consent requires further consideration with respect to the means by which it is obtained. The authors of this study thus recommend that multimedia resources be harnessed as part of the process of obtaining the informed consent of patients prior to surgical intervention.

**Key words:** laparoscopic cholecystectomy, informed consent

The cholecystectomy procedure is the most routinely performed intervention in general surgery. The current international gold standard is via the laparoscopic approach. In accordance with universally accepted and required medical norms, it is the surgeon's responsibility to obtain the informed consent of patients prior to the undertaking of each procedure. To this end, the Association of Polish Surgeons have developed a standardized informed consent form. Utilizing a clear, mainstream approach, this form describes the nature of the proposed laparoscopic cholecystectomy, the details of the surgical protocol to which the surgeon must adhere, as well as all

possible complications which may arise as a result of the surgical intervention.

The purpose of this study was to analyze patient feedback, provided by means of a survey, obtained post-operatively. The survey consisted of four questions and was presented to each patient immediately prior their discharge from the hospital. Post-operative recovery time after the minimally invasive laparoscopic cholecystectomy procedure is expected to be rapid. Therefore, it was necessary to enquire about the patients' experience after having undergone this procedure yet just prior to their discharge in order to rule out any influence the anesthetists or any strong anal-

gesic drugs may have had on the patients' evaluation of their surgical course of treatment.

## MATERIAL AND METHODS

Fifty-one patients were recruited for this study: 23 men and 28 women, at a median age of 49 years, the majority of whom having achieved a secondary level of education and currently residing in a large city (tab. 1). The patients in this study were operated on in the years 2014 and 2015. All of them had familiarized themselves with the laparoscopic cholecystectomy informed consent form on the day preceding their scheduled procedure. Specifically, the form in question is the one developed by the team of experts, under the direction of Professor Marek Krawczyk, at the Association of Polish Surgeons.

The patients in this study were first asked to respond to a short survey on the day of their admission to the hospital. This survey enquired about their total number of lifetime hospitalizations, including previous admissions to surgical wards. They were also asked about their underlying disease state, that being the purpose of their current admission. The patients evaluated their level of satisfaction with regard to the nature and amount of information they possessed about their planned surgical treatment. This was assessed on a 3-point scale: satisfied, unsatisfied, lack of information. The survey also asked the patients to indicate their source of information about the procedure, a sub point of which required the patients to indicate whether or not they were familiar with the following medical terms: laparoscopy, videosurgery, and minimally-invasive surgery.

The next phase of the study consisted of a second survey carried out immediately prior to each patient's discharge from the hospital. It consisted of four questions:

1. List one indication for the conversion of a laparoscopic surgical method to a classic laparotomy.
2. List three complications which may arise from the undertaken therapeutic procedure, as described in the informed consent form and in other sources.
3. List three post-operative recommendations which patients are encouraged to follow, based on the information each patient had acquired from various sources: the Internet, surgical outpatient clinic, primary care physician.
4. Of the above recommendations, which one does the patient believe is the most important to observe.

## RESULTS

Fifty-one patients admitted to the Department of Thoracic Surgery, General and Oncologic Surgery in the years 2014 and 2015, were involved in the survey. For 21,6% of whom this was their first lifetime hospitalization; for approximately 60% of the total patients surveyed, it was their first hospitalization in a surgical ward (tab. 2).

Thirty-one patients had been consulted by a surgeon in the surgical outpatient clinic attached to the Hospital prior to their admission. Fifty-eight percent of these patients indicated their consulting surgeon as the primary source of information about their disease state, while 42% indicated their primary care physician as such (tab. 3). Seventy percent declared that they were satisfied with the amount of infor-

Table 1. Demographic data

Number of patients 51					
M=23	F=28		Min.	Max.	Med.
45%	55%	age	23	77	49
Education		basic	vocational	secondary	higher
		2	12	24	13
Living		big city	small city	country	
		23	15	13	

Table 2. No. of hospitalization

Number of hospitalization		
1x	11	21,6%
2x	15	29,4%
3x	13	25,5%
4x	12	23,5%
Number of hospitalization in surgical ward		
1x	31	60,8%
2x	19	37,25%
3x	1	1,95%

Table 3. Past history of consultations

Did the patients have consultation in surgical outpatients before the admission		
20	nie	
31	tak	
By whom was the consultation performed (who was pointed by the patients)		
Family doctor	21	42%
Surgeon	30	58%

mation they possessed concerning their disease state; likewise, approximately 72,5% of patients declared that they were satisfied with the amount of information they had about their planned surgical treatment (tab. 4). Thirty-five of the 51 patients surveyed had constant access to the Internet, 31 of whom indicated that a doctor was their primary source of medical information (tab. 5). Among those surveyed, 37 associated the term "laparoscopy" with a type of surgical procedure, 46 associated "video surgery" as an operation involving the use of a camera, and 37 of whom indicated their belief that "minimally-invasive surgery" is associated with a more aesthetically-pleasing post-operative effect (tab. 6).

The results of the second phase of testing, which consisted of four questions presented to the patients immediately prior to their discharge from the Department, was cause for concern for the authors of this study.

In the case of the first question above, 21 (41%) patients did not provide any response (tab. 7); similarly, no response was given to the second question by 25 (49%) of patients. The remainder of the responses are presented in tab. 8.

In the case of the third question, the second most frequent response indicated by 19 patients was the need for post-operative follow-up

in the surgical outpatient clinic; the third most common response being the need to refrain from lifting heavy objects (tab. 9).

Forty-one patients responded to question four by indicating that adherence to a strict diet is the most important post-operative recommendation, whereas ten patients did not provide a response to this question (tab. 10).

## DISCUSSION

The concept of informed consent only recently became a key issue in the Polish legal

Table 4. Level of satisfaction with existing knowledge related with disease and operational treatment

Satisfaction level related with the knowledge of disease		
Satisfied	36	70%
Dissatisfied	10	19%
Not know anything	5	11%
Satisfaction level related with the knowledge of surgical treatment		
Satisfied	37	72,5%
Dissatisfied	10	19,6%
Not know anything	4	7,9%

Table 5. Source of knowledge on medical topics

Internet access	
Posiada / has	35
Does not have	16
Source of knowledge in medical issues	
Internet	11
Doctor	31
TV	4
Press	2
Not interested in medical issue	3

Table 6. Associations with terms: laparoscopy, videosurgery, small invasive surgery

Association with the term laparoscopy	
Don't know	14
Type of surgical procedures	37
Association with the term videosurgery	
Don't know	5
Operation using the camera	46
Association with the term minimally invasive surgery	
Improved cosmetic result	37
Shorter hospital stay	10
Less pain	4

Table 7. List one indication for the conversion of a laparoscopic surgical method to a classic laparotomy

21	no answer
16	unclear changes in abdominal cavity
5	blockage of the bile ducts
7	no possibility of removing the gall-bladder, laparoscopic
1	faster recovery
1	the wounds are smaller and faster to heal

Table 8. List three complications which may arise from the undertaken therapeutic procedure, as described in the informed consent form and in other sources

25	no answer
Total number of similar responses given by respondents	
10	the development of postoperative hernia
17	haemorrhage
3	the increase in body temperature
1	death
2	obstruction of bile duct
3	dyscomfort in digestive system
4	peritonitis
1	development of intolerance to lactose

Table 9. List three post-operative recommendations which patients are encouraged to follow, based on the information each patient had acquired from various sources: the Internet, surgical outpatient clinic, primary care physician

51	diet
10	reducing weightlifting
5	moderate exercise
2	abstinence
19	control in outpatients surgical ambulatory
7	daily wound toilet

Table 10. Of the above recommendations, which one does the patient believe is the most important to observe

10	no answer
41	diet

system. It was introduced in response to the need to protect patient autonomy. In accordance with Article 19, Section 1, Point 3 of the statute governing healthcare institutions, the patient has the right to give informed consent for the receipt of specific courses of medical treatment as well as to withdraw their consent

thereof, upon obtaining information relevant to the proposed treatment (1). In addition, the Medical Profession Act in Poland of 1996, Article 31, Section 1 stipulates that “the doctor is responsible for providing to the patient or his/her legal representative all information that is relevant to the patient’s state of health, diagnosis, proposed as well as possible diagnostic and treatment methods, treatment outcomes and complications which may arise due to treatment, as well as prognosis”. The question of what constitutes an appropriate extent to which the patient must be informed about the risks and results of the medical procedure is also contained in Article 10 of the European Convention on Bioethics, according to which: “every person has the right to be informed about the collective information concerning his or her state of health. It is important to respect the wishes of those persons who do not wish to be so informed” (2).

In the above case, the scope of the information provided was determined by a group of experts at the Association of Polish Surgeons, resulting in the development of the informed consent form presented to all the patients in this study. Of course the patient has the right to obtain additional information from various other sources (doctor in charge of treatment, primary care physician, the Internet, television, print media, friends and family). Thirty-five patients among those involved in our study had declared that they possess constant access to the Internet, yet only 11 (21%) indicated the Internet as their primary source of medical information. This of course comprises a small group of subjects due to the increasing worldwide trend of obtaining such information running contrary to the manner in which patients obtain medical information of their own accord. In the USA in 2005, at least 57 million residents had declared their use of Internet-based resources for the purpose of furthering their knowledge about medical topics (3, 4, 5). According to data available in international academic literature (3, 4), approximately 60% of patients does not corroborate medical information obtained from the Internet with a medical specialist. Not taking into account the validity of the medical information available on the World Wide Web, Allen J.W. et al. revealed that web pages containing medical information, including that specifically about laparoscopy, are in no way reviewed nor is the infor-

mation contained within certified by any medical authority. Many of these web pages also contain controversial information which serves to mislead patients. Given that patients do not consult with medical professionals, the patient's basing his or her decision whether or not to embark on a course of treatment based on medically invalid information results in a misunderstanding between the patient and the specialist. This may invariably lead to legal action being taken against the medical professional by the patient (6).

For 31 (61%) patients in this study, a doctor was in fact their primary source of medical information, of which 42% indicated their primary care physician provided them with information about their disease state and proposed course of treatment.

In the study group, 70% assessed their state of health based on the information they possessed about the condition in question, gallstones, as satisfactory. Similarly, 72.5% of patients rated their level of information about surgical treatment as satisfactory. In no way does this correlate with the responses to the survey taken immediately prior to discharge from the Department. Twenty-one patients did not provide a response to the first question; similarly, the second question was left unanswered by 25 patients. The questions posed to the patients were not intended to be complex but rather as a review of the information contained in the informed consent form. In addition, 14 patients did not provide a response in the survey taken on their day of admission to Hospital concerning their familiarity with the term "laparoscopy"; five patients did not associate the term „video surgery" with any specific concept. This casts their actual amount of knowledge about their treatment in a negative light.

Authors of related studies had also obtained similarly disconcerting feedback conducted via similar post-operative surveys. These studies involved patients having undergone courses of treatment carried out in the scope of other medical specialties: orthopedic surgery, thoracic surgery, gynaecology, etc (7, 9, 10, 11).

The results were based upon the fact that many people consciously appreciate their actual state of health. Among the subjects of this study, 70% assessed their level of knowledge about their condition and surgical treatment as rather high ("satisfactory" response in the

survey). Only 13 patients (25%) had achieved a post-secondary level of education, albeit not necessarily in any area of medicine or biological science. This group was found not to have diligently read through the informed consent form. Although these patients gave their informed consent prior to undergoing their surgical procedure, the patients' overall lack of due diligence was illustrated in their responses to the post-operative survey.

In Poland, the laparoscopic cholecystectomy operation is not regarded by patients as a major procedure. The reality is that it is a serious procedure, although undertaken by surgeons in such a manner as to maximize the positive cosmetic effect. This attitude adopted by patients may be a reason why 25 patients had refrained from providing a response to the question asking about complications. Other reasons for the withholding of feedback in the literature include: the age of the patient, his or her cognitive abilities, present emotional state, and IQ. Many authors also note the fact that patients who intentionally avoid providing a response to questions regarding complications are typically of an advanced age, who trust their fate to the surgeon based on his or her perceived authority (7). In the aforementioned studies, it is evident that a higher percentage of feedback is obtained from patients with whom the discussion concerning their disease state is of a duration of 15 – 30 minutes. In addition, this was also found to be true with patients whose consultation with a specialist was preceded by the perusal of brochures containing detailed and specific information about the proposed procedure. A further stimulus to more patient feedback being provided is the utilization of multimedia resources in the self-education about the disease state in the pre-operative period (7, 8).

At the same time, it is also necessary to note that information communicated even in the most direct and professional manner by the surgical specialist does not guarantee the complete internalization of this information by the patient. This is also due to the phenomenon of selective hearing on the part of patients; their working memory is active during the consultation; however, they are unable to focus on the content of the discussion during the entire conversation (12). Dawes discovered that the more information is passed to the

patient, the less of it they are able to retain (13).

Surgeons must comply with the legal requirements for consent whilst patients hope for compassionate advice about whether or not to undergo surgery and reassurance following treatment. A thorough discussion concerning the risks involved can easily incite feelings of helplessness by making patients aware of the element of uncertainty associated with every treatment option available to them, whichever they ultimately decide upon.

In the process of obtaining informed consent, it is important to remember about guidelines dictating proper clinical conduct. Patients must be treated sincerely and their dignity must be safeguarded. In the West, instructional opportunities, brochures, and multimedia applications, are made available to patients regularly. These aim to describe in a proactive manner the widest possible range of treatment options available to as many patients as possible (7). Some authors have suggested that recall could be enhanced by asking patients to paraphrase the information about their disease state described by a medical specialist, as if offering an explanation to another patient.

According to an article published in "Lancet", in brochures describing surgical treatment, the following information should be found:

- Simple anatomical diagrams illustrating the nature of the operation.
- A description of the post-operative period, including information about possible catheterization, probes, venous cannulations, as well as rehabilitation and dietary recommendations.
- The drugs and drug types the patient should be prescribed before and after the procedure.
- The expected duration of convalescence, during which the patient may experience fatigue and whatever limitations to his or her personal and professional lives.
- A clear and comprehensible description of possible complications and risks related with the procedure as well as the probability of their occurrence (14).

A brochure such as this would constitute a valuable tool in the Polish healthcare system,

which is characterized by an established bureaucracy in which few surgical specialists available to provide pre-operative consultations to the many patients in the system, particularly those of an advanced age. Nevertheless, the option of harnessing this bureaucracy in part as a substitute for discussions about treatment too lengthy and tiresome for some patients to endure, remains to be explored. Such a method of reinforcing patients' being informed about treatment options and subsequent ability to give their consent to the proposed procedures could be developed and presented for certification to the Association of Polish Surgeons. Following this process of research and development, the resulting information aimed at patient self-education could be published on web pages, each specifically dedicated to an individual medical procedure, containing succinct written information complemented by multimedia presentations.

## CONCLUSIONS

The process of obtaining the informed consent of a patient is a difficult undertaking, achieved through various means dependent upon the point of care. Therefore, this process warrants the adoption of a standardized method. In the age of widespread access to technology, particularly with respect to its being harnessed in patient education about disease state, it is possible to also include information concerning specialized medical treatment. The exception to this being directives from specialist doctors concerning preparation prior to the provision of treatment as well as information pertaining to informed consent, which must be communicated verbally. Mobile applications, many of which are already capable of providing basic medical information to patients, may be harnessed to deliver further direct information to patients, such as that pertaining to informed consent, as certified by the Association of Polish Surgeons. It is therefore possible that mobile applications may serve as additional tools in patient self-education, thus reducing the proportion of grievances brought forth against medical professionals directly involved in the treatment process.

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