



A Well-understood Surgical Informed Consent: A Scoping Review

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Abstract

The implementation of surgical consent has shifted from simply getting a signature to a focus on doctor-patient communication. Providing adequate information is very important for patients in making decisions so that patients voluntarily agree to medical action. Understanding of the medical information that has been provided is the basis for patients to give consent, but in reality many patients find it difficult to understand and doctor fail to administer proper information. The purpose of this scoping review are to evaluate patient's understanding of the standard surgical informed consent process or those given by other methods and to identify factors that influence this patient's understanding. Three electronic database (ProQuest, ScienceDirect, and Scopus) were used to search literature from 2017 until 2022. A total of 391 articles were identified and 25 articles were selected according to the PRISMA guidelines and the PCC framework. 9 of 11 articles stated that patient understanding level was low. Factors that influence it include education background, age and language limitations. 12 studies (85%) showed that patient understanding improved with the use of additional information media. Overall, the patient's understanding of surgical informed consent is still low. Communication between doctor and patient plays a big role in it. Various interventions to improve the communication process can be used to improve patient understanding.

INTRODUCTION

Patient safety has become a major concern in healthcare for the last few years. This concern is an awareness of "to err is human", the understanding that medical errors are very likely to occur by health workers. To anticipate this, a system was created that aims to prevent medical errors. The system is carried out based on the awareness that the health services provided must prioritize patient safety. The real form of implementing

the system is well understood informed consent (Khan, 2012; Richardson, 2013; Mudiyansele et al., 2019). 'Informed consent' is defined as a process of communication between doctors and patients with the aim that medical information provided to patients can be understood and used as material for consideration in making decisions to approve or refuse medical action without coercion (Pallett et al., 2018; Villanueva, Talwar and Doyle, 2018).

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Although it remained anonymous until 1957, "informed consent" which originated in legal decisions based on patient autonomy became a necessity to provide information about the benefits and risks of medical action to patients. Until finally the use of informed consent is increasingly widespread, not related to medical practice but also to clinical research (Cocanour, 2017; Bazzano, Durant and Brantley, 2021). The urgency contained in the informed consent is that the patient able to understand the information provided and use it as a reference in making the right decision. Several important things were identified in it, namely the information provided and patient understanding. Information is defined as an explanation given by the surgeon to the patient or family regarding the diagnosis, surgical action plan, how to perform it, the benefits, risks, complications, how to manage risks and complications as well as alternative actions. The purpose of providing this "key information" is to obtain a good understanding of the patient as a basis for giving consent or refusal. Patient comprehension is the most important thing in an informed consent (Bazzano, Durant and Brantley, 2021).

Currently, informed consent became a medical ethics contained in the regulations of medical practice (Cocanour, 2017; Moeini, Shahriari and Shamali, 2020; Khoshrang et al., 2021). It is stated that informed consent is more than just signing legal document. Implementation of informed consent encourages active patient involvement in making decisions on medical action (Lin et al., 2017). We need to remember that not all patients who agree and sign the informed consent document have understood all the information explained by the doctor, it's not an easy thing to make patients understand (Dewar, Pieters and Fried, 2021). It was concluded that the most important variables in informed consent were patient competence in making decisions, obtaining medical information clearly and making it without coercion (Cocanour, 2017; Lin et al., 2019; Pucher et al., 2019). They must be able to understand the information provided, inform their decisions and understand the consequences of the decisions they make. The Physician's efforts to provide adequate information and to assess the patient's understanding are a critical measure for the success of the informed consent process (Cocanour, 2017; Lin et al., 2017).

Surgery is a frightening experience for the patient and information in medical terms which is difficult for the patient to understand causes anxiety in the patient. Limited time for communication in the informed consent process due to

surgical procedures that must be performed immediately, emotional stress, physical pain and fear affect patient to listen and understand the information given by the doctor. (Nuraeni, 2016; Lin et al., 2017, 2019; Agozzino et al., 2019).

It is a challenge for health workers, especially surgeons, to provide important information about surgical plans in lay language that is easy for patients to understand. Most patients find it difficult to understand medical terms and clinical concepts used by surgeons, this is often not realized and is the biggest cause of a surgeon's failure to provide information to patients (Villanueva, Talwar and Doyle, 2018). This condition is a challenge in itself because a harmonious relationship between doctors and patients is created through an informed consent process (Khoshrang et al., 2021). Accordance to various methods of delivering informed consent, the level of patient understanding that is formed also varies. The language barrier, the patient's education level and the doctor's ability to communicate affect the patient's understanding of informed consent. These three things are the most common barriers to communication between doctors and patients (Fink et al., 2010; Cocanour, 2017; Fudman et al., 2019).

Implementation and patient understanding of surgical informed consent is still not optimal. Patient understanding and surgical informed consent process are still not optimal. The publication of Hall et al states that 69% of patients decide to undergo surgery without seeing a surgeon and 47% of patients' decisions are not influenced by a doctor. Most of the patients (68%) said informed consent was only a formality. (Hall et al., 2012). Informed consent documents fail to bridge communication between doctors and patients because the language contained in them is difficult for patients to understand (Zimmermann et al., 2021).

Publications regarding patient understanding of surgical informed consent have not been widely published in Indonesia. Ulfa et al revealed that surgeons' awareness of the importance of applying informed consent is still very low, this can be seen from the completeness of filling out informed consent documents which have not reached 100% (Ulfa, 2018). Herfiyanti et al stated that 54.1% of doctors' explanations did not mention prognosis, 52.5% did not mention alternatives and risks and 50.8% did not mention complications (Herfiyanti, 2015). Susanto et al stated that additional information media were needed to facilitate the informed consent process and increase patient understanding of the information provided (Susanto, Pratama and Hariyanto,

2017). Alvionita et al said that the informed consent process would go well if the doctor provided an explanation according to what had been stated in the informed consent document (Alvionita, Harahap and Aini, 2021).

Failure to carry out informed consent illustrates the difficulty of gaining patient understanding of surgical procedures. The question is what are the underlying causes, what are the difficulties in the informed consent process and what additional information media is ideal to use. Through these questions, the best strategy and method can be made that can be used by surgeons in providing information and carrying out informed consent. This scoping review aims to assess patient understanding through standard informed consent or by using additional information media and to look at the factors that influence patient understanding of surgical informed consent.

METHOD

The selection of this scoping review was based on the consideration that a scoping review is a suitable method for summarizing findings that is heterogeneous in a research method. Article searches using the ProQuest, Science Direct and Scopus databases were conducted from 2017 to 2022. The search strategies for each included database are presented in table 1. The search used the framework from the Joanna Briggs Institute Methodology for scoping review and keywords: patient understanding, patient understanding, patient knowledge, consent surgery; and the Boolean operators "OR" and "AND" to ensure a broad capture of the existing articles.

PCC (Population, Concept and Context) question in this scoping review are: (1) Population: adult surgical patients; (2) Concept: patient understanding of surgical informed consent; (3) Context : Hospital.

Desired articles include published articles, in English and full text. The topic used is a study that assesses patient understanding, factors that influence patient understanding and interventions to increase patient understanding of surgical informed consent. Exclusion criteria, namely consent to clinical research, screening, diagnostics, and prescriptions; research on geriatric patients, the patient was unconscious and unable to give informed consent.

Three reviewers evaluated the title and abstract of the article sought. After the search process, all selected articles will be collected and uploaded to the Mendeley Reference Manager and duplicates removed. Differences of opinion between reviewers regarding the data extraction

process were resolved through discussion and the final decision was based on an compliance between the three. Data is presented in tabular form.

The search results and inclusion process of articles in this scoping review are described and presented according to the preferred reporting format for systematic review and meta-analysis extension for scoping review (PRISMA-ScR) flowchart (Tricco et al., 2018) The prismatic study selection is shown in Figure 1.

RESULT AND DISCUSSION

391 articles were identified in this scoping review in the initial search. After removing duplication, language barriers and full text only articles, a total of 127 articles were screened for eligibility. After filtering the abstracts on the articles obtained, 102 articles were successfully excluded and 25 articles were found at the end of the search. The articles obtained are summarized in table 2.

The articles in this scoping review were obtained from 5 continents and 14 countries, 57.1% of the articles (n=8) were from the United States. Most of the articles are observational and experimental research designs, two studies are systematic reviews. The number of respondents was quite varied, ranging from 10 to 420 patients. The basic characteristics of the articles in the scoping review are presented in table 1.

11 articles described the patient's understanding of surgical informed consent and the factors that influence it. Patient understanding was assessed after standard informed consent was given, namely during the surgical informed consent process, the patient met and received important information about the surgical procedure from the surgeon verbally and then used that information to express consent and sign the operating agreement. Then, patient understanding was assessed through questionnaires, 4 of which used structured questionnaires, 2 used special questionnaires, 2 used open-ended questionnaires and 2 used multiple choice questionnaires. Most of the assessment is done using a Likert scale. 6 articles immediately assess patient understanding and 5 articles evaluate several days to several months. The results obtained by 81.8% or 9 of the 11 articles said that the patient's understanding of surgical informed consent was still low. Several factors that influence it include education, age and language.

14 articles assessed patient understanding with standard informed consent and by using additional information media such as written media (pamphlets and leaflets) and digital media

(web, mobile applications and interactive videos). Significant differences in the level of patient understanding using additional information media were found in 12 articles.

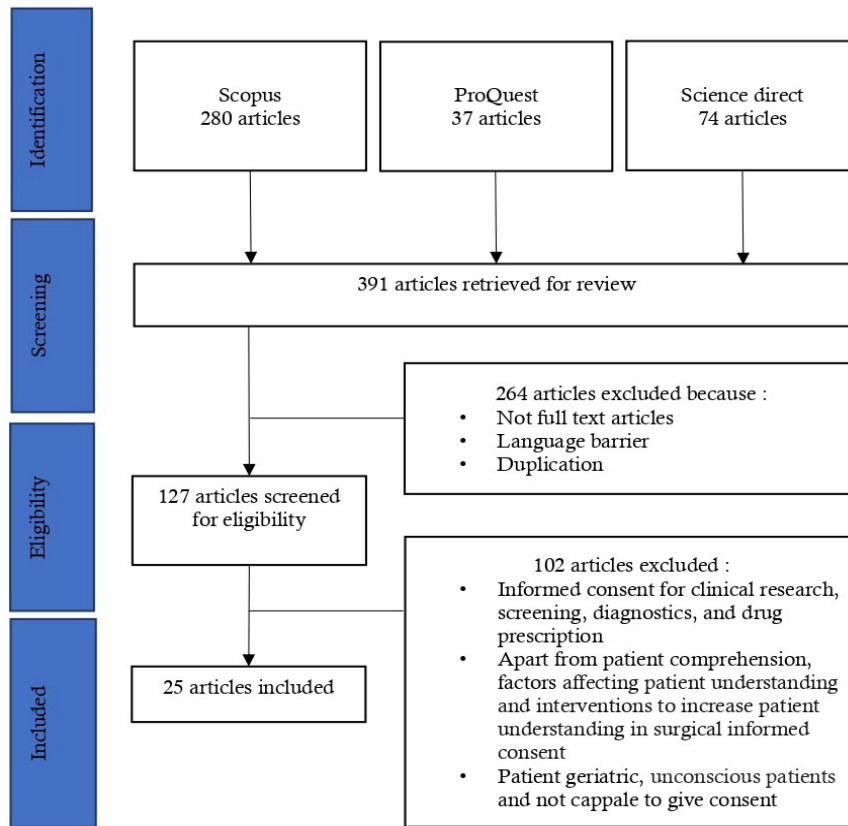


Figure 1. PRISMA-ScR Research Diagram

Table 1. Characteristics of The Articles

Place	
America	8
Australia	2
Asia	6
Europe	5
Africa	2
Methods	
Observational	11
Experimental	12
Systematic Review	2
Year of Publications	
2017-2019	21
2020-2022	4
Participant	
<100	16
100-200	2
200-300	4
>300	3

Table 2. Selected Articles

No	Author, Country and Year of Publication	Method	Purpose	Result
1	Dewar et.al, United States, 2021	A Systematic Analysis	To describe the informed consent process	The patient's decision was made before seeing the doctor. The patient's expectations and beliefs influence the decision
2	Nnabugwu et.al, Nigeria, 2017	Cross-sectional	To evaluate the patient's understanding and the patient's ability to remember the information provided	78.3% of respondents were able to remember appropriately. Education affects the level of understanding and the patient's ability to remember.
3	Fudman et.al, United States, 2018	Cohort	To assess the improvement of patient understanding through the interventions provided.	Additional information media increases the patient's ability to remember information
4	Weise et.al, Germany, 2021	Mixed Methods	To evaluate evidence-based informed consent documents	Evidence-based information can enhance patient understanding
5	Axelrod et.al, United States, 2017	Multistage Analysis	To assess the use of illustrated animation in mobile applications as a medium of information on informed consent	The use of animated images on mobile applications significantly provides a reference for patients in making the right decisions
6	Moeini et.al, Iran, 2017	Cross-sectional	To evaluate the ethics of the surgical consent process	A framework needs to be used to assess the quality and difficulty of the surgical informed consent process
7	Stewart et.al, United States, 2020	Pilot Study	To evaluate the use of visual images as additional information media in the informed consent process	The use of visual images during the consent process is useful for helping patients recall surgical risk, reduce anxiety, and improve understanding
8	Benning et.al, United Kingdom, 2019	Cross-sectional	To evaluate the effect of using medical terminology that is often used by doctors on patient understanding	Medical terms are not easily understood by patients, influenced by differences in language and level of education
9	Rouf et.al, France, 2017	A Prospective Study	To compare the use of verbal, written and digital information in surgical informed consent	The use of digital information media significantly improves patient understanding, especially in patients with hearing loss

No	Author, Country and Year of Publication	Method	Purpose	Result
9	Rouf et.al, France, 2017	A Prospective Study	To compare the use of verbal, written and digital information in surgical informed consent	The use of digital information media significantly improves patient understanding, especially in patients with hearing loss
10	Wiesen et.al, United States, 2018	Cohort	To evaluate Pre-operative Surgical Assesment System	The SURPAS tool significantly improves patient understanding compared to the standard consent process
11	Kong et.al, Malaysia, 2017	Prospective Study	To assess the effectiveness of leaflet compared to verbal information in improving patient understanding	Although the use of leaflets can increase patient satisfaction, it does not significantly increase patient understanding
12	Marcus et.al, 2018	Cohort	To assess the effectiveness of using digital interactive media on informed consent	The use of interactive multimedia information on multimedia websites can assist in the informed consent process
13	Villanueva et.al, Australia, 2017	A Systematic Review	To evaluate preoperative education in improving patient's memory and comprehension	The patient's ability to remember and understand information is significantly improved with the use of various additional information media
14	Chia et.al, Singapore, 2018	Cross-sectional	To evaluate the quality of informed consent by assessing the patient understanding and ability to recall the information provided	Patient understanding of surgical information and complications is generally low, especially in geriatric patients
15	Ng. et.al, Australia, 2019	Observational Study	To analyze the effect of using videotape on the surgical informed consent process	The patient is only able to understand part of the information provided by the surgeon
16	Lemmu et.al, 2018	Cross-sectional	To assess the patient's perception and understanding of surgical consent	In general, patients have limited knowledge, perception and understanding of surgical informed consent

No	Author, Country and Year of Publication	Method	Purpose	Result
17	Lin et.al, Taiwan, 2017	Pilot Study	To evaluate the use of educational videos on the knowledge, understanding and satisfaction of patients with the informed consent process	Educational videos can be used to increase patient knowledge and satisfaction
18	Lin et.al, Taiwan, 2019	A Systematic Review	To evaluate the use of various methods of providing information to improve patients' understanding of surgical informed consent	The patient's memory and understanding of the risks of surgery both on the use of written or video information media than if the information is given verbally
19	Singh et.al, India, 2021	Cross-sectional	To evaluate the patient's perspective and understanding of the contents of the informed consent	The patient's level of awareness, perception and understanding of surgical informed consent was found to be good
20	Perin et.al, Italy, 2017	Clinical Trial	To evaluate the use of 3-dimensional images in improving doctor-patient communication	3D images significantly assist surgeons in establishing communication, enhancing patient understanding
21	Sceats et.al, United State, 2018	Mixed-methods	To evaluate information content and quality of informed consent.	The language the surgeon uses affects the patient's memory and ability to understand
22	Ruske et.al, United State, 2018	Cross-sectional	To evaluate the patient's level of understanding of the basic information	The patient understanding of the basic information provided by the surgeon is low
23	Yoon et.al, Seoul, 2018	Pilot Trial	To asses 3D image in improving patient understanding	Three-dimensional images significantly improve patient understanding
24	Kinman et.al, United State, 2018	Control Trial	To evaluate the effect of using additional information media using the iPad application on the informed consent process for pelvic organ prolapse surgery (POP).	Aplikasi ipad berbasis POP tidak meningkatkan pemahaman pasien terhadap informed consent bedah
25	Shemesh et.al, Israel, 2018	Cohort	To evaluate the quality of the informed consent in emergency versus elective surgery	Patient understanding of emergency surgery in trauma patients is lower than in elective orthopedic surgery

Most of the articles describe the patient's poor understanding of surgical informed consent in both elective and emergency cases (Shemesh et al., 2019). Patients' understanding of low surgical informed consent is very worrying. The two articles get different results. Nnabugwu et al found 78.3% of respondents had the ability to remember information well, this indirectly illustrates the patient's ability to understand the information provided (Nnabugwu et al., 2017). Singh et al explained the same thing, in their article they mentioned the high level of patient understanding of surgical informed consent (Singh, Rochwani and Oberoi, 2021).

Applying informed consent properly is not an easy thing in medical practice, there are many complicating factors (Overcarsh, Arvizo and Harvey, 2019). That matter lead to low understanding of the patient. It is not easy for surgeons to provide information and make patients understand it, but it still has to be done. Various difficulties need to be identified to be able to make an optimal strategy.

In understanding the low patient understanding, we need to review the important variables in informed consent, namely the medical information provided, the patient's ability to understand and the consent given voluntarily (Lin et al., 2019; Overcarsh, Arvizo and Harvey, 2019). Informed consent is said to be good if there is good communication between the surgeon and the patient before the surgery is carried out and the patient can understand the information provided by the surgeon and use it as a basis for approving or rejecting the planned surgery.

Some of the information that must be conveyed includes diagnosis, surgical action plans, risks and complications of surgical procedures, how to overcome them, alternative actions and roles of team members (Overcarsh, Arvizo and Harvey, 2019). All of those information must be explained by the surgeon, but some doctors fail to explain properly so that many patients are unable to remember the diagnosis, surgical procedure, benefits, risks and complications of the procedure (Lin et al., 2019).

Ruske et al found that the cause of low patient understanding was the lack of information provided by doctors, often patients were not informed about the surgical procedure to be performed (Ruske et al., 2021) Surgeons often do not realize the importance of building patient communication and trust as a safeguard against future legal cases (Ruiz López, 2013; Lemmu et al., 2020). Not all surgeons are aware of this, they think that all information is included in the infor-

med consent document that can be read by the patient, but unfortunately many patients do not read the informed consent document carefully before signing it (Ruiz López, 2013; Lin et al., 2019; Lemmu et al., 2020).

Basic education and age of the patient is the biggest influence on the patient's level of understanding (García-García et al., 2019; Ruske et al., 2021). The patient's ability to understand surgical information is in line with the level of education, so it is very important to provide information that is easy to understand (Sceats et al., 2019). The level of education that is directly proportional to the patient's understanding was noted by Shemesh et al where patients with a higher education level than high school had a better understanding (Shemesh et al., 2019). The same results were also obtained by Moeni et al, the higher the level of education, the more patients wanted to get more information. therefore it is very important to present the information according to the educational level of the patient (Moeini, Shahriari and Shamali, 2020).

Chin et al found that age influences patients to be able to understand information, it takes a longer time to provide information to geriatric patients with various comorbidities and cognitive decline (Chia et al., 2019). Zimmermann also found a positive correlation between age and patient understanding, where young patients (under 39 years) are better able to understand difficult information (Zimmermann et al., 2021). Nnabugwu et al obtained different results, there was no difference in the level of understanding in young or old patients. Further described the effect of limited access to information in the young group causing a lack of information in both young and old patients (Nnabugwu et al., 2017). García-García revealed the influence of age and gender, where the percentage of uneducated women is higher than men so that the level of understanding is better in the male group. The low level of education in the youth group is due to the opportunity to get a better education in the male group (García-García et al., 2019).

The effect of language on the patient's level of understanding was found in several articles (Sceats et al., 2019). Perbedaan bahasa dan kompleksitas istilah medis yang digunakan dokter bedah kurang dipahami oleh pasien (Benning et al., 2021). Not only that, limited communication time causes patients to ignore important information and are only able to understand basic things (Shemesh et al., 2019). Li Ching Ng et al stated that surgeons' inconsistency in using medical terms made patients even more confused and

difficult to understand the information provided (Li Ching Ng et al., 2021).

The above description emphasizes the importance of surgeons' communication skills, especially in using time efficiently, using language that is easy to understand and consistent medical terms so that they are easily remembered by patients (Shemesh et al., 2019; Benning et al., 2021).

Often the standard informed consent process fails to make the patient understand the information provided, so that additional information media can be used to make it easier for surgeons to provide information and shorten communication time (Paterick, Paterick and Paterick, 2020).

Various information media can be used, both written and digital media. Several publications state that the extent of written education given to patients before the day of surgery can increase patient understanding because patients can re-read the information (Zimmermann et al., 2021). Two articles found different results, Kong et al said there was no significant difference in the level of understanding of patients with the use of written media (Koong et al., 2021). This statement was supported by Agozzino et al who stated that written informed consent documents were not sufficient to provide information and make patients understand. It was further explained that patients rarely read informed consent documents, especially geriatric patients and low education levels (Agozzino et al., 2019). Wong et al described that the patient's interest in reading plays an important role (Wong et al., 2016). Not only that, the perception of surgeons who are only concerned with signatures on consent to the procedure causes written information media to be given several hours before surgery so that there is not enough time for patients to read it (Agozzino et al., 2019).

Kong et al wrote in their article that it is not enough just to provide written information, additional information media are needed which are more interactive. Several articles feature the use of information media with three-dimensional images that increase patient interest in viewing and listening to information. The use of additional information media significantly increases the patient's understanding of informed consent (Yoon et al., 2019; Perin et al., 2021; Stewart et al., 2021).

Various multimedia applications provide technological convenience in the health service process, including the informed consent process. The 6 articles in this scoping review use websites, audio visuals and mobile applications as information media to provide education about surgical

procedures. Obtained significant results in increasing the level of patient understanding (Axelrod et al., 2017; Lin et al., 2017; Rouf et al., 2017; Marcus et al., 2018; Fudman et al., 2019; Wiesen et al., 2020; Weise et al., 2021). Interesting audio visuals can be used in disabled patients. Rouf et al in their article said that digital information media used in hearing loss patients can improve patient understanding of cochlear implantation plans (Rouf et al., 2017). Attractive, interactive and convertible information media can be used to facilitate the informed consent process, but good verbal communication is an important part and should not be replaced by other forms of communication (Kinman et al., 2018).

CONCLUSION

Numerous articles have described the low level of patient understanding of surgical informed consent. It is not easy for doctors to provide information about surgical plans. Several factors affect the patient's ability to understand the doctor's explanation, including the patient's education level and the doctor's communication skills. Structured education is very important given to patients before surgery. Several informational methods can be used to increase patient understanding.

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