e-ISSN: 0975-5160, p-ISSN: 2820-2651

Available online on www.ijtpr.com

International Journal of Toxicological and Pharmacological Research 2023; 13(11); 06-10

Original Research Article

Digitalization of Informed Consent for Surgery: A Contemporary Perspective

Divyeshkumar Keshavjibhai Vadgama[1], Ojas Bharatkumar Solanki[2], Amitkumar Dilipkumar Modi[3], Piyush Makwana[4*]

[1]Associate Professor, Department of Forensic Medicine, Government Medical College, Bhavnagar, Gujarat, India

[2]Senior Resident, Department Forensic Medicine, Dr. N.D. Desai Medical College & Hospital

[3]Assistant Professor, Forensic Medicine Department, GMERS Medical College, Vadnagar, Gujarat, India

[4]Assistant Professor, Department of Physiology, GMERS Medical College Himmatnagar, Gujarat, India

Received: 01-11-2023 / Revised: 03-11-2023 / Accepted: 05-11-2023

Corresponding author: Dr. Piyush Makwana

Conflict of interest: Nil

Abstract:

Background and Objectives: In the realm of surgical practice, informed consent holds a position of paramount significance. The utilization of digital media emerges as a promising approach to augment patients' comprehension of the proposed surgical procedures. This study aimed to investigate the impact of incorporating an online digital educational presentation (DEP) alongside the conventional informed consent (CIC) for laproscopic cholecystectomy.

Material and Methods: This prospective, randomized study involved allocation of 67 patients of laparoscopic cholecystectomy, into two groups: DEP+CIC (intervention, n=33) or CIC (control, n=34). The DEP entailed a comprehensive online 13-slide video-enhanced module that provided a detailed account of the risks, benefits, expectations, and anticipated outcomes associated with laparoscopic cholecystectomy. A 20-item MCQ test was used for assessment of baseline and post-consent comprehension, modified Client Satisfaction Questionnaire (CSQ-8), was used for patient satisfaction and the duration of the consent process was quantified in seconds using a stop watch.

Results: Baseline demographic data and procedure-specific knowledge were equivalent between groups. Post-consent knowledge was significantly higher in the DEP+CIC vs CIC group. The duration of time to obtain informed consent was significantly shorter for the DEP+CIC group. Significantly higher patient satisfaction was observed in DEP+CIC group.

Conclusion: The incorporation of an online DEP module into the conventional informed consent process for surgery resulted in enhanced patient comprehension, high levels of patient satisfaction and remarkable reduction in time required for consent.

Keywords: Informed Consent, Patient Satisfaction, Comprehension, Laparoscopic Cholecystectomy.

Introduction

The contemporary relationship between physicians and patients, characterized by shared decision-making, significantly diverges from the traditional paternalistic healthcare models. Within the field of surgery, the practical application of this shared decision-making framework is exemplified by the concept of true informed consent. Despite the legal incorporation of informed consent in the healthcare systems of many nations, its execution in practice often falls short of the intended standards. Notably, an extensive report revealed that a significant proportion (65%) of medico legal cases pertained to issues surrounding informed consent for surgical procedures [1-3] Achieving genuine informed consent necessitates that patients have a comprehensive understanding of the information presented to them. Consent devoid of comprehension undermines the collaborative decision-making process essential in the context of the contemporary surgeon-patient relationship. However, numerous factors inherent to current surgical practices frequently lead to suboptimal consent procedures. A quality assurance review on informed surgical consent, for instance, disclosed that a documented consent discussion was present in only 26% of surgical dictations [4-6]. Technology holds the potential not only to enhance a patient's comprehension of the risks, benefits, and alternatives associated with a proposed surgical procedure but also to standardize and ensure the

thoroughness of the consent discussion [6]. Regrettably, the existing literature on the use of technology in informed consent discussions is relatively limited.

One randomized controlled trial, for instance, demonstrated an 18% increase in knowledge about a urological procedure when a 7-minute video was employed in comparison to the conventional verbal communication during the consent process [7]. Conversely, the incorporation of an iPad application alongside standard verbal consent for pelvic reconstructive surgery did not result in immediate improvements in patient comprehension and led to poorer retention of information six weeks after the surgery [8]. These conflicting findings underscore the current state of the literature examining the role of technology in the context of informed consent discussions.

The aim of this study was to introduce online video-enhanced presentation (DEP) as a supplement to the conventional informed consent (CIC) for the laparoscopic cholecystectomy procedure. Additionally, the study sought to investigate the effects of completing the DEP module on patients' understanding of the risks, benefits, alternatives, expected outcomes associated with operation, their satisfaction with the consent appointment, and the time required for a face-to-face interaction between a surgeon and a patient to obtain informed consent.

Material and Methods

This prospective randomized study enrolled adult patients aged 18 years and above who underwent a multidisciplinary evaluation and were deemed eligible candidates for laparoscopic cholecystectomy. Exclusion criteria included patients undergoing a conversion laparoscopic procedure, those with a language barrier, individuals unable to access and view the interactive Digital Education Presentation (DEP), and those incapable of providing informed consent.

Participants were randomly assigned in a 1:1 ratio to either the intervention group (receiving the interactive digital education presentation in addition to conventional informed consent, DEP+CIC) or the control group (receiving conventional informed consent, CIC). Demographic data of participants, including age, gender, and level of education, were collected. Participants were also questioned about any prior consultations with a surgeon.

A baseline assessment was conducted through a multiple-choice test (MCQ) consisting of 20 questions. This test aimed to evaluate the participants' initial understanding of the risks, benefits, alternatives, and expected outcomes associated with the laparoscopic procedure. Importantly, results of this baseline knowledge test were not disclosed to the participants. Furthermore, participants were asked to self-assess their comprehension of the procedure using a scale ranging from 0 to 10, with 0 representing no prior knowledge and 10 indicating a comprehensive understanding.

Participants assigned to the DEP+CIC group initiated their consultation with the surgeon, commencing with a standardized history-taking, physical examination, and a review of relevant investigations. Subsequently, participants were provided access to a computer with a link to an online interactive DEP module, encompassing 13 slides that detailed the risks, benefits, alternatives, and expected outcomes of the operation. During the completion of the DEP module, the surgeon exited the room to facilitate the participant's independent progress. There was no time limit for module completion, allowing participants to navigate back and forth to review specific topics. Once the DEP module was completed, the surgeon returned to address consent issues, clarify any queries, and assume informed consent, which was documented with a signed consent form.

Participants allocated to the CIC group initiated their consultation with the surgeon by undergoing a standardized history-taking, physical examination, and a review of pertinent investigations. The surgeon then engaged in a comprehensive discussion covering the procedure, surgery indications, alternatives, risks, complications, expected weight loss, and recovery prospects. Participants were encouraged to ask questions during this consent process. After the discussion, informed consent was assumed and documented with a signed consent form.

Following the clinical interaction with the surgeon and the signing of the consent form, participants were required to complete the same 20-question MCQ test to assess their understanding of the procedure's risks, benefits, alternatives, and expected outcomes. This test was identical to the one administered during the baseline assessment. Additionally, participants rated their comprehension of the operation on a scale from 0 to 10, indicating their level of prior knowledge. Both groups were requested to complete a modified Client Satisfaction Questionnaire (CSQ-8, maximum score 32) [9] after signing the consent form. This questionnaire was designed to assess the level of satisfaction with the clinical encounter.

The duration of the face-to-face interaction between the surgeon and the participant was quantified in seconds. This timeframe excluded the time needed for history-taking, physical examination, and investigation review. For participants in the DEP+CIC group, the timer was

initiated when the surgeon returned to discuss consent issues and answer additional questions following DEP module completion.

The timer ceased once the consent form was signed. In the CIC group, the timer was initiated when the surgeon commenced the discussion on the operation, its indications, alternatives, risks, benefits, and expected outcomes, and it concluded when the consent form was signed. Descriptive statistics were computed, encompassing two-sample t-tests for inter-group comparisons and paired t-tests for intra-group comparisons of continuous variables.

A Pearson Chi-squared test was utilized for between-group comparisons of categorical variables. The threshold for statistical significance was set at $\alpha = 0.05$ and all data analysis was executed using Epi Info™ version 7.

Results

Table 1, which presents baseline demographic data for participants in each group, shows that participant characteristics were largely similar between the groups.

Table 1: Demographic details of study participants

Parameter	Control Group (CIC) (n=34)	Intervention Group (DEP+CIC) (n=33)	p-value
Age (years) (Mean ± SD)	41.5 ± 6.7	43.7 ± 7.4	0.72
Gender			
Male	10	14	0.23
Female	24	19	
Level of education			
12th standard	1	3	0.67
Diploma	7	9	
Graduation	19	15	
Postgraduate	7	6	
Medical background			
Yes	14	10	0.23
No	20	23	
Previously consulted a surgeon?			
Yes	12	12	0.67
No	22	21	

The initial knowledge about the procedure and the self-assessed understanding of it were comparable in both groups, as indicated in Table 2.

Participants in the DEP+CIC group showed a significantly greater improvement in knowledge from the baseline to post-intervention. The self-reported level of understanding of the operation, the time saved in obtaining informed consent, and the satisfaction with the consent encounter was all significantly higher in the DEP+CIC group (Table 2).

An impressive 95% of participants in the intervention group expressed satisfaction with the online DEP module.

Table 2: Comparison of comprehension, satisfaction and duration of consent

Parameter	Control Group (CIC) (n=34)	Intervention Group (DEP+CIC) (n=33)	p-value
Baseline Assessment			
Comprehension Level (%)	73.5 ± 10.2	75.2 ± 9.1	0.44
Self-reported understanding of operation (%)	68.5±17	70.5±16	0.67
Post-intervention Assessment			
Comprehension Level (%)	79.1±8.4	84.3±9.0	0.03*
Self-reported understanding of operation (%)	86.2±1.2	89.7±0.8	0.14
Time to complete the consent process (sec)	745±218	363±194	0.02*
Patient satisfaction with the consent appointment (out of 32)	31.2 ± 2.5	31.6 ± 1.3	0.32

*p value <0.05, significant

Discussion

The integration of the online DEP module into the conventional CIC process led to improved knowledge specific to the procedure post-consent, and notably shortened the duration of the consent procedure.

Importantly, this was accomplished while upholding a high level of patient satisfaction.

Comparable findings have been reported in previous research studies [7, 10-12].In our study, the DEP module offered a unique combination of textual content, images, and videos. We argue that this approach to delivering information facilitated a more interactive and dynamic learning experience.

Our study has several limitations. Firstly, we couldn't implement blinding for both the surgeon and the patient regarding group randomization due to the necessity for the surgeon to be aware of when to introduce the DEP module and when to proceed with standard verbal consent. However, the significant increase in knowledge within the CIC group from baseline to post-intervention assessment, along with an average of 11.6 minutes spent on a comprehensive discussion of the operation in that group, reduces the likelihood of biased information delivery between the surgeon and the patient.

Secondly, our findings should not be extrapolated to other procedures or different settings, such as emergency surgery. The relatively high baseline procedure-specific knowledge in our study may be attributed to the majority of our patients having at least a high secondary school level of education, and conducting some prior research on the risks and benefits of the operation before meeting the surgeon for the consent appointment. We wouldn't anticipate such a high baseline level of procedure-specific knowledge for operations performed without a multidisciplinary assessment or in an emergency context. Also, we could not assess delayed post-intervention assessment of procedure-specific knowledge.

As our findings clearly demonstrate, the utilization of the digital education platform offers distinct advantages to patients. They are more likely to attain a comprehensive understanding of their procedure and express high satisfaction with the consent process.

We also hold optimism that our results can be replicated across diverse patient populations and within other surgical specialties, especially in emergency settings where time constraints may limit comprehensive discussions of risks and benefits. Translating these modules into local languages would enable us to better serve a diverse and multicultural patient population. There is still significant untapped potential in utilizing digital education modules to address a wide range of surgical procedures and cater to the diverse patient population that constitutes modern surgical practice.

Conclusion

Integrating an interactive, video-enriched online Digital Education Module (DEP) alongside the Conventional Informed Consent (CIC) process for laparoscopic cholecystectomy has resulted in an amplified comprehension of procedure-specific details among patients. This innovative approach has also led to substantial time savings for the surgical team. Crucially, these enhancements have transpired without any compromise to patient satisfaction or the quality of the surgeon-patient relationship. The prospective introduction of this module within surgical clinics is poised to yield enhanced efficiency, optimize patient workflow, and mitigate the waiting period for consultations with surgeons. These developments show promise in the quest to streamline healthcare procedures and provide more expeditious care to patients seeking laparoscopic cholecystectomy.

References

1. Evans KG. Consent: A guide for Canadian physicians. 2006.
2. Murphy G. Law Reform Agencies. 2004; Department of Justice Canada.
3. Reibl v. Hughes. Dominion Law Reports. 1980; Supreme Court of Canada: 1-35.
4. Armstrong AW, Alikhan A, Cheng LS, Schupp C, Kurlinkus C, Eisen DB. Portable video media for presenting informed consent and wound care instructions for skin biopsies: a randomized controlled trial. Br J Dermatol. 2010; 163:1014-1019.
5. Murphy WJ. Canterbury v. Spence – the case and a few comments. Forum. 1976; 11:716-726.
6. Hanson M, Pitt D. Informed consent for surgery: risk discussion and documentation. Can J Surg. 2017; 60:69-70.
7. Winter M, Kam J, Nalavenkata S, Hardy E, Handmer M, Ainsworth H, Lee WG, Louie-Johnsun M. The use of portable video media vs standard verbal communication in the urological consent process: a multicentre randomised controlled, crossover trial. BJU Int. 2016; 118:823-828.
8. Kinman CL, Meriwether KV, Powell CM, Hobson DTG, Gaskins JT, Francis SL. Use of an iPad application in preoperative counseling for pelvic reconstructive surgery: a randomized trial. Int Urogynecol J. 2018; 29:1289-1295.
9. Larsen DL, Attkisson CC, Hargreaves WA, Nguyen TD. Assessment of client/patient satisfaction: development of a general scale. Eval Program Plann. 1979; 2:197–207.
10. Zevin B, Almakky M, Mancini U, Robertson DI. Digital approach to informed consent in bariatric surgery: a randomized controlled trial. Surg Endosc. 2022; 36(1):809-816.
11. Saglam K, Kayaalp C, Aktas A, Sumer F. Educational Video Addition to the Bariatric Surgery Informed Consent Process: a Randomized Controlled Trial. Obes Surg. 2020 Jul; 30(7):2693-2699.

12. Kiernan A, Fahey B, Guraya SS, Boland F, Moneley D, Doyle F, Harkin DW. Digital technology in informed consent for surgery: systematic review. BJS Open. 2023 Jan 6; 7(1):zrac159.