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Optimizing the consent process for emergent laparoscopic cholecystectomy using an interactive digital education platform: a randomized control trial

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Abstract

Background Informed consent is essential for any surgery. The use of digital education platforms (DEPs) can enhance patient understanding of the consent discussion and is a method to standardize the consent process in elective, ambulatory settings. The use of DEP as an adjunct to standard verbal consent (SVC) has not been studied in an acute care setting.

Methods We conducted a prospective randomized control trial with patients presenting to the emergency department of a tertiary care hospital with acute biliary pathology requiring a laparoscopic cholecystectomy (LC) between August 2021 and April 2023. Participants were randomized 1:1 to receive either a DEP module with SVC or SVC alone. Baseline procedure-specific knowledge and self-reported understanding of risks and benefits of LC were collected using a questionnaire. Primary outcome was immediate post-intervention knowledge assessed using a 21-question multiple choice questionnaire. Secondary outcomes were delayed procedure-specific knowledge and participants' satisfaction with the consent discussion.

Results We recruited 79 participants and randomized them 1:1 into the intervention group (DEP + SVC, $n = 40$) and the control group (SVC, $n = 39$). Baseline demographics and baseline procedure-specific knowledge were similar between groups. The immediate post-intervention knowledge was significantly higher for participants in the intervention versus the control group with a Cohen's d effect size of 0.68 (85.2(10.6)% vs. 78.2(9.9)%; $p = 0.004$). Similarly, self-reported understanding of risks and benefits of LC was significantly greater for participants in the intervention versus the control group with a Cohen's effect size of 0.76 (68.5(16.4)% vs. 55.1(18.8)%; $p = 0.001$). For participants who completed the delayed post-intervention assessment ($n = 29$), there continued to be significantly higher retention of acquired knowledge in the intervention group with a Cohen's effect size of 0.61 (86.5(8.5)% vs. 79.8 (13.1)%; $p = 0.024$). There was no difference in participants' self-reported satisfaction with the consent discussion between groups (69.5(6.7)% vs. 67.2(7.7)%; $p = 0.149$).

Conclusion The addition of digital education platform to standard verbal consent significantly improves patient's early and delayed understanding of risks and benefits of LC in an acute care setting.

Keywords Informed consent · Digital education platform · Laparoscopic cholecystectomy · Acute care · Technology

Required elements for an informed consent (IC) in surgery are well established and must include details of the procedure, complications, and proposed alternatives [1]. Shortcomings in the IC process can manifest as lack of patient comprehension and loss of autonomy, potentially leading to patient complaints and legal ramifications [2]. A retrospective analysis of malpractice claims and complaints conducted between 2004 and 2013, at a large center in the Netherlands, demonstrated 6% of claims and 10% of complaints involved a deficiency in the surgical IC process [3]. Canadian data show that surgical procedures account for 65% of all medical-legal cases involving inadequacy of informed consent [1]. Laparoscopic cholecystectomy (LC) was the most common procedure cited in medical-legal cases in 2017, with 29% of cases citing inadequacy of the consent process [2]. A systematic review examining the indications for judges' ruling of malpractice relating to IC showed lack

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of information on surgical risks in 68% of cases, lack of documentation in 65% of cases, and insufficient information on alternatives in 13% of cases [4].

With deficiencies in IC potentiating poor patient satisfaction and legal consequences, the use of digital education platforms (DEP) has been shown to enhance patients' understanding of the risks, benefits, and alternatives to a proposed elective operative procedure and to standardize the consent discussion in the ambulatory clinical setting [5]. We previously demonstrated that addition of a digital education platform (DEP) to a standard verbal consent (SVC) versus SVC alone for an elective laparoscopic Roux-en-Y gastric bypass procedure resulted in patients' improved knowledge of the risks, benefits, and alternatives to the procedure with equivalent patient satisfaction [5]. However, the generalizability of these findings to an inpatient acute care setting, where the environment can be chaotic with shortened time for comprehensive informed consent discussions, is currently unknown.

The objective of our study was to explore the effects of adding a DEP module to a SVC on patients' immediate and delayed knowledge of the risks, benefits, alternatives, and expected outcomes of a laparoscopic cholecystectomy (LC) performed in an acute care setting, as well as patients' satisfaction with the informed consent discussion.

Hypothesis 1. Patients who complete the DEP module in addition to the SVC (intervention group) will demonstrate significantly greater immediate and delayed knowledge of the risks, benefits, alternatives and expected outcomes for a LC as compared to patients who only undergo the SVC (control group).

2. Patients who complete the DEP module in addition to the SVC (intervention group) will demonstrate equivalent satisfaction with the consent process as compared to patients who only undergo the SVC (control group).

Methods

Study design

We conducted a prospective single-blinded randomized controlled trial with patients who presented to an academic tertiary care hospital (Ontario, Canada) with biliary pathology requiring an urgent LC in an acute care setting between August 2021 and April 2023. CONSORT study flow diagram is shown in Fig. 1. The study was approved by the University Research Ethics Board (6031730).

Participants, inclusion, and exclusion criteria

We recruited individuals > 18 years of age who presented to Kingston Health Sciences Center (Kingston, Ontario, Canada) emergency department with biliary pathology (intractable biliary colic, acute cholecystitis, choledocholithiasis, cholangitis, gallstone pancreatitis) requiring an urgent laparoscopic cholecystectomy. We excluded patients who were not able to read, write, or speak English; who were unable to provide informed consent due to acute (delirium) or chronic cognitive decline (dementia); and those who were unable to access and view the DEP module.

Randomization

We recruited and randomly allocated study participants to the intervention group (DEP with SVC) or the control group (SVC) in a 1:1 ratio using an unrestricted randomization sequence once the surgery team made the clinical decision to recommend a LC.

Baseline assessment

Demographic data

We collected the following baseline demographic variables: age, sex, level of education ("no high school diploma," "high school diploma," "college or university degree," "postgraduate degree"), background in a medical field (yes/no), and previous consultation with a surgeon regarding a laparoscopic cholecystectomy (yes/no). We collected data regarding admission diagnosis and the setting of clinical encounter (emergency department, surgery ward). An online Qualtrics platform (Provo, UT, USA) was used to collect this data.

English literacy

We collected baseline English Literacy data using a 4-item reading test (Appendix 2). Score of 0 or 1 indicated low literacy level (maximum score 4).

Procedure-specific knowledge

We asked study participants to complete a 21-question multiple choice test (MCQ, maximum score 21) to assess their baseline knowledge of indications for surgery, risks, benefits, alternatives, and anticipated recovery for a LC (Appendix 3). The knowledge test was pilot tested for readability and comprehension with five patients. We also

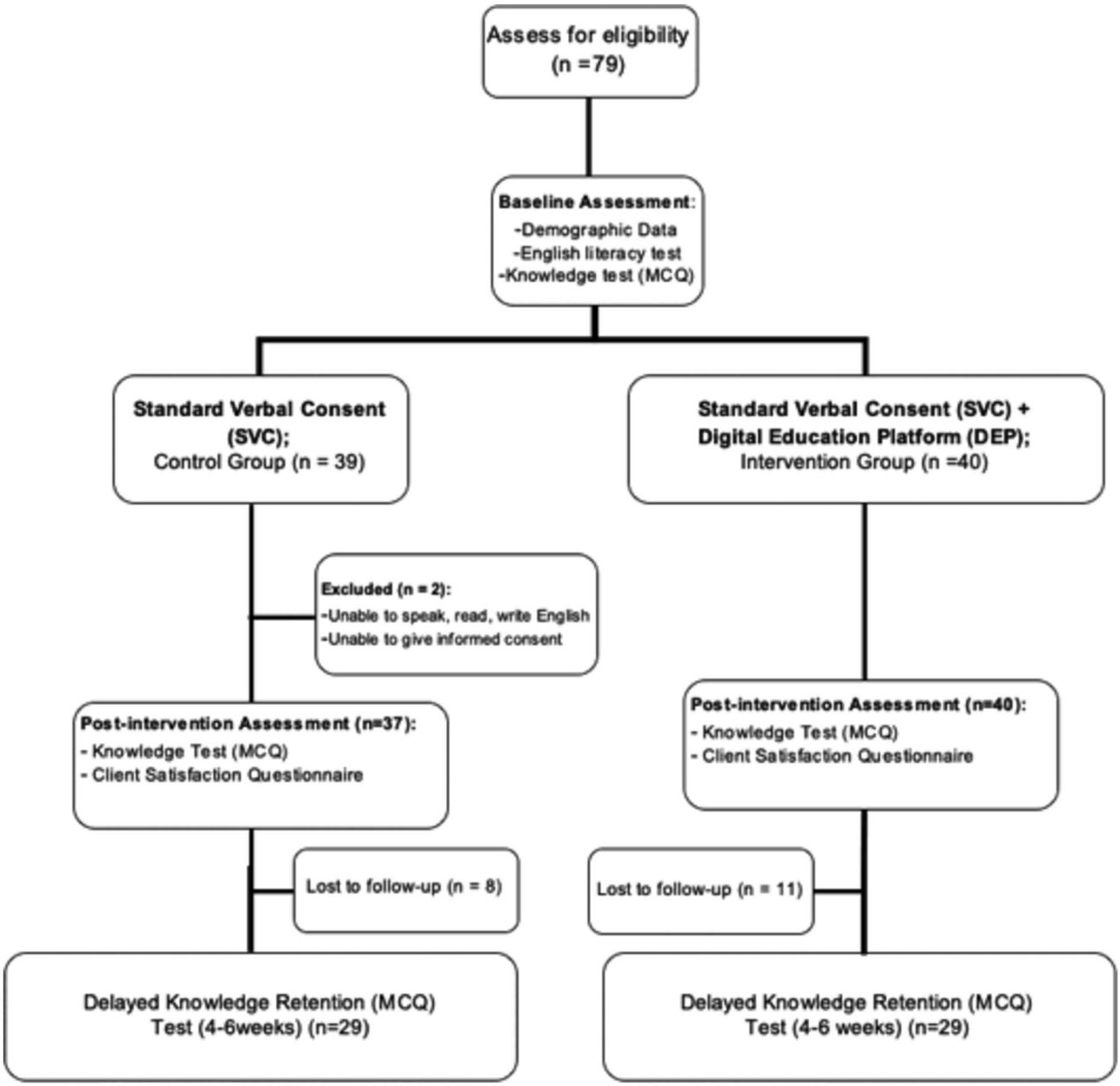

Fig. 1 CONSORT study flow diagram. DEP digital education platform, SVC standard verbal consent

asked study participants to complete a self-reported understanding of LC on a scale from 0 to 10 (0—I have no prior knowledge/10—I know everything).

Intervention group (DEP and SVC)

We presented study participants, randomized to the intervention group (DEP and SVC), with an iPad containing an interactive 29-slide DEP module that discussed the indications, alternatives, risks, complications, expectations, and anticipated recovery after a LC. We asked to participants to review the DEP module at their own pace and to confirm understanding of all of the material presented. We gave participants the opportunity to advance and go back within the module as required to ensure their understanding. Once participants completed the DEP module, they informed the research associate, who in turn notified a member of the surgery team (resident or attending surgeon) that the study participant was ready to undergo the standard verbal consent (SVC). The member of the surgery team acquiring the SVC was blinded to the group allocation of the study participant.

Control group (SVC)

Once the participant was randomized to the control group, a research associate notified a member of the surgery team (resident or attending surgeon) that the study participant was ready to undergo the standard verbal consent (SVC). The member of the surgery team acquiring the SVC was blinded to the group allocation of the study participant.

Post-intervention assessment

Procedure-specific knowledge

Our primary outcome was the immediate post-consent knowledge of the risks, benefits, alternatives, and expected outcomes for the LC assessed using the same 21-question MCQ test that participants completed during the baseline assessment. This questionnaire was provided to patients within a maximum of 3 h from the consent process. We also asked participants to self-report their understanding of LC on a scale from 0 to 10 (0—I have no prior knowledge/10—I know everything). Lastly, we assessed retention of acquired procedure-specific knowledge in 4–6 weeks using the same 21-question MCQ test.

Participant satisfaction

We used a modified Client Satisfaction Questionnaire (CSQ-8, maximum score 32) [6] to assess participants' level of satisfaction with the consent process (Appendix 4).

Sample size

Based on the results of our previous study [2], assuming a standard deviation of 9.0 and medium Cohen's d effect size of 0.66 for the MCQ test, we planned to recruit 36 patients per group to detect a 1.2 point difference in MCQ score (6%) change between two groups, with 80% power for the two-sample t test ($\alpha = 0.05$).

Statistical analyses

We compared baseline demographic data, English literacy scores, procedure-specific knowledge test scores, and self-reported understanding of LC between intervention and control groups using the Student's t test (continuous variables) and the Chi-squared test (categorical variables). We compared immediate and delayed post-intervention knowledge test scores and participants satisfaction with the consent process (CSQ-8 scores) between groups using a Student's t test. We compared within-group changes in procedure-specific knowledge of LC using a paired t test. We used Cohen's d to calculate effect sizes and set statistical significance as $\alpha = 0.05$. We report data as mean (standard deviation) unless otherwise stated. All statistical analysis were performed using SPSS version 28.0.1.1.

Results

We recruited a total of 79 patients for this study and randomized them to the intervention group (DEP and SVC, $n = 40$) and the control group (SVC, $n = 39$). Baseline demographic characteristics of study participants in the intervention and control groups were equivalent for all variables except for the English literacy scores (3.68(0.47) versus 3.31(0.86); $p = 0.02$; Table 1).

Procedure-specific knowledge

Baseline knowledge of the risks, benefits, alternatives, and expected outcomes for LC was moderate and equivalent between groups (DEP + SVC: 78.6(12.9)% vs. SVC: 74.3(13.4)%; $p = 0.16$; Table 2). Similarly, self-reported baseline level of understanding of LC was low and equivalent between groups (Table 2). The immediate post-consent (post-intervention) knowledge of the risks, benefits, alternatives, and expected outcomes for LC was significantly higher for participants in the intervention group versus the control group with a Cohen's d effect size of 0.68 (85.2(10.6)% vs. 78.2(9.9)%; $p = 0.004$; Table 2). Similarly, self-reported understanding of LC post-consent was significantly higher for participants in the intervention group versus the control group with a Cohen's effect size of 0.76 (68.5(16.4)% vs. 55.1(18.8)%; $p = 0.001$; Table 2).

With respect to delayed assessment of knowledge, there was no significant difference in the average interval of time taken to complete the delayed knowledge test (42.7(16.5) days vs. 39.1(9.3) days; $p = 0.317$). Participants in the intervention group had significantly higher procedure-specific knowledge scores on delayed post-intervention assessment as compared to participants in the control group with a Cohen's d effect size of 0.61 (86.5(8.5)% vs. 79.8(13.1)%; $p = 0.024$). There was no significant difference in self-reported understanding of LC on delayed post-intervention assessment (Table 2).

Within-group comparisons between baseline and immediate post-intervention assessment demonstrated a significant increase in the procedure-specific knowledge of LC for participants in the intervention group with a medium Cohen's d effect size of 0.70; however, there was no significant increase in procedure-specific knowledge of LC for participants in the control group (Table 3). There was a significant increase in self-reported understanding of LC for participants in both intervention and control groups with large effect sizes (Table 3).

Table 1 Demographic characteristics of study participants

	Control (SVC) ($n=39$)	Intervention (DEP + SVC) ($n=40$)	p-Value
Age (years)	54.1 (18.1)	56.3 (17.9)	0.58
Sex			0.32
Male	13	16	
Female	24	24	
Non-binary/third gender	2	0	
Level of education			0.18
No high school diploma	6	1	
High school diploma	11	17	
College/university degree	13	12	
Postgraduate degree	9	10	
Medical background			0.71
Yes	6	5	
No	33	35	
Had a previous consultation with a surgeon regarding laparoscopic cholecystectomy?			0.11
Yes	9	16	
No	30	24	
English literacy score (out of 4)	3.31 (0.86)	3.68 (0.47)	0.02*
The setting of the clinical encounter			0.74
ER	10	9	
Ward	29	31	
Presenting diagnosis			0.50
Biliary colic	5	2	
Acute cholecystitis	12	19	
Gallstone pancreatitis	10	10	
Choledocholithiasis	11	8	
Cholangitis	1	1	

SVC standard verbal consent, *DEP* digital education platform module

Data presented as mean (SD)

*Statistical significance

Table 2 Baseline and post-intervention knowledge, self-reported understanding of laparoscopic cholecystectomy, and patient satisfaction scores for participants in the control and intervention groups

	Control (SVC)	Intervention (DEP + SVC)	p-Value	ES
Baseline assessment				
Knowledge (%)	74.3 (13.4) $n=35$	78.6 (12.9) $n=40$	0.16	
Self-reported understanding of laparoscopic cholecystectomy operation (%)	38.5 (25.3) $n=35$	37.8 (21.5) $n=40$	0.88	
Immediate post-intervention assessment				
Knowledge (%)	78.2 (9.9) $n=36$	85.2 (10.6) $n=39$	0.004*	0.68
Self-reported understanding of laparoscopic cholecystectomy (%)	55.1 (18.8) $n=37$	68.5 (16.4) $n=40$	0.001*	0.76
Patient satisfaction with the consent discussion (%)	67.2 (7.7) $n=37$	69.5 (6.7) $n=40$	0.149	
Delayed post-intervention assessment				
Knowledge (%)	79.8 (13.1) $n=29$	86.5 (8.5) $n=29$	0.024*	0.61
Time to complete the delayed assessment (days)	39.1 (9.3) $n=29$	42.7 (16.5) $n=29$	0.317	
Self-reported understanding of laparoscopic cholecystectomy (%)	63.3 (17.1) $n=27$	70.7 (16.2) $n=29$	0.105	

SVC standard verbal consent, *DEP* digital education platform module, *ES* effect sizes reported as Cohen's d

Data presented as mean (SD)

*Statistical significance

Table 3 Within-group comparisons of change in procedure-specific knowledge and self-reported understanding of laparoscopic cholecystectomy in intervention and control groups

Group		Baseline assessment	Immediate post-intervention assessment	Delayed post-intervention assessment	Baseline vs. immediate post-intervention assessment		Immediate vs. delayed post-intervention assessment
					ES (d)	*p*-value	*p*-value
Intervention (DEP + SVC)	Procedure-specific knowledge (%)	78.6 (13.1) *n* = 39	85.2 (10.6) *n* = 39	86.5 (8.5) *n* = 29	0.70	< 0.001	NS
	Self-reported understanding (%)	37.8 (21.5) *n* = 39	70.7 (14.9) *n* = 39	70.7 (16.2) *n* = 29	1.18	< 0.001	NS
Control (SVC)	Procedure-specific knowledge (%)	75.3 (13.3) *n* = 31	79.1 (10.2) *n* = 31	79.6 (13.3) *n* = 28		NS	NS
	Self-reported understanding (%)	38.5 (25.3) *N* = 35	55.2 (1.9) *n* = 35	63.3 (1.7) *n* = 27	0.93	< 0.001	NS

SVC standard verbal consent, *DEP* digital education platform module, *N* number of participants, *NS* not significant

Data presented as mean (SD). Effect sizes reported as Cohen's d

Within-group comparisons between immediate versus delayed post-intervention assessments demonstrated no significant change in procedure-specific knowledge and self-reported understanding of LC for participants in both groups (Table 3).

Participant satisfaction

There was no significant difference between groups in reported participants' satisfaction with the consent discussion (69.5(6.7)% vs. 67.2(7.7)%; $p = 0.149$).

Discussion

We demonstrated that completion of a digital education platform module in addition to the SVC for an urgent LC resulted in significantly higher immediate and delayed post-consent knowledge of the risks, benefits, alternatives and expected outcomes of LC, a significantly higher self-reported understanding of LC, and equivalent satisfaction with the consent process as compared to the SVC. There are several features of this study which strengthen our conclusions: (1) a single-blinded randomized controlled study design ensured that members of the surgery team obtaining consent for LC were unaware of the group allocation of the study participants; (2) the objective and subjective assessments of participants' knowledge of LC allowed for comparisons of perceived versus actual knowledge; and (3) inclusion of patients with various biliary pathologies.

Our result demonstrating significantly higher immediate and delayed procedure-specific knowledge of LC in the DEP + SVC group in an acute care setting is in agreement with prior research exploring the benefits of DEP in an ambulatory setting [5]. A study that examined immediate and delayed procedure-specific knowledge of laparoscopic Roux-en-Y gastric bypass demonstrated significantly higher immediate knowledge in the group that reviewed a DEP module in addition to the SVC vs SVC alone with a Cohen's d effect size of 0.72 [5]. Taken together, this suggests that addition of DEPs to SVC is beneficial in both ambulatory and acute care settings.

Interestingly, our study participants who did not review the DEP module did not objectively gain any additional knowledge despite reporting a significant improvement in their understanding of LC. This is a concerning finding as patients' may perceive to understand the information presented verbally to them during the consent process without actually improving their comprehension of the risks, benefits, and alternatives of the proposed operation. Routine use of DEPs during consent discussions may facilitate a greater cognitive understanding of the information being discussed with them.

Participants in the intervention group maintained a significantly higher objective understanding of knowledge of LC at 5–6-week post-consent discussion compared to the control group with equivalent subjective self-reported understanding of LC. Moreover, there was no significant within group decrease in the knowledge scores over time. This suggests that once patients understand the material presented to them during the informed consent discussion, they do not lose this understanding over time. As such, the main impact of completing the DEP at the time of SVC is on the immediate knowledge acquisition with retention of acquired knowledge over time. It is important to note, however, that participants in the intervention group did not score 100% on

their knowledge test despite the comprehensive SVC discussion with the surgery team and completing the DEP module. While we do not have a clear explanation for this result, it is in line with prior studies of DEP in the ambulatory settings [5, 7]. We hypothesize that the medical condition of the patient, clinical environment, and/or emotional distress may contribute to the inability to fully comprehend all aspects of the informed consent process [8, 9].

English and health literacy, language barriers, or cultural differences may also impact the ability of patients to understand the information presented to them during the informed consent discussion [9]. In our study, participants had an overall moderate to high English literacy scores (Table 1); however, the literacy scores were significantly higher for participants randomized to the intervention (DEP + SVC) group. There were 6 participants in the control group with low English literacy scores (1 or 2 out of 4) compared to none in the intervention group. Given the possible risk of confounding, we repeated our analysis after excluding these 6 patients from the control group (Appendix 4) and demonstrated a persistent significant difference in the immediate post-consent knowledge scores between the SVC and DEP + SVC groups (79.1(10.2)% versus 85.2(10.6)%; $p = 0.018$; Cohen's $d = 0.59$). This suggests that poor English literacy did not contribute to the significant difference in immediate knowledge scores between groups.

Participants in both groups were equally moderately satisfied with the consent discussion (Table 2). These satisfaction scores were lower than those reported in a study that used a DEP in an ambulatory setting (average reported satisfaction over 95%) [5]. Similarly, other studies that incorporated DEPs into the informed consent process also demonstrated overall high patient satisfaction scores [10, 11]. One study randomized participants to receiving either a virtual multimedia interactive informed consent (VIC) presented on a tablet or a paper-based consent [10]. Participant satisfaction was high for participants in both the VIC group (6.4 out of 7) and the paper-based consent group (6.3 out of 7) [10]. The National Health Service (NHS) in England implemented a web-accessible digital consent application called Concentric® that provides tailored consent forms with clear language with in-application multimedia educational content [11]. Patient satisfaction with Concentric® platform was high (4.5 out of 5), but challenges with technology and connection issues were cited as barriers to its use [12]. Comparatively, our participants' satisfaction scores were lower than expected. One explanation for this finding is the acute care setting for the informed consent discussion in our study. In the elective setting, there is more time available to have the consent discussion, where patients may experience lower stress as compared to an inpatient in the acute care setting [13]. In addition, patients seen in ambulatory settings may have been seen by several members of an interprofessional team (nursing, registered dietitian, social work, etc.) on several occasions prior to the consent discussion with the surgeon [5]. This interprofessional approach provides multiple opportunities for information sharing, clarification of information, and additional questions, likely contributing to higher patient satisfaction scores. Further studies with DEPs in acute care settings are required to identify reasons for lower patient satisfaction scores identified in our study.

The use of DEPs offers opportunities to improve patients' comprehension, while addressing equity, diversity, and inclusion (EDI) concerns involving the informed consent process. A systematic review in 2020 examined interventions used to improve the comprehension of informed consent for patients undergoing medical and surgical procedures [14]. It demonstrated significant improvements in patient comprehension with audiovisual interventions, multicomponent interventions, and interactive digital interventions as compared to SVC [14]. The use of DEPs allows physicians to standardize the content of the consent discussion, presenting the information in easily understandable format, with the flexibility of being translatable to other languages to facilitate patients' understanding. Content standardization for informed consent discussion has been a longstanding issue in healthcare, with differences in content provided by different physicians [15]. There are differences in what is discussed verbally and what is documented in the patient's medical record [16]. A study from the Netherlands examined audiovisual recordings of the informed consent discussion between patients and either plastic surgeons or residents [16]. These recordings consisted of 41 consultations among 25 different plastic surgeons and residents and demonstrated inconsistency among the choice of consultation items discussed. Only 44% of participants discussed treatment risks and 33% outlined the typical post-operative recovery [16]. More concerning was the finding that the written documentation of the consent process did not match the verbal discussion in 59% of consultations [16]. Use of DEPs can help physicians address the current concerns regarding EDI and consistency in the consent process.

Improved shared decision-making (SDM), defined as the collaboration between patients and healthcare workers to achieve an optimal treatment plan, is another benefit of the DEPs [17]. Better-informed patients are more likely to participate in conversations regarding healthcare management and exert autonomy over their decisions [17]. The improvements in SDM are often a result of presenting the informed consent information in an easily accessible and often simplistic format [18]. A digital information-sharing platform to support the informed consent process was launched in the UK for patients presenting with symptomatic gallstones to a surgeon in an ambulatory setting [18]. Patients were provided with multimedia information on gallstones and available treatment options prior to

their appointment with the surgeon. Patients were asked to document a summary medical history and to complete multiple choice questions as a form of self-assessment. Time spent accessing the multimedia information was recorded [18]. Overall patients felt that the distribution of information prior to their appointment with a surgeon was welcomed, allowed them to feel empowered and better informed to participate in SDM [18]. Integration of DEPs into informed consent discussion may improve SDM and augment patient autonomy; however, this needs to be explored in future research studies.

Limitations

Our study was conducted in a single center, in an acute care setting, with a focus on a single procedure (LC) limiting the generalizability of our results to other procedures or contexts. There is a possibility of selection bias with less than 100% follow-up for the delayed post-intervention assessment, requiring caution in the interpretation of those outcomes. Sixteen participants in the intervention group compared to 9 participants in the control group had previous discussion with a surgeon regarding LC. This may have biased our results in favor of the intervention group; however, baseline knowledge scores for both groups were similar suggesting that previous consultations may have very little to no impact on the intervention group's understanding of LC.

Conclusion

The addition of a digital education platform module to the standard verbal consent for a laparoscopic cholecystectomy procedure in an acute care setting resulted in significantly higher immediate and delayed knowledge of the risks, benefits, alternatives, and expected outcomes of LC, a significantly higher self-reported understanding of LC, and equivalent satisfaction with the consent process. The use of DEPs in acute care settings can standardize the delivery of content during informed consent discussion and can address EDI challenges facing patients.

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Declarations

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