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Using a Mobile Application for Real-Time Collection of Patient-Reported Outcomes in Hepatopancreatobiliary Surgery within an ERAS® Pathway

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Patient-reported outcomes (PROs) are essential for patient-centered health care. This pilot study implemented a mobile application customized to an hepatopancreatobiliary Enhanced Recovery After Surgery (ERAS®) program—a novel environment—for real-time collection of PROs, including ERAS® pathway compliance. Patients undergoing hepatectomy, distal pancreatectomy, or pancreaticoduodenectomy through the ERAS® program were prospectively enrolled over 10 months. The application provided education and questionnaires before surgery through 30 days postdischarge. Thresholds were set for initial adoption of the application (75%), PRO response rate (50%), and patient satisfaction (75%). Daily postdischarge health checks integrated customized responses to guide out-of-hospital care. Of 165 enrolled patients, 122 met inclusion criteria. Application adoption was 93 per cent (114/122) and in-hospital engagement remained high at 88 per cent (107/122). Patients completed 62 per cent of PRO on quality of life, postoperative pain, nausea, opioid consumption, and compliance to ERAS® pathway items, including ambulation and breathing exercises. During postcharge tracking, 12 patients reported that the application prevented a phone call to the hospital and three patients reported prevention of an emergency room visit. PRO collection through this mobile device created an integrated platform for comprehensive perioperative care, patient-initiated outcome tracking with automatic reporting, and real-time feedback for process change. Improving proactive outpatient management of complex patients through mobile technology could help restructure health-care delivery and improve resource utilization for all patients.

ENHANCED RECOVERY AFTER Surgery (ERAS®) is a comprehensive multidisciplinary approach to the entire perioperative period for reducing physiologic stress and improving patient recovery through standardized evidence-based multimodal practices.[1] ERAS® programs were the first established colorectal surgery and have consistently demonstrated significant improvements in lowering postoperative morbidity and reducing hospital length of stay.[2] Expansion to other surgical specialties, including hepatopancreatobiliary (HPB), has demonstrated similar improvements in postsurgical length of stay and morbidity without compromising readmission rate, morbidity, or mortality[3, 4] and ERAS® consensus guidelines now exist for major pancreas[5] and liver operations.[6]

Simply implementing an institutional enhanced recovery protocol, however, does not itself guarantee improvement in outcomes. A clear correlation has been demonstrated between increased compliance to ERAS® pathway measures and improved clinical outcomes.[7] Notably, the greatest improvement related to compliance has been shown with protocol steps dependent on active patient engagement.[8] A foundational component to successful ERAS® programs,

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therefore, is institutional tracking of compliance to pathway items through continuous auditing and rigorous adjustment of implementation strategies to generate improved outcomes.[1, 9]

Unfortunately, multiple barriers typically exist at an institutional level, which create unique challenges to effective implementation and auditing of an ERAS® program. Sufficient data collection for meaningful analysis requires allocation of limited resources and can impede the clinical responsibilities of the already burdened care providers. Patient education and active participation are also crucial for much of the perioperative plan; however, dynamic feedback from the patient perspective is often limited. Finally, traditional measures for outcome tracking (*e.g.*, questionnaires, chart review, and phone interviews) require extensive time for collection and analysis with most conclusions out-of-date before they can be reported.

Patient-reported outcomes (PROs) have been well validated for measuring patient experience during perioperative care and are becoming foundational in the growing movement toward patient-centered care.[10, 11] However, not until recently have they been recognized as a novel strategy for tracking clinical outcomes as well using the patient's perspective and initiative.[12] In addition, with the exponential rise in mobile patient-centered electronic platforms for health care, the opportunity to leverage technology to engage and educate patients throughout their entire perioperative journey while simultaneously reporting and tracking patient participation in clinical outcome measures (such as ERAS® pathway items) offers an unprecedented opportunity. Recently, Pecorelli and colleagues first described the use of a mobile application for PRO collection specifically within an ERAS® program for colorectal surgery; however, this concept has yet to be explored for the often deconditioned and comorbid HPB population undergoing major abdominal surgery. Therefore, we aim to demonstrate the novel implementation of an established mobile health application for PRO collection in an ERAS® program for HPB surgery.

Methods

Study Design

This investigation is a prospective, single-group, pilot study at a large tertiary HPB center. Patients aged 18 years or older, who were scheduled for elective surgery within an established ERAS® program in our institutional HPB service, were eligible for participation. Three ERAS® programs for HPB operations were ongoing at the time of the study for pancreaticoduodenectomy, distal pancreatectomy, and hepatectomy. The study design and methodology were approved as a quality improvement initiative by the institutional review board.

Mobile Application

An established mobile application developed by SeamlessMD® (Seamless Mobile Health Inc., Montreal, Canada) was customized to the ERAS® programs for the division of HPB at Carolinas Medical Center. The application is a web-based platform accessible by any smartphone and tablet device and is available at no charge to the patients. The application provides a patient- and surgeon-specific portal to their individual perioperative surgical plan guided by the established ERAS® pathway. Preoperatively, patients are provided with scheduled task reminders for both general preoperative preparation (*e.g.*, reminders to keep exercising and eating healthy before surgery) and presurgery anxiety and quality-of-life benchmark surveys, as well as specific ERAS® pathway steps, including no food past midnight and drinking the recommended carbohydrate drink two hours before surgery. Patients are also prompted to access a customized digital educational library reviewing details of their medical condition, scheduled operation, and anticipated ERAS® expectations. All educational materials were developed in collaboration with the HPB providers to reflect the material provided in the standardized preoperative ERAS® educational classes and was verified as low literacy English at 6th-grade level according to the Flesch-Kinkaid readability test.

Beginning on the day of surgery, the application then provides prompts to complete daily surveys to track symptoms, opiate use, anxiety and quality-of-life scores, and ERAS® pathway compliance. These surveys are prompted daily in hospital and after discharge until 30 days postoperatively. At the end of the 30-day study period, patients are asked to complete a survey to assess their impression and likelihood to recommend the application. After discharge, patients are also prompted to complete daily health checks to monitor symptoms at home. Responses to preset questions trigger recommendations customized specifically by the HPB surgeons for education and reassurance, guidance for continued self-care at home, directions to call the HPB office nurse, or instruction to seek immediate medical attention at the nearest ED.

All patient-reported data were stored in the application's secure database and transmitted *via* secure encryption to secure HIPAA-compliant SeamlessMD® servers. Deidentified data were used to generate regular reports, which were provided to the HPB service to track progress during the pilot study.

Patient Enrollment and Education

All patients scheduled for eligible operations under ERAS® protocols were introduced to the pilot study at their standard preoperative ERAS® education appointment. Patients who were elected to enroll provided informed consent for participation. All patients, regardless of enrollment in the pilot, were treated with the standard of care with small-group multidisciplinary counseling at the preoperative class and hard-copy materials given to all patients in the ERAS® program. For patients who elected to enroll, a detailed description of the study was provided by the ERAS® nurse leader and a hands-on tutorial on how to download and navigate the application. All patients were instructed to use their personal mobile device for the application before and after surgery. The application was also designed as a tool for use by all members of the patient's support system; therefore, patients were encouraged to involve their family and/or friends to enter in their responses into the application at any time during their recovery. Patients were seen daily by the ERAS® nurse leader and provided encouragement and any assistance with using the application throughout their hospital recovery. On discharge, the patients continued to receive daily surveys at home or rehabilitation facility by the application until postoperative day (POD) 30, as well as access to educational material on recovery issues.

Outcomes

The primary intent was to evaluate the application's ability to capture and track PROs in real time and patient's responsiveness to the application. Therefore, primary outcome measures and minimum success metrics were established for patient adoption (logging in and completing at least one PRO after enrollment) at $\geq$ 75 per cent, overall PRO response rate at $\geq$ 50 per cent, and patient satisfaction as defined by patient's recommendation of the application to others at $\geq$ 75 per cent. The secondary intent was to evaluate the application's ability to capture and track specific responses for traditional PROs, including postoperative pain, nausea, and opiate use, as well as nontraditional PROs for compliance to ERAS® pathway items in the preoperative and postoperative phases. Quality-of-life assessments were integrated into the scheduled survey prompts using the abbreviated Quality of Recovery (QoR-15)[13] and PROs Measurement Information System (PROMIS)[14] surveys both of which have been well validated in surgical populations.[15, 16] Patient responses to postdischarge health checks and actions prompted by the application and/or HPB clinical staff were also tracked.

Statistical Analysis

Statistical analysis was performed using Stata (Version 13, StataCorp, College Station, TX). Descriptive data were reported as mean [95% confidence interval] or median IQR. Categorical variables were compared using chi-squared analysis. A P value < 0.05 was considered statistically significant.

Results

Patient Participation

Patients were enrolled in the pilot study from March 27 through December 31, 2018. Figure 1 shows the flowchart for patient selection and exclusion. During the pilot, 213 patients were eligible with 165 (77%) elected to enroll at their preoperative ERAS® education class. All patients whose operations were aborted before or at the time of surgery (n = 27) or had not completed the 30-day postoperative period before data

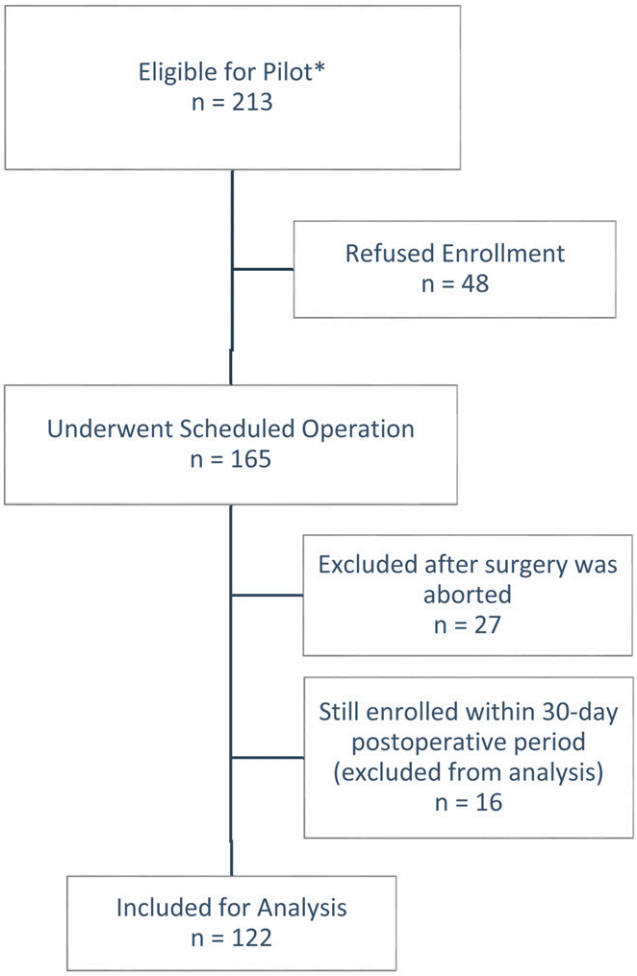

FIG. 1. Flowchart for patient selection and exclusion.* Undergoing scheduled pancreaticoduodenectomy, hepatectomy, or distal pancreatectomy under ERAS® program.

analysis were excluded. At the conclusion of the pilot period, 122 patients had completed the entire 30-day postoperative study period and were included in the study.

Adoption and Engagement

Patient adoption and engagement with the application is shown in Figure 2. Patient adoption was high with 93 per cent (114/122) of enrolled patients using the application at least once before surgery. Immediate postoperative engagement remained high at 88 per cent (107/122). Engagement at after discharge showed the highest decline in participation yet still remained above 50 per cent (63/122). Health check-ins performed after discharge demonstrated high retention through the remainder of the postdischarge period.

Patient Reported Outcomes

During the study period, patients submitted 540 of 944 prompted PROs for an overall PRO response rate of 57 per cent. Table 1 shows a breakdown of PRO response categories for specific preoperative, in-hospital, and postdischarge questionnaires. Survey compliance remained above goal (>50%) in aggregate and individually for all but one of the benchmark surveys. The 30-day end-of-study PROMIS survey was completed by 41 per cent of participants (just below the individual 50% target); however, surprisingly more than 30 per cent were still engaging with the application at 90 days after surgery to complete the same PROMIS survey despite this being outside of the 30-day study period.

Table 2 reports responses regarding patient satisfaction with the application. The response rates were somewhat low; however, of the collected responses, the satisfaction rate was very high with 86 per cent (43/50) recommending the application. Responders also indicated that the application helped 97 per cent (29/30) "feel more prepared for surgery" and allowed 78 per cent (69/88) to "feel more confident" and "worry less" during their recovery in the hospital or after discharge. The application also successfully tracked traditional patient-reported data for opiate use, pain, and nausea daily up to 30 days after surgery (Fig. 3). By the completion of the pilot, we also successfully implemented a pathway for immediately uploading individual patient-reported pain and nausea scores to the electronic medical record (EMR) which could be used to make real-time interventions.

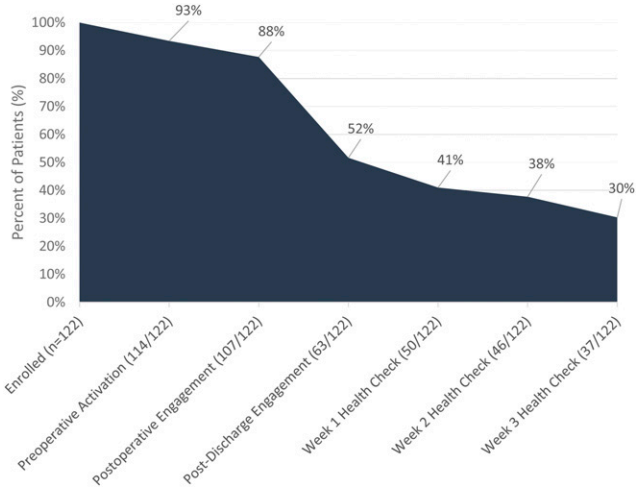

FIG. 2. Engagement with SeamlessMD® application throughout the perioperative period.

PROs for ERAS Compliance

Table 3 shows the patient-reported data for compliance to the institutional ERAS® protocol for HPB surgery. Patients successfully reported compliance to postoperative questions for ambulation, breathing exercises, and time spent in bed. Participation in compliance surveys was lowest on POD 1 for both liver and pancreas surgeries but remained stable through POD 7.

Postdischarge Health Tracking

Table 4 displays the patient responses to postdischarge health checks and subsequent recommendations provided by the application and/or the HPB nursing staff. During the pilot, patients submitted 521 health checks to track their recovery and symptom

TABLE 1. *PROs Survey Participation*

Survey	Responses (Liver)	Responses (Pancreas)	Responses (Total)	Goal
Tailor your program (presurgery)	62% (29/47)	74% (66/89)	70% (95/136)	≥50%
In-hospital health check	57% (26/46)	57% (48/84)	57% (74/130)	≥50%
QoR-15[a] (14 days presurgery)	57% (27/47)	60% (52/86)	59% (79/133)	≥50%
QoR-15[a] (3 days postsurgery)	57% (26/46)	54% (44/81)	55% (70/127)	≥50%
PROMIS[b] (30 days postsurgery)	45% (20/44)	39% (28/72)	41% (48/116)	≥50%
PROMIS[b]* (90 days postsurgery)	31% (11/36)	31% (16/52)	31% (27/88)	–

* The PROMIS survey at 90 days was sent to patients but not included in the analysis of 30-day results for overall survey participation.

[a] QoR-15, Quality of Recovery 15 question survey, [b] PROMIS, Patient Reported Outcome Measurement Information System.

TABLE 2. *Patient Experience Survey Response Rates*

Per cent of Patients who …	Total Response
would recommend the application	86% (43/50)
felt the application helped them feel more prepared for surgery	97% (29/302)
felt the application made them more confident about taking care of themselves after surgery	78% (69/88)
felt the application helped them worry less after surgery	78% (69/88)

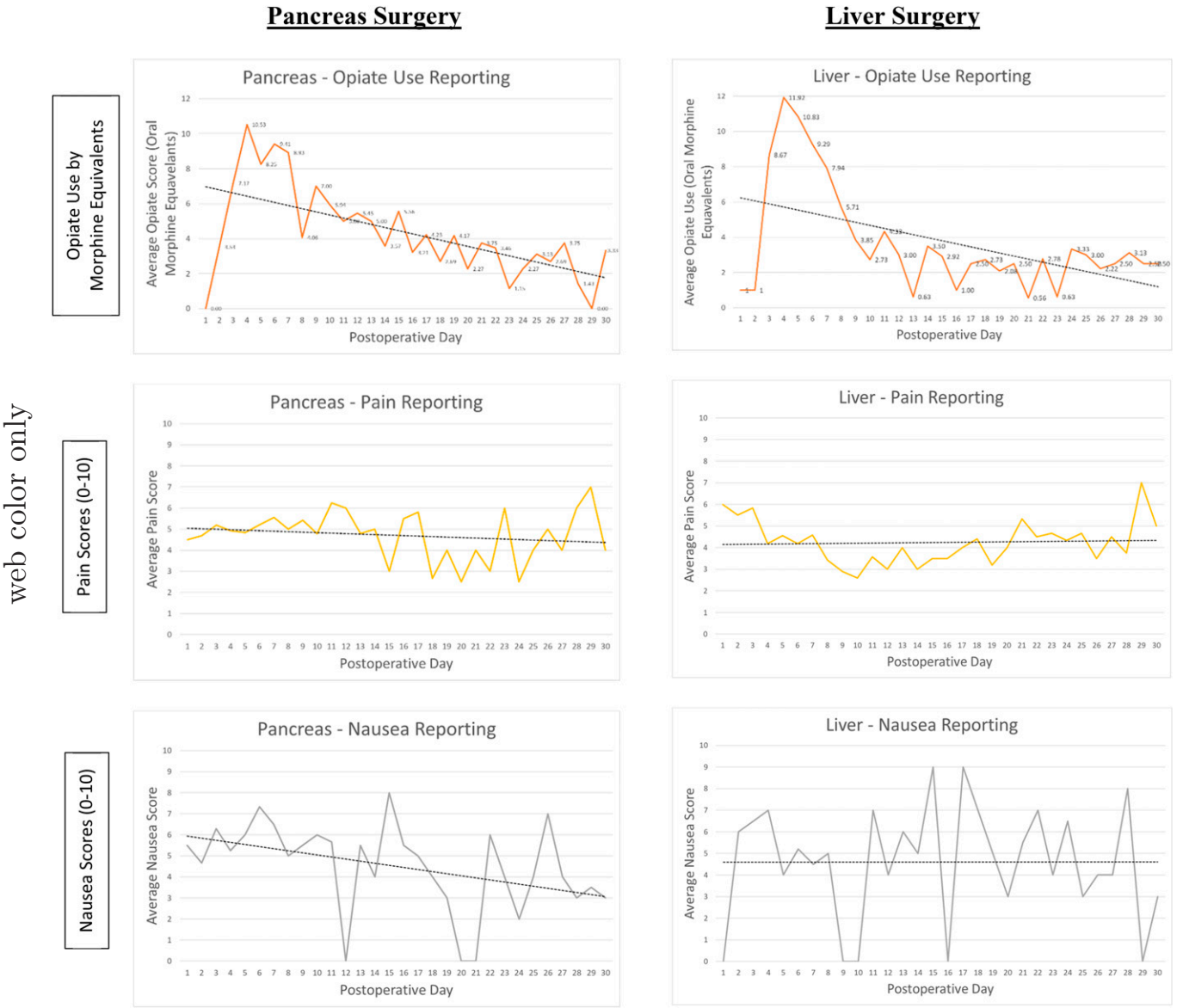

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FIG. 3. PROs for opiate consumption, pain, and nausea through 30 days postoperatively.

progress after discharge. Of these total responders, 12 patients reported that the application prevented one or more phone calls to the office and three patients reported the application prevented a visit to the ED because of reassurance from the application's responses to recovery questions. Conversely, postdischarge health checks were triaged by the customized application to provide reassurance for 167 responses and guide 226 responses to further self-care educational resources immediately accessible on the hand-held application. In addition, the application instructed patients to call the HPB office nurse for 121 responses and directed seven patients to seek immediate medical care at the nearest ED.

TABLE 3. *Patient-Reported Compliance to ERAS® Pathway Items Beginning the Day after Surgery*

ERAS® Item Question* (*Compliance definition*)	POD 1 (n = 22)	POD 2 (n = 36)	POD 3 (n = 25)	POD 4 (n = 25)	POD 5 (n = 25)	POD 6 (n = 27)	POD 7 (n = 23)
Did you do all your breathing exercises yesterday? (*Compliance = "Yes, I did them all"*)							
Pancreas surgery	2/11	14/26	7/20	10/21	10/21	7/22	10/17
Liver surgery	4/11	4/10	2/5	1/4	3/4	2/5	2/6
How many walks did you take yesterday (*Compliance = "4 or more walks"*)							
Pancreas surgery	0/11	0/26	13/20	12/21	4/21	11/22	8/17
Liver surgery	0/11	0/10	0/5	0/4	1/4	3/5	3/6
How much time did you spend out of bed yesterday? (*Compliance = 4 or more hours*)							
Pancreas surgery	0/11	17/26	11/20	14/21	12/21	11/22	10/17
Liver surgery	0/11	5/10	2/5	1/4	1/4	2/5	3/6

* Questions were prompted in open-ended format with multiple-choice options; however, compliance was set as a binary outcome defined uniquely as listed below each question.

TABLE 4. *Postdischarge Health Check Triage Responses and Alerts*

Patient-Reported Reduction in Health-Care Visits	Response Frequency, n = 15
"Application prevented one or more phone calls to the office"	12
"Application prevented one or more visits to the ED	3
Health check alert type	**Alert Frequency n = 521**
"On-track" (No issues)	167
"Try these self-care tips" (customized education provided)	226
"Call your nurse"	121
"Go to the ED"	7
Alerts sent to HPB nurse (September–December 2018 only)	**Guidance Provided n = 27**
Reassurance or Self-care	10
Clinic appointment scheduled	8
Directed patient to ED immediately	9

During the final four months of the pilot (September–December 2018), all patient health checks, which prompted patients to seek medical advice or immediate care, were also sent directly to an HPB nurse practitioner for further investigation through a phone call to the patient (n = 27) (Table 4). Ten patients were provided direct guidance for further self-care, eight patients were scheduled for a clinic appointment, and nine patients were instructed to go to the ED for urgent evaluation.

Discussion

This is the first prospective pilot study evaluating the implementation of a mobile application in an HPB surgery ERAS® program as a comprehensive platform for real-time capture of PROs throughout the entire perioperative course. The customized application provided patients with a service-specific perioperative guide to facilitate patient education, track symptom experience and management, and remind patients of daily recovery steps. Simultaneously, the application enabled patient-driven reporting of in-hospital and postdischarge recovery outcomes as well as compliance to ERAS® pathway items without additional resource utilization. Patient enrollment, adoption before, surgery, and engagement in the immediate postoperative settings were excellent, and ongoing retention after discharge through the 30-day study period remained high. Patients reported high satisfaction with the application, and most agreed that this mobile platform was beneficial during hospital recovery and at home before and after surgery. Finally, postdischarge health checks facilitated not only a novel method for ongoing mobile PRO collection but also created an integrated triage system to improve real-time monitoring and guidance during recovery at home.

Emphasis on adopting enhanced recovery programs have been frequently focused on producing the well-demonstrated reduction in lengths of stay, cost, and morbidity which are often the primary benchmarks for new adopters of ERAS® programs. A comprehensive perspective of recovery, however, requires addressing the complex dynamic of convalescence for restoration of a patient's physical, emotional, social, and even

economic well-being. Enhanced recovery guidelines have consistently stressed the importance of measuring and tracking all such outcomes of recovery, which remains a key distinction between ERAS® and purely fast-track protocols.[5, 6, 17–19] PROs are becoming well recognized as an essential tool in the era of patient-centered care for understanding the full impact of disease and recovery;[10] however, unfortunately, their use remains limited, particularly in enhanced recovery programs. A systematic review by Neville et al.[20] on 38 studies on enhanced recovery programs reported that patient-reported symptoms, long-term functional status, and impact on quality of life were consistently reported less than short-term physical recovery and most commonly through provider observations. They concluded that PRO should be used to assist in tracking recovery through all perioperative phases to more accurately the patient's assessment of their multidimensional recovery.

The value of PRO collection may be even greater in HPB surgery, particularly when performed in conjunction with ERAS® protocols. The significant morbidity and mortality associated with both the disease process and major abdominal HPB operations suggest that a more comprehensive understanding of different patient's preoperative preparedness and postoperative recovery through PROs could influence their perioperative care delivery. In a prospective study by Day et al.,[21] validated PROs performed at preoperative and postoperative ERAS® clinic visits for patients undergoing liver resection for malignancy demonstrated the ability of PROs to track functional recovery. They also specifically demonstrated that enhanced recovery protocols were independently associated with improved recovery as measured by these PROs and that improved patient-reported recovery for ERAS® patients was associated with higher rates of return to oncologic therapy, an underappreciated but critical metric after oncologic resection.

This study also highlights the power of harnessing emerging mobile health technology to facilitate both patient-specific and population data tracking without increasing the burden on care providers. Traditional collection of PROs typically implies direct patient questioning during hospitalization, clinic visits, or telephone surveys, which can result in a significant challenge for sustainability because of need for dedicated time, resources, and personnel. In addition, in the present era of real-time data-driven process change, information obtained through traditional PRO is often obsolete because of the inherent delay in collection, analysis, and reporting. Efforts to streamline this process have driven the development of mobile application platforms for PRO input directly by the patients.[22, 23] The first prospective usability study on implementation of a mobile application to capture PRO specifically in an enhanced recovery program was performed in colorectal surgery.[12] In addition to traditional PROs for symptoms (*e.g.*, pain, nausea, and bowel function scores), this study also evaluated the use of a mobile PRO platform to specifically track compliance to ERAS® pathway items by patient self-audit. Notably, in this study, however, patients were not provided access to the application until the day of surgery and responses were only collected until the day of discharge, limiting scope of PRO collection, and tracking of the entire recovery period. Patients were also only able to access the application on devices provided by the study. Consequently, the mobile application served primarily as an alternate mode for capturing PRO collection and ERAS compliance during hospitalization only.

Before our pilot study, no published investigation has evaluated the implementation of a mobile patient-reporting application within the HPB population to track both patient experience as well as ERAS® pathway compliance. We intentionally allowed patients to participate through any preferred personal device, which enabled a fully mobile experience. Consequently, this facilitated the use of a single platform for integrated PRO collection throughout the entire perioperative period with access to preoperative educational materials and checklists, in-hospital tracking, and continued postdischarge surveys.

The very high adoption noted in our study is consistent with the results seen in other mobile platform studies.[12] Patients in our study were not excluded for age or experience level with using mobile technology, yet 77 per cent of patients enrolled, suggesting that most patients are amenable to incorporating patient-centered technology into their surgical care experience. Despite the high morbidity associated with major HPB operations, a remarkable 88 per cent continued to engage with the application during their hospitalization. The most notable decline in patient engagement occurred after discharge as would be expected, although participation still remained above the 50 per cent target with high retention through the conclusion of the study period. This represents the first study to our knowledge to successfully track postdischarge PRO captured daily through a patient-directed mobile application outside of the clinical environment.

The postdischarge impact of this application holds possibly the greatest potential for revolutionizing the delivery of perioperative care. Previous electronic-based patient applications have demonstrated promising results for postdischarge monitoring;[4, 24–27] however, none have attempted to combine patient-driven tracking through the entire perioperative experience using the same mobile platform. The SeamlessMD® application infrastructure was developed for continuous

data download, analysis, and assimilation of PRO into the EMR. Within the last several months of the pilot, we successfully incorporated a digital pathway to the EMR patient dashboard for real-time displays of pain and nausea scores collected by the application. Similarly, an automatic alert system for all postdischarge health checks that prompt patients to contact their medical providers is being integrated into the same EMR interface to improve communication with patients regarding these concerns.

In the digital era, use of an application on a handheld device to collect PROs is not only feasible but should be recognized as nearly essential for improving the surgical care of patients. A comprehensive mobile health platform such as the one described in this study can dramatically transform patient care by allowing continuous access to two-way communication between patients and the surgical team, facilitating earlier intervention on warning signs provided by patients in real time and improving patient engagement with their own care every day. Furthermore, the ramifications of improving proactive outpatient management of complex patients through mobile technology could help restructure health care and improve resource utilization for all patients.

Limitations

The specific results of this study have limited generalizability because of its small sample size, patient selection, and resources required for initial mobile platform launching. However, adoption of this platform to other service lines and hospital systems should not be aimed at producing identical results, but rather this pilot study establishes the framework on which similar systems can be developed customized to each population's needs. The PROs captured by the application require further validation compared with traditional reporting means. Compliance to ERAS® pathway items should also be similarly compared with standard reporting of compliance to establish validity.

Future Direction

Mobile applications can transform and integrate PRO collection across all aspects of a patient's enhanced recovery pathway. The growing emphasis on prehabilitation for ERAS® to improve a patient's physiologic status before surgical intervention creates an excellent opportunity for expansion of real-time PRO collection. Dynamic feedback can be used to track patient nutrition, physical conditioning, and emotional well-being and allow the multidisciplinary team to adjust the care plan accordingly. In addition, integration of PRO into existing predictive modeling may help to more accurately identify patients at the highest risk for poor recovery and be used to allocate prehabilitation resources appropriately.

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