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Developing and validation of a smartphone app for post-discharge early follow-up after colorectal cancer surgeries

Bruna Elisa Catin Kupper[1], Elaine Cordeiro Bernardon[2], Camila Forni Antunes[2], Natalia Martinez Martos[2], Carlos Alberto Ricetto Sacomani[3], Mauricio Azevedo[4], Mario Sergio Adolfi Junior[5], Tiago Santoro Bezerra[1], Tomas Mansur Duarte de Miranda Marques[1], Paulo Roberto Stevanato Filho[1], Renata Mayumi Takahashi[1], Wilson Toshihiko Nakagawa[1], Ademar Lopes[1] and Samuel Aguiar Jr[1]

Abstract

Background: Colorectal surgeries are complex procedures associated with high rates of complications and hospital readmission.

Objective: This study aimed to develop an electronic post-discharge follow-up plan to remotely monitor patients' symptoms in the postoperative period of colorectal surgeries and evaluate the outcomes of emergency department visits and the rate of severe complications within 15 days after hospital discharge.

Design: We developed a digital tool capable of remotely assessing symptoms that could indicate complications related to colorectal surgical procedures and directing early management. This project was divided into two stages. The first was platform development with an algorithm for identifying symptoms and directing conduct, and the second was clinical validation of the program and evaluation of patient's experience. Patients who underwent elective oncological colorectal surgery were invited to participate in this study. We used commercial software (CleverCare) that was adjusted according to the clinical algorithm developed in this study, predicting complications and directing conduct with minimal human intervention using a Chatbot with Natural Language Processing (NPL) and artificial intelligence.

Results: We planned three Interim Analyses to evaluate the outcomes of complications, referrals to the Emergency Department (ED), ED visits, adherence, and patient satisfaction. After each analysis, specialists validated the changes before implementation. A total of 92 eligible participants agreed to participate in the study. The ability to detect complications increased with each adjustment phase, and after the third and last phase, the digital solution identified 3(4.8%) real complications, with a sensitivity of 75%, specificity of 83%, accuracy of 82%, positive predictive value of 27%, and negative predictive value of 97%. Complete adherence to the monitoring program was 83.7% with an NPS score of 94 in the last evaluation phase.

Conclusion: The digital platform is safe with high adherence rates and good patient acceptance.

Keywords

Mobile app, mobile health, telemedicine, transitional care, readmissions, health services research

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[1]Colorectal Cancer Reference Center, AC Camargo Cancer Center, Sao Paulo, Brazil
[2]Value Based Office, AC Camargo Cancer Center, Sao Paulo, Brazil
[3]Innovation and Technology Department, AC Camargo Cancer Center, Sao Paulo, Brazil
[4]Johnson & Johnson MedTech, Sao Paulo, Brazil
[5]Kidopi, Sao Paulo, Brazil

Corresponding author:
Bruna Elisa Catin Kupper, Colorectal Cancer Reference Center, AC Camargo Cancer Center, Sao Paulo, Brazil.
Email: bruna.catin@accamargo.org.br

Introduction

Colorectal surgeries are complex procedures associated with higher rates of complications and readmissions than those performed at other surgical sites. Literature shows that hospital readmission rates for these patients vary between 8% and 17%, but more than half of these complications do not require hospitalization, suggesting that they may be preventable.[1–6]

Currently, due to the adoption of Enhanced Recovery After Surgery (ERAS) programs, discharge occurs early. However, many complications occur outside the hospital environment, making it difficult to assess, manage, and monitor these patients to avoid unnecessary Emergency Department (ED) visits, as well as under treatment and clinical deterioration.[7–9]

In addition, mild adverse events outside the hospital environment can lead to anxiety and unnecessary searches for emergency care, which can often be resolved and clarified remotely through systems that provide monitoring and follow-up of patients.[10]

Electronic systems for recording symptoms and monitoring health status filled in by the patients themselves have already been used in other studies to assess different treatment contexts, with positive results regarding quality of life, satisfaction with the care provided, complications, and survival.[11–15]

However, few studies have evaluated the efficacy of Patient Reported Outcomes (PROs) using mobile health (mHealth) apps for colorectal cancer surgical patients.

This study aimed to develop a digital tool that is accessible on smartphones, easy to use, simple to understand, and capable of remotely assessing symptoms that could indicate complications related to colorectal surgical procedures and directing early management. The primary outcomes were the capacity for complication detection and admission to the ED within 15 days after hospital discharge. The secondary outcomes were adherence and patient satisfaction.

The project was conceived using a low-code programming tool called CleverCare, which was employed to enhance the structuring of communication to flow smoothly between the sender and receiver. The platform facilitated the rapid development and deployment of the platform, ensuring it was user-friendly and efficient.

We believe that enabling patients to report symptoms in real time using an online platform accessible via smartphone will provide accurate information on how patients tolerate the postoperative period. This may allow early detection and management of complications in a less invasive manner, potentially leading to a lower need for emergency care and/or hospital readmissions. Additional advantages of this approach include improved patient engagement, reduced anxiety through timely interventions, and overall enhancement in the quality of postoperative care.

Methods

This project was conducted in a Cancer Center in Sao Paulo —Brazil, between November 2021 and November 2022. This is a feasibility study, developed in two stages. First, we structured a Digital Care Pathway for patients with colorectal cancer on a remote monitoring platform by creating an algorithm to predict the main colorectal surgical complications based on patient symptoms. This stage was followed by clinical validation, intending to achieve a minimum viable product (MVP). The Digital Care Pathway developed in this project is illustrated in Figure 1.

First stage: development of the monitoring solution

We mapped the main colorectal surgical complications based on institutional database analysis, literature review, and expert panel. The most frequent and severe complications were selected for evaluation in this project, namely anastomotic leak, postoperative ileus, postoperative infection, deep venous thrombosis (DVT), pulmonary thromboembolism (PTE), and bleeding.

We selected the signs and symptoms that could predict the complications tracked in this project and created an algorithm based on each mapped symptom. The interaction moments and the language used in each interaction with the patient were also designed. The Delphi methodology was used to evaluate and validate the data collection instrument created by a team of surgeons and nurses.[16]

The data obtained through the remote monitoring program was stored in commercial software for controlling, managing, and guiding patients (Clever Carer, KIDOPI). The software was adjusted according to the clinical algorithm developed in this study, to detect the symptoms reported by patients and predict early complications. The system can initiate dialogue or answer patients' doubts, creating natural conversations by a Chatbot using Natural Language Processing (NLP) and artificial intelligence.

This NLP module is constructed through the fusion of various techniques, such as Machine Learning and Information Retrieval, and also integrates advanced and specific NLP strategies, including Named Entity Recognition, Part-of-Speech Tagging, Word Embeddings, and word-adjacency networks.

The platform was designed in Portuguese once all the participants were Portuguese native speakers. Although it was not the target of this study, we see no issues in using this algorithm in other languages. This information was incorporated into the original file.

Second stage: feasibility trial

We validated the program in a prospective cohort to evaluate the effectiveness of the proposed remote monitoring

Figure 1. Digital care pathway.

system in the early identification of complications and participant satisfaction. sample selection took place consecutively. We planned three Interim Analyses to evaluate the outcomes of complications, referrals to ED visits, ED visits, adherence, and patient satisfaction. After each analysis, specialists validated the changes using the Delphi technique prior to implementation.[16]

The tested system was integrated with our Hospital's Electronic Health Record (EHR) and routine clinical practice. When a patient was recruited to the study it was registered on the EHR. Therefore, the monitoring platform was designed to receive notification at patient discharge, admission to the emergency department, or readmission to the hospital. During the study period, patients submitted to elective primary oncological colorectal surgeries performed by a colorectal surgeon at our cancer center were invited to participate in the monitoring program, as part of our routine clinical practice.

The patients who participated in the study received standard care and were not discharged earlier than patients who received the traditional follow-up plan, but we excluded from the study patients with serious complications (Clavien-Dindo scale score ≥ 3) during hospitalization.

A nurse navigator was responsible for training participants to identify and adequately report symptoms. Participants received an SMS and an e-mail daily with a link to report symptoms within the first 15 days after discharge. There was no need to download an app. Patients who could not use Smartphones or e-mail were encouraged to have their caregivers report their symptoms.

Patients were strongly advised that if an issue was deemed urgent outside working hours, they should present themselves to the ED for assessment.

Symptoms were classified as severe, moderate, or mild, with severe symptoms indicating urgent ED visits for evaluation, while moderate and mild symptoms were monitored remotely according to the algorithm.

Conducts and guidelines for managing reported symptoms were standardized and sent to participants via a digital solution.

When the reported symptoms were classified as severe, the nurse navigator received alerts via e-mails. In cases where the participants were indicated to visit the ED, the surgeon received an SMS. If the patient did not show up, the nurse contacted the patient to address the finding and reason for non-attendance.

If the reported event was not mapped on the system, the nurse navigator contacted the participant by phone to understand the complaint and provide guidance on the best conduct.

Participants also received alerts by SMS when they did not interact with the platform and phone calls if they did not interact for more than 48 hours.

At the end of the follow-up period, on the 16th day after hospital discharge, all patients evaluated their experience as participants in the remote monitoring program through response to the Net Promoter Score (NPS) and an evaluation questionnaire of the patient experience.[17]

We consulted patients' experiences during the monitoring program using the instrument proposed by Williams et al.[18] Of the 14 dimensions evaluated in this instrument,

five were compatible with our study's scope: coordinated care, communication, information on adverse effects, care plan, and safety.

Inclusion and exclusion criteria

Patients were eligible for recruitment if they were scheduled to undergo elective primary oncological colorectal surgery performed by a colorectal surgeon at our cancer center. Surgeries included colectomies and anterior resection. Patients submitted to palliative surgery or experienced tumor recurrence were not eligible for recruitment. We excluded from study patients with serious complications (Clavien-Dindo scale score ≥ 3)[19] during hospitalization.

Statical analysis

Categorical variables were described by descriptive statistics and presented as frequency. Continuous variables were presented as measures of central tendency (mean and median) and dispersion (standard deviation, maximum and minimum). To assess the diagnostic accuracy of the algorithm developed, the sensitivity, specificity, positive predictive value, and negative predictive value were calculated. The software used to record the collected data was the REDCap 11.1.18 platform. Statistical analyses were performed with SPSS, version 24.0 (SPSS Inc., Chicago, IL, USA). For all tests, the significance level was fixed at 0.05.

Sample calculation

The sampling plan adopted was made for convenience, including patients undergoing oncological colorectal surgery performed by a colorectal surgeon at our cancer Center, between November 2021 and November 2022. This is justified by the fact that this is a feasibility trial to find a minimum viable product for this monitoring system. A total of 92 participants were included in all phases of the study.

Results

A total of 92 eligible participants agreed to participate in the study and were monitored between November 2021 and November 2022. Table 1 describes the clinical characteristics of the participants.

Three interim analyses were performed to evaluate the frequency of primary outcomes. The symptom reporting questionnaire and algorithm were changed after each analysis to achieve higher accuracy in predicting complications.

Of the 16 participants monitored in the first interim analysis, 11 reported at least one symptom, 9 of which had severe events, and only 4 considered mild. Of the 9 severe symptoms reported, 3 were classified as true positives, indicating that the solution could detect complications. All complications detected were classified as Clavien-Dindo grade 2.

Two ED visits were mapped without indicating the platform; however, they were not real complications. The sensitivity for identifying complications was 100%, with a specificity of 50% and an accuracy of 56%. Positive and negative predictive values were 22% and 100%, respectively.

Table 2 presents ED visits and complications identified in each phase of the study.

Based on the results of this first interim analysis, the study team decided to make minimal changes to the daily query intending to correct misinterpretation regarding gastrointestinal elimination.

In the second interim analysis, 22 participants were monitored; 14 reported at least one symptom, 11 reported events considered severe, and 3 reported only mild events. Despite being referred to the ED, none of the 11 patients had attended the ED. However, no real complications were detected when monitored by the nurse navigator in the phone call follow-up.

The results of the second interim analysis motivated a significant algorithm adjustment once the platform overestimated the complication detection. The flow change was validated in two rounds of Delphi analysis with surgeons and nurses participating in the program. In the first round of evaluation, specialists were consulted regarding the feasibility of converting high-risk flows into moderate- or low-risk flows. They were also asked about the pertinence of the symptoms evaluated in the daily questionnaire and suggested logical combinations to the system.

Some of the symptoms that triggered high-risk flows were replaced by moderate- or low-risk flows; that is, the algorithm started to indicate the reassessment of symptoms or included other estimates in the initial assessment before referral to the ED.

The algorithm changes according to referral flow to the ED, as illustrated in Figure 2.

The final version of the daily questionnaire to assess patient symptoms and algorithm flow predefined is illustrated in Figure 3.

A total of 54 participants were included in the third interim analysis and 38 patients reported at least one type of symptom, 14 of which were considered severe, and 24 were mild adverse events.

Of the 14 participants who reported severe symptoms, 10 did not attend the ED and were monitored through phone calls by the nurse navigator without clinical complications. We also had three symptoms erroneously reported, which were not considered in the sensitivity and specificity analyses.

There were four patients who visited the ED without platform referral, one had a real complication (Clavien-Dindo grade 2).

In the third interim analysis, we achieved the highest accuracy of the algorithm (82%), as shown in Table 3.

Table 1. Participants clinical characteristics.

Categorical Variable	N(%)
Gender	
Male	45(48.9)
Female	47(51.1)
Total	92(100)
Surgery	
Colectomies	32(34.8)
High anterior ressection	59(64.1)
Low anterior ressection	1(1.1)
Total	92(100)
Surgical approach	
Open	12(13.0)
Laparoscopic	67(72.8)
Robotic	13(14.1)
Total	92(100)
Conversion rate	
Yes	85(92.4)
No	7(7.6)
Total	92(100)
Estoma	
Yes	19(20.7)
No	73(79.3)
Total	92(100)
ASA	
ASA 1	14(15.2)
ASA 2	63(68.5)
ASA 3	15(16.3)
Total	92(100)

(continued)

Table 1. Continued.

Categorical Variable	N(%)
ECOG	
ECOG 0	81(88.0)
ECOG 1	10(10.9)
ECOG 2	1(1.1)
Total	92(100)
Clavien (hospital stay)	
Clavien 0	67(72.8)
Clavien 1	11(12.0)
Clavien 2	14(15.2)
Total	92(100)
Number of participants	
Interim Analysis 1	16(17.4)
Interim Analysis 2	22(23.9)
Interim Analysis 3	54(58.7)
Total	92(100)

Numeric Variable	N	Min.	Max.	Mean	Median	S.D
Age	92	29	81	59.3	60	11.8
Hospital Lenght of hospital stay (days)	92	2	19	5.8	4	3.6

All participants were invited to answer a form containing the NPS and the patient experience assessment questionnaire. Table 4 shows the patient experience, described as adherence, and the NPS value obtained in each of the evaluation phases.

We identified a high percentage of passives (score 7 to 8) at the NPS evaluation who mostly had any telephone contact with the nurses due to the absence of triggering severe flows. Therefore, we decided to include a telephone call on the fifth day of discharge in the project's scope, regardless of the reported symptoms, to check up on patients, reinforce the importance of daily responses, and summarize the flow of the project. The NPS score in the subgroup that was in contact with the 5th-day telephone call was 94.

A high proportion of patients positively evaluated the experience, and 67 (90,5%) agreed that they felt safe about being remotely monitored. More than 80% of the participants indicated that the program contributed to better communication, coordinated care, and patient engagement.

Discussion

The main objective of this study was to assess the capacity of the developed algorithm to detect complications and to measure its acceptance.

Literature shows the increasing use of mobile health (m-Health) for post-discharge monitoring. The use of m-Health is justified by earlier discharge, predisposing most complications to occur at home.[20]

Early hospital discharge for patients without comorbidities admitted for colectomies was evaluated in a study comparing daily remote monitoring detection using telephone

Table 2. Emergence department visits and complications.

Variable	N(%) Total	Interim Analysis 1	Interim Analysis 2	Interim Analysis 3
ED visits referred by the algorithm				
No	58(63.0)	7(43.8)	11(50.0)	40(74.1)
Yes	34(37.0)	9(56.3)	11(50.0)	14(25.9)
Total	92(100)	16(100)	22(100)	54(100)
Erros de preenchimento				
No	87(94.6)	15(93.7)	21(95.5)	51(94.5)
Yes	5(5.4)	1(6.3)	1(4.5)	3(5.5)
Total	92(100)	16(100)	22(100)	54(100)
ED visits				
No	26(76.5)	5(55.6)	11(100)	10(71.4)
Yes	8(23.5)	4(44.4)	0(0.0)	4(28.6)
Total	34(100)	9(100)	11(100)	14(100)
Readmission				
No	88(95.7)	14(87.5)	22(100)	52(96.3)
Yes	4(4.3)	2(12.5)	0(0.0)	2(3.7)
Total	92(100)	16(100)	22(100)	54(100)
ED visits that were not referred by the algorithm				
No	83(90.2)	14(87.5)	19(86.4)	50(92.6)
Yes	9(9.8)	2(12.5)	3(13.6)	4(7.4)
Total	92(100)	16(100)	22(100)	54(100)
Real Complication				
Identified by the algorithm				
Yes	6(85.7)	3(100)	0(0.0)	3(75)
No	1(14.3)	0(0.0)	0(0.0)	1(25)
Total	7(100)	3(100)	0(0.0)	4(100)

calls and mobile apps. In this study, the discharge was on the same day of surgery, and monitoring signs and symptoms, both through the app and by telephone, lasted 7 days, focusing on pain, gastrointestinal symptoms, and fever.[21] There were no statistical differences between the two groups considering the outcomes of hospital readmission and complications. Our study had broader inclusion criteria than the previously mentioned study once we included patients who underwent colectomies and anterior resections, regardless of the length of stay, and patient conditions at discharge. The broader selection criteria used made the results potentially reproducible for different samples.

Although we have implemented an enhanced recovery protocol in our service since 2016, our median length of stay is still as high as 4 days, which is higher than our planned goal of 3 days. As a national reference cancer center, we received patients from other cities or states. In this context, we noticed that some patients continue to stay in hospital due to insecurity or difficulties related to being in a foreign city after discharge. Our results of the safety in detecting post-operative complications by the digital tool developed and validated in our study can allow earlier discharge, even for patients who come to the city only for treatment.

A meta-analysis published in 2017 evaluated 62 studies that examined the use of digital technology over the last decade in different health contexts. The study argues that the applicability of implementing devices to assess the clinical conditions of patients on a large scale can be economically challenging owing to the high cost of technological implementation, infrastructure maintenance costs, and costs for implementation in routine clinical practice. In addition, there are challenges in educating patients regarding the use of devices and training staff in data collection and analysis of results.[22]

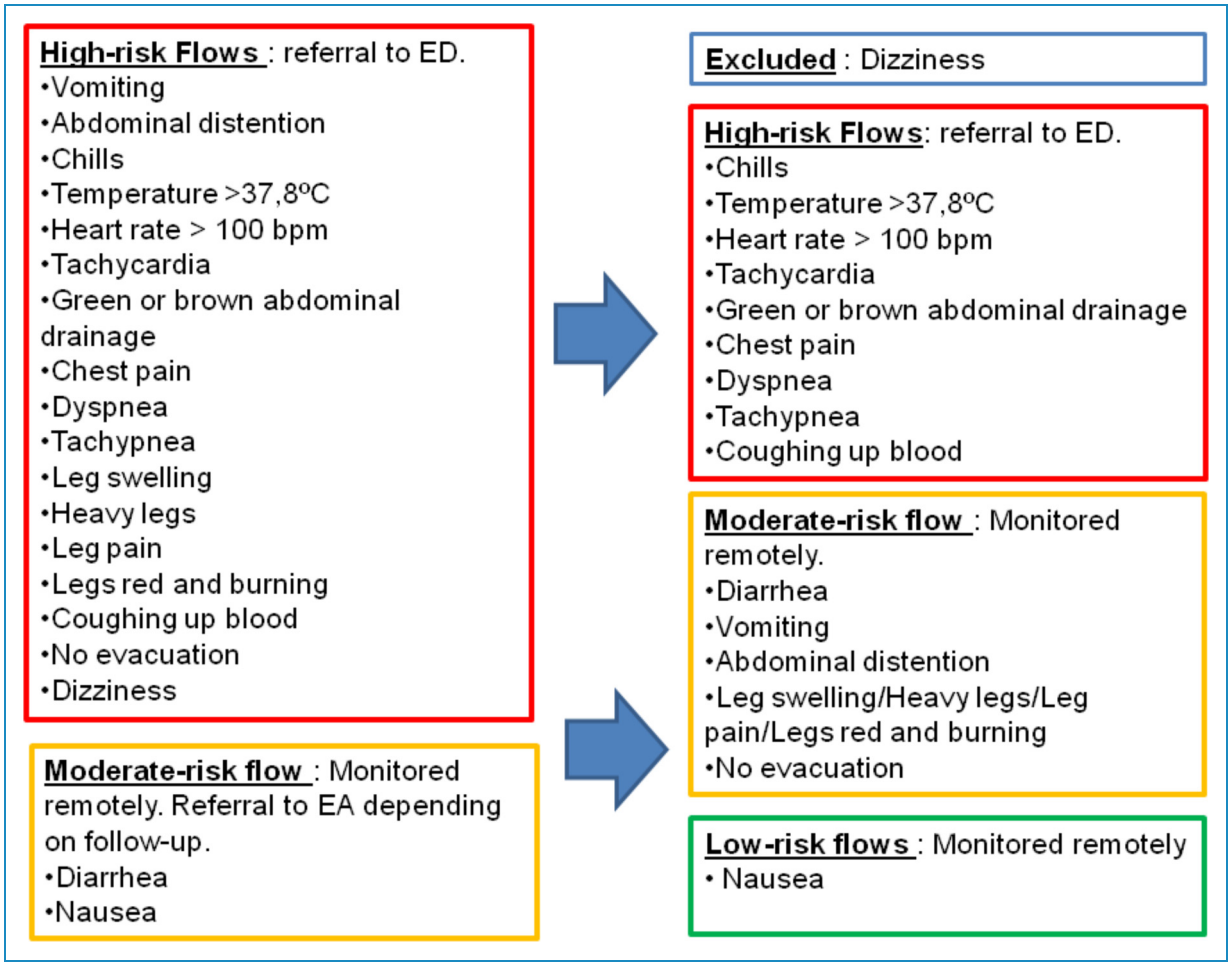

Figure 2. Algorithm changes regarding the referral flow to the ED, after second analysis.

Previous studies have highlighted poor technological skills as a barrier to the implementation of health-related technology on mobile devices.[23,24] Health literacy and technological skills were not assessed in this study, but we did not include age restrictions, technology use, or skill level in using smartphones among the exclusion criteria. Moreover, in our trial, family members and caregivers could report the symptoms, helping participants with low health literacy or those with no experience using digital technologies. Despite such a diverse population, we had high adherence (83.7%), and more than 95% of the participants rated the platform as simple and easy to use. The high adherence and high rate of positive evaluations in this sample with wide diversity can be considered a strength of this study because it can increase the generalizability of the results.

Recent studies have evaluated the use of m-Health for post-operative home follow-up patients, focusing on assessing patient acceptance and detection of complications.[25–27] A systematic review published by Eustache et al. (2021) evaluated 29 randomized or cohort studies from different oncological specialties and found no apparent difference in the outcomes of reducing ED visits or readmissions.[26]

The same group also evaluated the outcomes of surgical complications and patient satisfaction in a prospective cohort of colorectal surgeries. Using a mobile app was associated with fewer potentially preventable ED visits and a shorter length of hospital stay after major elective colorectal surgery, likely due to enhanced post-discharge monitoring and patient–provider communication.[26]

Similar data were also found in the study by Borsuk et al., who also found better results in the remotely monitored group, both regarding ED visits and readmissions.[27]

Despite previous studies showing positive results, the effectiveness of m-Health for post-colorectal surgery follow-up deserves to be better elucidated with randomized studies. We also hypothesized that the COVID pandemic may have influenced data from recent real-world studies regarding emergency visits and length of stay.[28]

Moreover, none of the recent studies evaluating patients' follow-up at post-colorectal surgeries developed an algorithm for predicting complications and directing conducts,

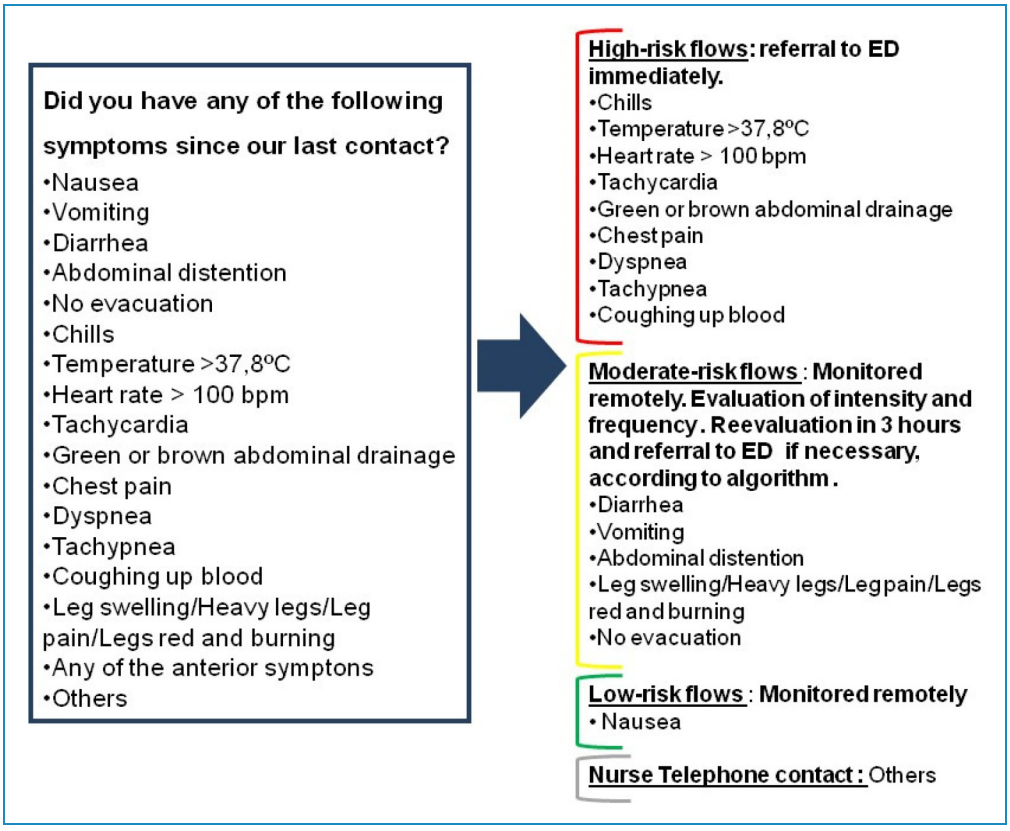

Figure 3. Daily questionnaire to assess patient symptoms and algorithm flow predefined.

Table 3. Sensitivity and specificity of the algorithm.

		Detected		
		Yes	No	Total
Real	**Yes**	3	1	4
	No	8	39	47
	Total	11	40	51

Sensitivity = 75%,
Specificity = 83%
Positive Predictive Value = 27%
Negative Predictive Value = 97%
Acuracy = 82%

Table 4. Adherence and NPS value in each of the interim analyses.

	N(%)			
Variable	Total	Interim Analysis 1	Interim Analysis 2	Interim Analysis 3
Adherence				
Parcial	15(16.3)	3(18.8)	1(4.5)	11(20.4)
Complete	77(83.7)	13(81.3)	21(95.5)	43(79.6)
Total	92(100)	16(100)	22(100)	54(100)
NPS Score	81	69	83	84

with minimal human intervention and using a Chatbot with NLP, as proposed in our study.

The tool created in this study is an MVP with great potential to facilitate early discharge and it was created and validated in-house, but is ready to be used publicly. The algorithm not only favors the patient's involvement in self-care and their active participation in identifying and reporting symptoms but also predicts complications and directs conduct without the need for a telephone call at each reported event, as in other studies. In addition, the results showed that patient satisfaction was comparable to studies that proposed direct contact with the surgeon at each symptom report.[28,29] Monitoring symptoms in the home environment and managing them using a predefined clinical prototype enables a single nurse to monitor a larger volume of patients, and the need for fewer phone calls may also reduce costs. Future studies should evaluate the cost-effectiveness of this tool.

We did not evaluate the effectiveness of the device in the early detection of complications or its capacity to prevent complications from worsening. However, all identified complications were classified as Clavien II, suggesting that the program could detect complications early, with the possibility of management without aggravating the clinical condition. However, this aspect should be evaluated in future studies.

It is important to highlight that, although it is a sustainable instrument and of great importance for nurse navigation during the postoperative period of colorectal procedures, it does not replace human intervention in patient follow-up. Furthermore, it requires the expertise of the health team, both in the use of the digital platform and in the guidelines to support patients according to the defined clinical algorithm.

The program proved safe in identifying real complications, with a high negative predictive value. We reinforce that the only case of an unidentified real complication was due to a reporting error and did not indicate algorithm error detection.

The major limitations of this study are the response errors to the daily questionnaire and the high number of preventable Emergency Department visits, despite the recommendation of being home. Training patients to use the tool is essential to ensure adherence to follow-up and the proper identification and reporting of symptoms. The central gap in the program was due to response errors, resulting in a lower detection rate of real complications and a more significant number of false positives. All participants were trained in the use of the device as well as in detecting the symptoms, but reporting errors may reflect inadequate training.

We also believe that program implementation in the preoperative phase may be important for patient training and would increase familiarity with the digital platform, thus reducing reporting failures in the postoperative period and increasing the program's effectiveness. We intend to implement the tool in the preoperative phase in future studies and to design educational materials for patients to reduce failures and promote health education.

The digital tool is safe for monitoring patients during early hospital discharge, but it needs to be adjusted to reduce the cost of preventable ED visits. Despite the low admission rate, the solution failed to prevent ED visits. Recent studies evaluating the same condition in the Canadian population have succeeded in reducing ED visits.[25,27] We believe that as a cultural characteristic, Latin American people tend to feel safer having in-person medical professional care, which can have influenced the higher number of ED visits.

The data obtained in this trial is a proof of concept essential for creating an artificial intelligence algorithm in the future, potentially achieving more accurate results than those of this algorithm based on clinical decisions.

Conclusion

The Digital Care Pathway created for post-hospital discharge follow-up of patients in the postoperative period of colorectal surgeries proved to be safe, with high accuracy to detect complications after discharge, high adherence rates, and good acceptance by patients; however, it still needs to be adjusted to reduce preventable visits to the ED.

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Ethical approval: The study was carried out in accordance with the Helsinki Declaration principles and was approved by the A.C.Camargo Cancer Center Research Ethics Committee, (IRB number: 2701/19). Written consent was obtained from the participants.

ORCID iD: Bruna Elisa Catin Kupper https://orcid.org/0000-0003-3430-3336

Supplemental material: Data supporting this study are available from Whimsical (https://whimsical.com/monitotamento-remoto-cirurgias-colorretais-v5-pos-analise-2-vali-7UqsPncu4bfYdweqXKy4w8), free access. Access to the participant's data is subject to approval at the Redcap database (https://dados.accamargo.org.br/redcap/).

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