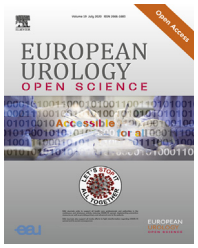
available at www.sciencedirect.com
journal homepage: www.eu-openscience.europeanurology.com



European Association of Urology

Bladder Cancer

Intensified and Standardized Digital Communication with Cystectomy Patients as a Potentially Simple and Effective Modality for Early Detection of Postoperative Complications: Results from a Pilot Study

Frédéric D. Birkhäuser[a], *Felix Moltzahn*[a], *Philipp M. Huber*[a], *Jean-Luc Zehnder*[b], *Sebastian Flückiger*[b], *Daniel Hasler*[b], *Anirban P. Mitra*[c], *Pascal Zehnder*[a,*]

[a] *Urologie St. Anna, Luzern, Switzerland;* [b] *Virtido by Recentis GmbH, Zürich, Switzerland;* [c] *Department of Urology, The University of Texas MD Anderson Cancer Center, Houston, TX, USA*

Article info

Article history:
Accepted August 20, 2020

Associate Editor:
Axel Bex

Keywords:
Cellphone-based health care application
Postoperative complications
Postoperative surveillance
Radical cystectomy

Abstract

Background: Postoperative readmission rates following radical cystectomy remain significant. Early identification of emerging complications could potentially allow for immediate institution of therapy.
Objective: To intensify postoperative patient-physician communication via a cellphone-based health care application (CHA) and to evaluate its potential for early detection of complications.
Design, setting, and participants: This was a pilot study involving 18 radical cystectomy patients. During the first 30 d, patients received a push cellphone notification twice a week requesting data input into the CHA. This was reduced to once a week from day 31 to day 90. De-identified recorded data were reviewed by the surgeon involved. If deemed necessary, patients were contacted by the surgeon via telephone to obtain more detailed clinical information.
Outcome measurements and statistical analysis: Descriptive statistics were used.
Results and limitations: Of the 18 patients enrolled, all completed the 90-d reporting period. On two occasions, interventions were necessary on the basis of data recorded on the CHA. One neobladder patient was given antibiotic therapy for pyelonephritis. Another patient reported weight loss and nausea with clinical suspicion of metabolic acidosis, and his sodium bicarbonate and fluid intake were increased. Limitations include the small number of cases from a single low-volume center.
Conclusions: CHA-based monitoring of clinical parameters within the crucial 90-d postoperative period following radical cystectomy provides meaningful information. In this pilot study, two potential readmissions were possibly avoided on the basis of recorded basic vital signs and early intervention.
Patient summary: Besides regular clinic follow-up visits after radical cystectomy, additional aids such as a cellphone-based health care application can provide

* Corresponding author. Urologie St. Anna, St. Anna-Strasse 32, 6006 Luzern, Switzerland.
E-mail address: pascal.zehnder@hin.ch (P. Zehnder).

http://dx.doi.org/10.1016/j.euros.2020.08.005
2666-1683/© 2020 The Author(s). Published by Elsevier B.V. on behalf of European Association of Urology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

treating physicians with relevant clinical information and may help to identify imminent deviations from normal postoperative recovery at an early stage.
© 2020 The Author(s). Published by Elsevier B.V. on behalf of European Association of Urology. This is an open access article under the CC BY-NC-ND license (http://creativecommons.org/licenses/by-nc-nd/4.0/).

1. Introduction

Radical cystectomy remains a complex operation with high perioperative morbidity and associated health care costs [1]. Readmission rates after radical cystectomy can be up to 30% [2,3]. Early detection and effective treatment of potential complications are therefore key to ensuring optimal outcomes [4]. Effective delivery of patient education during the preoperative, immediate postoperative, and late recovery phases, including self-monitoring ability, can potentially mitigate serious adverse events [5]. A cellphone-based health care application (CHA) may help with early identification of potential complications in the postoperative period and in optimizing follow-up care, which could not be achieved with regular phone calls [6,7]. Use of mobile digital technology can be an easy and effective tool for reminding patients to self-monitor and facilitating postoperative communication compared to phone calls [7,8].

Recent years have witnessed the emergence of mobile health aids, and the importance of these platforms has been further highlighted during the COVID-19 pandemic. However, adoption in urology has been relatively slow [9]. Monitoring of recovery and guiding postoperative care after major urologic surgery appears to be highly accepted by patients [10].

This pilot study was designed to address two goals: to assess the feasibility of developing a new CHA for patient self-monitoring and to evaluate its potential for reducing readmission rates after radical cystectomy.

2. Patients and methods

2.1. Study design

This prospective nonrandomized pilot clinical trial was performed at Hirslanden Klinik St. Anna, Lucerne, Switzerland, between January 2017 and November 2018. All patients provided informed consent before enrollment.

The primary endpoints were the feasibility of using a CHA to monitor relevant clinical metrics after radical cystectomy and the CHA impact on readmissions. Furthermore, patient satisfaction with use of the CHA for self-monitoring and direct communication with the surgeon was evaluated. The intensified observation period was set to 90 d after surgery.

The trial is registered in the Australian New Zealand Clinical Trials Registry (ACTRN12619001741178). All the participating surgeons have Good Clinical Practice certification.

2.2. Patients

All consecutive patients undergoing radical cystectomy were offered participation in the study. Enrollment and patient instruction were performed postoperatively during the hospital stay. The exclusion criteria were a lack of access to a cellphone that precluded use of the CHA and unwillingness to record personal data on the CHA.

2.3. Surgery and perioperative care

All study participants underwent an open radical cystectomy with extended pelvic lymph node dissection for bladder cancer with urinary diversion (Studer neobladder or Bricker ileal conduit), performed by the same surgical team of three urologists.

Anesthetic, surgical, and postoperative management were carried out according to standardized procedures at our institution. This included an established protocol for enhanced recovery after surgery [11] as the standard of care.

2.4. Cellphone-based health care application

The MedCom CHA was developed in collaboration with Virtido by Recentis, primarily for a nonprofit intent. The iOS- or Android-based CHA was downloaded on the patient's cellphone during their postoperative hospital stay. Patients were de-identified using a randomly generated quick response code. The CHA was activated and patients were able to start their data collection on their cellphone. Data security was ensured via end-to-end encryption. The link between a case number and the patient identifier could only be accessed by the surgeon responsible.

2.5. CHA functionality

At hospital discharge, all patients were provided with weighing scales, a thermometer, and measuring cups.

Individual data entry was carried out by the patient (Fig. 1A). Up to postoperative day 30, automatic push notifications were generated twice a week. Between postoperative days 31 and 90, these were reduced to once a week. Patients were asked to document body weight in kilograms, temperature in degrees Celsius, and fluid intake and output in liters (Fig. 1B). They also had to report on nausea or vomiting, defecation (each with "yes" or "no"), and a pain score (using a visual analog scale ranging from 0 for no pain to 10 for the worst pain).

Neobladder patients also entered the number of urine pads used and the number of sphincter trainingKegel) exercises performed.

In addition, patients had the option to enter individual remarks or questions on each day of data collection, and to record incisional wound healing with the photo-capture function.

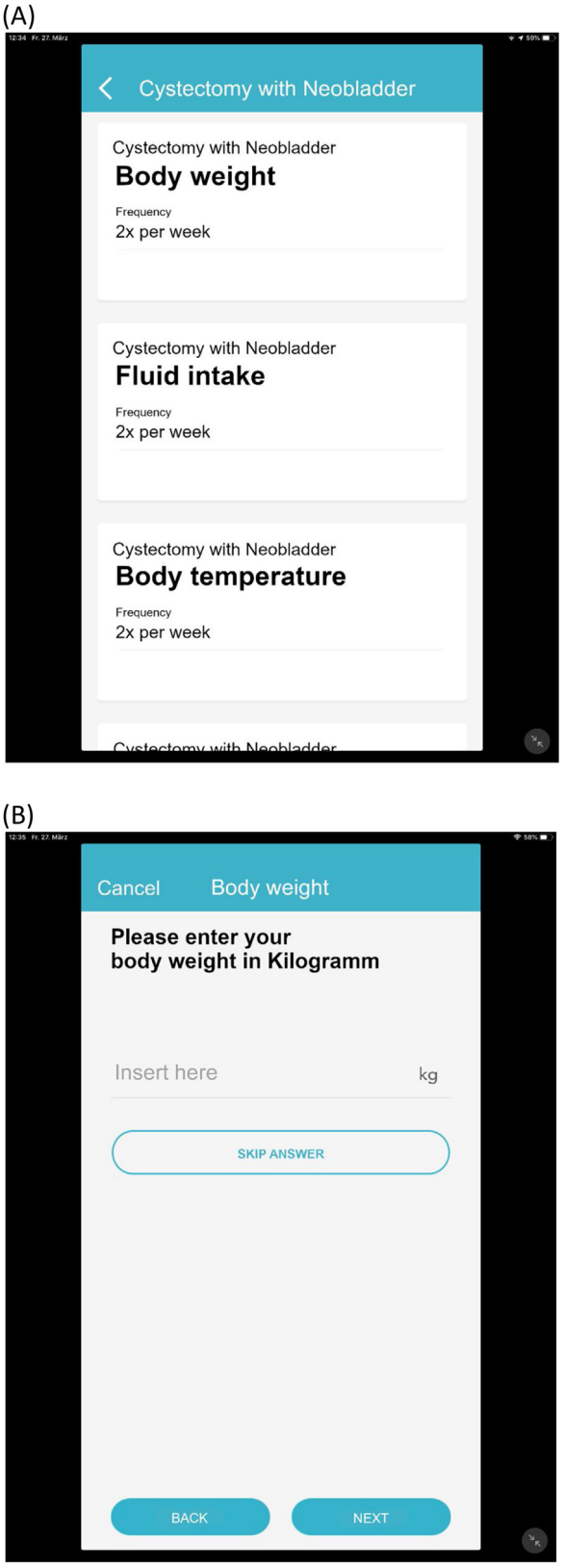


Fig. 1 – User screens: (A) main interface and (B) data input.

Patients were asked to value the CHA usefulness on a scale ranging from 1 (not useful) to 10 (extremely useful).

The participating surgeon had access to the patient's data via the CHA or online web access, and reviewed the data twice a week. Missing data entries were flagged red. Recorded data were displayed as tables (Fig. 2A) and graphs (Fig. 2B,C). For medicolegal reasons, no automated analysis of the raw data was performed and no critical threshold levels were predefined. If input or missing data aroused clinical suspicion, patients were directly contacted by the surgeon, who then decided whether a clinic visit was required.

2.6. *Postoperative complications*

Complications were assessed in the 90 d after surgery and were rated according to the Clavien-Dindo classification system. The number of interventions needed and readmissions were monitored.

2.7. *Postoperative visits*

Following hospital discharge, all cystectomy patients were seen in the outpatient clinic at 2 and 6 wk, and then every 3 mo thereafter in the first year.

3. Results

3.1. *Baseline characteristics*

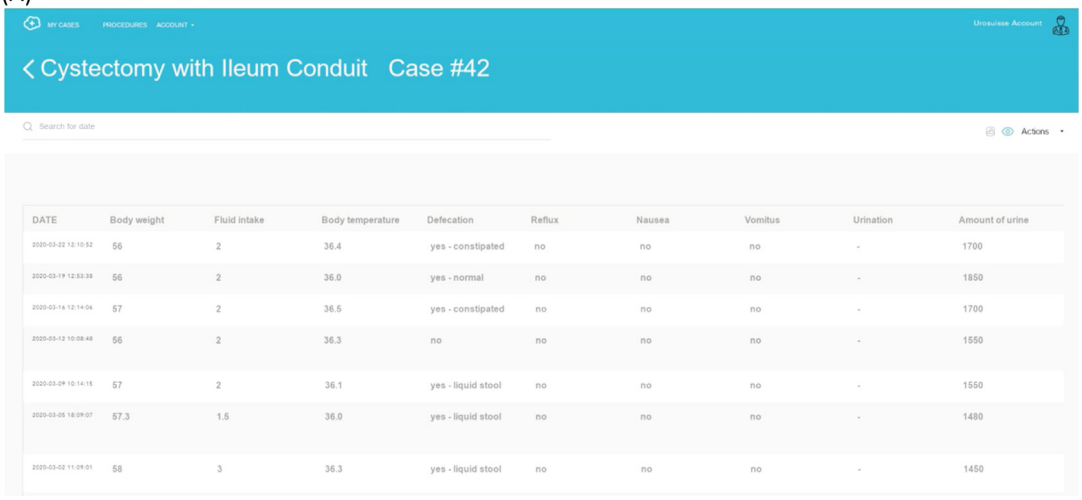
Twenty-three patients underwent radical cystectomy during the study period. Of these, five patients were excluded because they did not have a cellphone. Nine patients underwent urinary diversion with neobladder, and nine urinary diversion with ileal conduit (Table 1). All 18 patients (age range 40–87 yr) completed the 90-d postoperative surveillance using the CHA. Overall, 95% of push notifications were answered. No patient missed more than one data entry.

3.2. *Postoperative course*

During postoperative hospitalization, 11 relevant complications were noted (Clavien-Dindo grade $\geq$2), including six requiring blood transfusion (Table 2). Following discharge, two patients experienced a deviation from the normal postoperative course, as indicated by the CHA. One patient with ileal neobladder developed fever 3 wk after discharge. Given clinical suspicion for early pyelonephritis, oral antibiotic therapy was initiated and resulted in a quick recovery. Another patient experiencing weight loss and nausea 2 mo after surgery was treated with additional sodium bicarbonate and increased oral fluid intake because of suspicion of metabolic acidosis, which led to a complete clinical recovery.

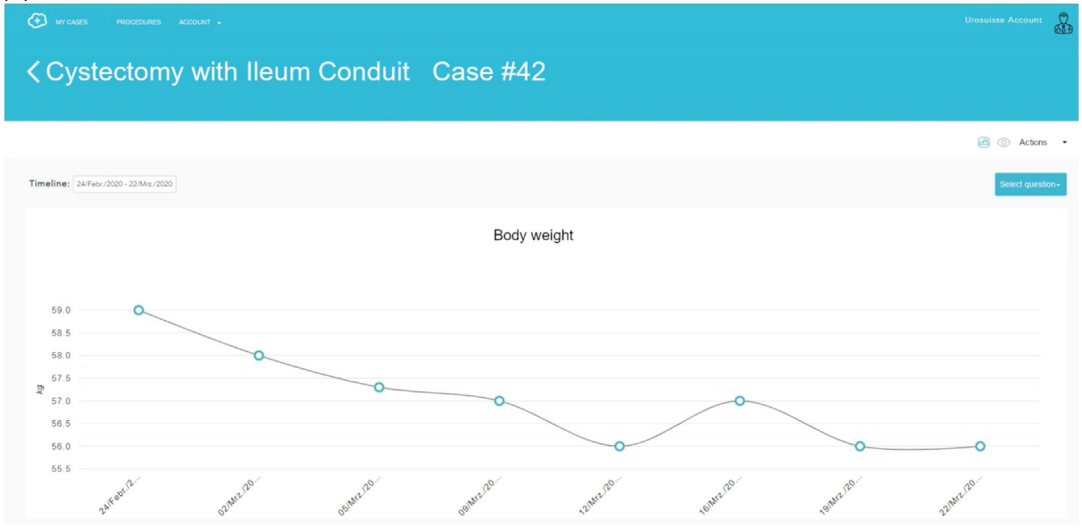
Another two patients required readmission. One oligosymptomatic patient developed an infected wound hematoma that had to be drained. The other patient developed high febrile spikes due to bilateral pyelonephritis necessitating intravenous antibiotic therapy.

(A)



DATE	Body weight	Fluid intake	Body temperature	Defecation	Reflux	Nausea	Vomitus	Urination	Amount of urine
2020-03-22 12:10:52	56	2	36.4	yes - constipated	no	no	no	-	1700
2020-03-19 12:53:38	56	2	36.0	yes - normal	no	no	no	-	1850
2020-03-16 12:14:06	57	2	36.5	yes - constipated	no	no	no	-	1700
2020-03-12 10:08:48	56	2	36.3	no	no	no	no	-	1550
2020-03-09 10:14:15	57	2	36.1	yes - liquid stool	no	no	no	-	1550
2020-03-05 18:09:07	57.3	1.5	36.0	yes - liquid stool	no	no	no	-	1480
2020-03-02 11:09:01	58	3	36.3	yes - liquid stool	no	no	no	-	1450

(B)



(C)

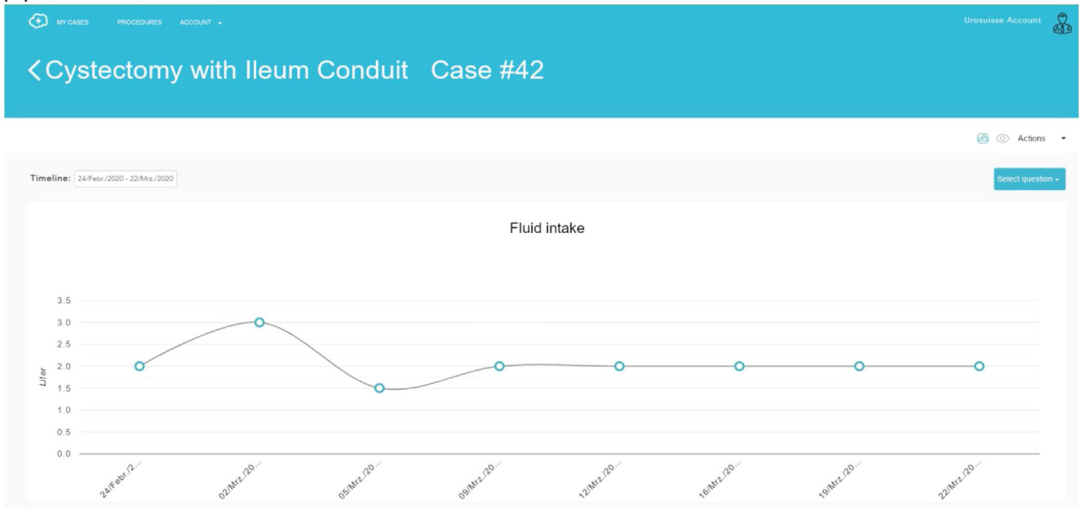


Fig. 2 – Data displays. (A) Summary of recorded data in table format. Recorded data as graphs for (B) body weight and (C) daily fluid intake.

Table 1 – Patient details.

Parameter	Result
Mean age at treatment, yr (range)	66 (40–87)
Neoadjuvant chemotherapy, *n* (%)	5 (28)
Tumor stage, *n* (%)	
pT0–1	4 (22)
pT2–3	9 (50)
ypT0–Tis	2 (11)
ypT3	3 (17)
Nodal stage, *n* (%)	
pN0	14 (78)
pN1–2	4 (22)
Resection stage, *n* (%)	
R0	17 (94)
R1	1 (6)

Table 2 – Perioperative and postoperative results.

Parameter	Result
Median operation time, min (interquartile range)	360 (360–405)
Median estimated blood loss, ml (interquartile range)	450 (300–700)
Median length of stay, d (interquartile range)	17 (16–20)
Clavien-Dindo complications during hospitalization, *n* (%)	
Grade 2	7 (39)
Grade 3a	1 (6)
Grade 3b	2 (11)
Grade 4a	1 (6)
Clavien-Dindo complications after discharge, *n* (%)	
Grade 2	3 (17)
Grade 3a	1 (6)

3.3. *Patients' experience with the CHA*

At the scheduled in-person follow-up visits with their surgeon, all participants subjectively reported feeling reassured by being under surveillance during the immediate postoperative period, and having the flexibility to communicate with their surgeon. Patients rated the CHA as an extremely valuable tool (median score 9, range 8–10).

4. Discussion

The aim of this pilot study was to develop and evaluate the potential of a CHA in detecting postoperative complications early for patients who had undergone radical cystectomy to help in triaging the need for active physician intervention and potential readmission. Furthermore, it was intended to intensify and improve active communication between the surgeon and patient, given that lack of actionable information following discharge has been associated with higher readmission rates [5]. The value of CHAs in supporting postoperative recovery has been reported for radical prostatectomy, for which it was helpful in regaining functional integrity and had demonstrable patient acceptance [10]. Others were able to demonstrate a reduction in postoperative in-person visits following ambulant surgery [12] and an increase in quality of life following gynecological oncology care [13].

All 18 enrolled patients completed the entire study period of 90 d. Overall, no patient missed more than one data entry, which demonstrates excellent compliance and a high level of discipline in self-monitoring and documentation. It also indicates the user-friendliness of the CHA, which motivated adherence to the self-reporting protocol among patients spanning a wide age range.

Overall, two patients required readmission within the study period of 90 d because of postoperative complications that the CHA was unable to comprehensively identify. In one case, an infected wound hematoma was noted in an oligosymptomatic patient that was diagnosed at a regular postoperative clinic visit. The second case developed acute bilateral pyelonephritis requiring intravenous antibiotic administration. However, interventions were initiated for two patients by the surgeon after analysis of data inputs from the CHA. We believe that the medical treatments initiated were successful because deviation from the standard postoperative clinical course was detected at an early stage by the CHA instead of waiting for a regularly scheduled follow-up visit. In essence, the CHA offers the opportunity for more frequent, flexible, and real-time monitoring compared to regular clinic visits scheduled every 2–6 wk. This can potentially lead to greater patient satisfaction and compliance. CHA-based self-monitoring appears to be simple and efficient, since patients are motivated to regularly measure and record basic vital parameters. While prior findings indicate that even calling patients on a regular basis may fail to significantly decrease readmission rates, this effort probably requires more than just standardized follow-up regimens [6]. Better patient-surgeon communication can result in increased awareness of unfavorable postoperative developments during recovery that may allow for early intervention.

Patients evaluated the usefulness of the CHA as a tool for self-monitoring and communication with their surgeon, and reported that they found it to be extremely valuable. Furthermore, the vast majority indicated that they would continue to use the CHA beyond the 90-d study period for self-monitoring and reassurance if given the opportunity.

Several areas of need following major surgery have been identified whereby complications can possibly be reduced or interventions made at an early stage. Besides preoperative education, increased self-awareness is a key aspect [5]. Patients require significant complex instruction and help to be able to distinguish symptom severity from various physiologic signs, and to appropriately report these symptoms. Regular monitoring of vital signs using digital devices can potentially assist the patient and treating physician in this process.

This pilot study demonstrates successful and actionable postoperative data collection for all enrolled patients. The current CHA version has not yet achieved its final potential. Further technical refinement is required to implement automated clinical data analysis. Automation will help in saving human resources, which is mandatory for high-volume centers.

However, digital aids are not meant to replace in-person clinic visits. Nevertheless, a CHA could serve as an important clinical adjunct and potentially help in pre-selecting data and indicating dangerous deviations from the standard course. Predefined abnormal responses could trigger alerts for further evaluation [14]. In addition,

unbiased, unfiltered, digitally collected patient-reported outcome measures provide objective and robust follow-up metrics. The recent worldwide COVID-19 pandemic has highlighted the need for remote monitoring of complex postoperative patients to minimize in-person clinic visits while ensuring that appropriate care and early intervention are delivered in a hospital setting when necessary [15].

There are limitations to this analysis. First, as a pilot study, it is based on a limited number of cases from a single low-volume center. Therefore, a larger randomized external validation is planned and will be useful in evaluating the full potential of this CHA. Monitoring a greater number of patients will require more physicians to review the higher volume of data generated. Second, the financial burden of developing a CHA is high. Although costs for health care systems may be reduced by decreasing the number of readmissions, current reimbursement frameworks typically do not incentivize this endpoint. Finally, security and data safety are other critical issues to be considered when collecting sensitive patient data using digital devices. There may also be legal implications concerning responsibility for analyzing patient CHA data, especially when automatically generated warnings are missed by the physician.

5. Conclusions

CHA-based monitoring of clinical parameters within the crucial 90-d postoperative period after radical cystectomy provides treating physicians with meaningful information. In this pilot study, two potential readmissions were avoided via relatively simple interventions by the surgeon after early detection of deviation from the standard clinical course. All patients rated this straightforward communication tool as reassuring and extremely valuable. Such CHA-based patient-physician communication allows for individual customization and expansion and is therefore applicable to remote therapeutic monitoring across all medical specialties. The planned external validation will help in evaluating the full benefit of this CHA.

Author contributions: Pascal Zehnder had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.
Study concept and design: Birkhäuser, Moltzahn, P. Zehnder.
Acquisition of data: Huber, P. Zehnder.
Analysis and interpretation of data: Huber, P. Zehnder.
Drafting of the manuscript: Birkhäuser, Moltzahn, Huber, P. Zehnder.
Critical revision of the manuscript for important intellectual content: Birkhäuser, Moltzahn, Huber, P. Zehnder, Mitra.
Statistical analysis: None.
Obtaining funding: Birkhäuser, Moltzahn, Huber, P. Zehnder.
Administrative, technical, or material support: J.-L. Zehnder, Flückiger, Hasler.
Supervision: None.
Other: None.

Financial disclosures: Pascal Zehnder certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), are the following: Jean-Luc Zehnder, Sebastian Flückiger, and Daniel Hasler are employees of Virtido by Recentis GmbH.

Funding/Support and role of the sponsor: Frédéric D. Birkhäuser, Felix Moltzahn, Philipp M. Huber, and Pascal Zehnder co-financed the app development.

References

[1] Leow JJ, Cole AP, Seisen T, et al. Variations in the costs of radical cystectomy for bladder cancer in the USA. Eur Urol 2018;73:374–82.
[2] Stitzenberg KB, Chang Y, Smith AB, Nielsen ME. Exploring the burden of inpatient readmissions after major cancer surgery. J Clin Oncol 2015;33:455–64.
[3] Altobelli E, Buscarini M, Gill HS, Skinner EC. Readmission rate and causes at 90-day after radical cystectomy in patients on early recovery after surgery protocol. Bladder Cancer 2017;3:51–6.
[4] Mossanen M, Krasnow R, Chang SJ, et al. Examining the relationship between complications and perioperative mortality following radical cystectomy: a population-based analysis. BJU Int 2019;124:40–6.
[5] Naylor M, Keatin SA. Transitional care: moving patients from one care setting to another. Am J Nurs 2008;108(9 Suppl):58–63.
[6] Metcalf M, Glazyrine V, Lee EK, et al. The feasibility of a health care application in the treatment of patients undergoing radical cystectomy. J Urol 2019;201:902.
[7] Krishnan N, Liu X, Hu M, et al. A model to optimize follow-up care and reduce hospital readmissions after radical cystectomy. J Urol 2016;195:1362–7.
[8] Brunner TH, DiFortuna K, LeTang M, et al. Feasibility of an iPad to facilitate communication in postoperative patients with head and neck cancer. J Perianesth Nurs 2018;33:399–406.
[9] Pereira Azevedo N, Gravas S, de la Rosette J. Mobile health in urology: the good, the bad and the ugly. J Clin Med 2020;9:1016.
[10] Belarmino A, Walsh R, Alshak M, Patel N, Wu R, Hu JC. Feasibility of a mobile health application to monitor recovery and patient-reported outcomes after robot-assisted radical prostatectomy. Eur Urol Oncol 2019;2:425–8.
[11] Cerantola Y, Valerio M, Persson B, et al. Guidelines for perioperative care after radical cystectomy for bladder cancer: enhanced recovery after surgery (ERAS) society recommendations. Clin Nutr 2013;32:87.
[12] Armstrong KA, Coyte PC, Brown M, Beber B, Semple JL. Effect of home monitoring via mobile app on the number of in-person visits following ambulatory surgery: a randomized clinical trial. JAMA Surg 2017;152:622–7.
[13] Graetz I, Anderson JN, McKillop CN, Stepanski EJ, Paladino AJ, Tillmanns TD. Use of a web-based app to improve postoperative outcomes for patients receiving gynecological oncology care: a randomized controlled feasibility trial. Gynecol Oncol 2018;150:311–7.
[14] Symer MM, Abelson JS, Milsom J, McClure B, Yeo HL. A mobile health application to track patients after gastrointestinal surgery: results from a pilot study. J Gastrointest Surg 2017;21:1500–5.
[15] Grenda TR, Whang S, Evans 3rd NR. Transitioning a surgery practice to telehealth during COVID-19. Ann Surg 2020;272:e168–9.