Feasibility of wearable activity trackers in cystectomy patients to monitor for postoperative complications

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Abstract

Background: To determine the feasibility of using wearables in patients undergoing radical cystectomy to monitor postoperative heart rate and activity and attempt to correlate these factors to complications and readmissions.

Materials and methods: We conducted a prospective study of 20 patients undergoing radical cystectomy for bladder cancer between June 2017 and March 2018. Each patient was provided with a Garmin Vívo HR activity tracker and instructed to wear it on their wrist for 30 days postoperatively. Heart rate, steps, and sleep data were collected during this time. Patients were called at 10-day intervals and surveyed for complications and device compliance. Univariable mixed effects logistic regression models were used to compare daily activity tracker measures with occurrence of an adverse event. Odds ratios, 95% confidence intervals, and p-values were reported.

Results: Median age was 65 (interquartile range 61–74) years. Patients had usable data for a median of 59.3% (interquartile range 25–71.7%) of the time. Five patients experienced a postoperative event (1 readmission for sepsis from urinary tract source, 1 inpatient rapid response called for tachycardic event, 3 unscheduled visits related to dehydration), where event data was recorded over a total of 17 days. Higher step count was associated with reduced odds of an adverse event (odds ratio 0.31, 95% confidence interval 0.10–0.98 per 1000 steps, p = 0.047).

Conclusions: Postoperative activity and heart rate monitoring in cystectomy patients is feasible though current wearables are not well suited for this task.

Keywords: Activity trackers; Cystectomy; Step count; Wearables

1. Introduction

Radical cystectomy is a highly morbid operation with readmissions approximately 25% within 1 month after surgery. Few advances in survival from bladder cancer have been made over the last 20 years, and there is room for improvement in postoperative care. Cystectomy patients often experience dehydration, poor nutrition, and susceptibility to other diseases requiring costly readmissions.

The recent emergence of wearable fitness trackers such as Garmin, Fitbit, and the Apple watch has opened an exciting door for health tracking and analysis. Preliminary research has shown these devices to be capable of detecting signs of illness up to 48 to 72 hours before patients reported symptoms. Even though an estimated 20% of US households own a fitness tracker, there is little to no published data on their implementation in health care and potential for postoperative follow-up. Due to their ability to track overall movement, number of steps taken and even heart rate, researchers can use these values for estimation of overall wellbeing and hydration status. Cystectomy patients requiring readmission have 42% higher hospital costs, and significantly contribute to Medicare spending more than $15 billion on postoperative readmissions each year. Each complication after cystectomy has been estimated to cost $15,000. By being able to predict cystectomy patients at high risk for readmission, we hope to intervene earlier in the disease course, allowing for improved morbidity and mortality as well as a significant reduction in costs.

We sought to determine the feasibility of using wearables in patients undergoing radical cystectomy to monitor postoperative heart rate and activity and attempt to correlate these factors to complications and readmissions.

2. Materials and methods

Twenty patients undergoing radical cystectomy for bladder cancer from June 2017 to March 2018 were recruited for this study. Patients were provided with a Garmin Vívo HR activity tracker and instructed to wear it on their wrist for 30 days postoperatively. The devices were placed from 1 to 5 days postoperatively while the patients were admitted following

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surgery and were instructed on device use and charging. To maximize simplicity of device management by patients, subjects were instructed not to connect the device to their smartphone.

Prior to initiation of the study, the devices were found to store 10 days' worth of data. Patients were provided with 3 devices and instructed to exchange the device every 10 days and mail the used unit to the study team. Patients were called at 10-day intervals to survey for postoperative complications and reminded to exchange and return the device by mail. HR, steps, and sleep were collected from the devices.

Patients with heart pacing devices, atrial fibrillation, or other cardiac rhythm disorders in addition to those who are immobile due to other medical conditions were excluded. Patients taking beta blockers were invited to participate and their medication usage was noted. Hours of compliance were determined and recorded by the availability of continuous heart rate information. A compliant day was defined as having at least 20 of 24 hours continuous heart rate availability.

Postoperative events were predefined to include hospital readmission, deep vein thrombosis, surgical site infection, pneumonia, transfusion requirement, mortality, intraabdominal urine leak, wound dehiscence, and unscheduled clinic visits. Other patients reported events were considered. To be considered for analysis, we required that data be available the day before and the day of the event.

2.1. Statistical methods

Continuous demographics variables (number of days compliant, percent of days compliant, age, and body mass index (BMI)) were summarized with median and interquartile range (IQR). Categorical variables (an indicator for whether the subject was compliant for 2 or more weeks, ethnicity, race, sex, and beta blocker use) were summarized by the number and percentage. Wilcoxon rank sum tests were used to test differences in the distributions between subjects with and without an event. Fisher’s exact test was used to test differences in distribution between subjects with and without an event. Our main analysis goal was to examine the association between the wearables data and our adverse events outcome. Wearables data included mean, minimum, and maximum heart rate, number of steps, and hours of sleep, which were analyzed for most days that met our definition of compliance (20/24 hours of heart rate data). We excluded the 7 days of postoperative data because patients would have limited mobility immediately postoperation and we excluded the 3 days following an event because it potentially reflected recovery information from the event. Due to limited data among subjects with adverse events, we chose to analyze the data at the subject level, averaging the wearables data for the included days. Comparisons of wearables data between subjects with and without adverse events were made using exact Wilcoxon rank sum tests. R 3.4.1 was used for all statistical analysis.\(^7\) Statistical significance was assessed at the 0.05 level using two-tailed tests.

3. Results

Twenty patients were included in this pilot study. Median age was 65 (IQR 61–74) years, 18 patients were male (90%), 2 were female (10%), and all were white (100%). Median BMI was 26.6 (IQR 23.5–29) kg/m\(^2\), 1 patient had concurrent beta blocker use (Table 1).

Patients had usable data for a median of 59.3% (IQR 25–71.7%) of the time, which corresponded to a median of 16 days (IQR 6.8–20.2 days) (Table 1). Eleven of 20 patients had at least 2 weeks' worth of data (Fig. 1). For any given postoperative day, the number of patients with available data varied from 1 to 13 (Fig. 2). Compliance dropped off by the end of the 1-month period (Fig. 2A), and step count increased over time (Fig. 2C).

Five patients had a postoperative event, 1 readmission, and 3 unscheduled visits related to dehydration. Of the patients with a postoperative event, the median age was 65 years, 4 out of the 5 were male, and the median BMI was 22.4 kg/m\(^2\). The only significant difference

| Variable\(^a\) | All subjects (n = 20) | Event (n = 5) | No event (n = 15) | \(p\) |
|---------------|---------------------|--------------|------------------|------|
| Median days compliant (IQR) | 16 (6.8–20.2) | 7 (5–17) | 17 (7.5–20.5) | 0.26 |
| 2+ wk compliant | 59.3 (25–71.7) | 25 (18.5–58.6) | 60.7 (26.8–73.2) | 0.11 |
| No | 9 (45%) | 3 (60%) | 6 (40%) | 0.62 |
| Yes | 11 (55%) | 2 (40%) | 9 (60%) | |
| Median age (IQR), yr | 65 (61–74) | 65 (65–75) | 65 (60.5–72) | 0.57 |
| Ethnicity | | | | |
| Not Hispanic/Latino | 19 (95%) | 5 (100%) | 14 (93%) | >0.99 |
| Hispanic or Latino | 1 (5%) | 0 (0%) | 1 (7%) | |
| Race | | | | |
| White | 20 (100%) | 5 (100%) | 15 (100%) | – |
| Sex | | | | |
| Female | 2 (10%) | 1 (20%) | 1 (7%) | 0.45 |
| Male | 18 (90%) | 4 (80%) | 14 (93%) | |
| Beta block | | | | |
| Yes | 1 (5%) | 0 (0%) | 1 (8%) | >0.99 |
| No | 16 (94%) | 4 (100%) | 12 (92%) | |
| Median BMI (IQR), kg/m\(^2\) | 26.6 (23.5–29.3) | 22.4 (22.1–26.3) | 27.8 (25.6–32.4) | 0.021 |

\(\text{BMI} = \text{body mass index; IQR} = \text{interquartile range.} \)

\(^a\) Missing values: beta block = 3.
between the event group and nonevent group was BMI ($p = 0.021$) (Table 1). Of these 5 patients, 3 had wearable data available around the time of the event.

The median number of daily steps was 2358 (IQR 1707–4289), the average heart rate was 78.2 (IQR 73.3–90), and the median hours of sleep was 8 (IQR 7.2–8.7). There were no statistically significant differences among any of the measures (average heart rate, minimum heart rate, maximum heart rate, daily step count, hours of sleep) between subjects who experienced an adverse event versus those who did not (Table 2).

4. Discussion

This paper represents the first study to use wearable activity trackers to monitor heart rate following cystectomy. We demonstrated that the use of wearables is feasible in this population. Early evidence suggests that postoperative steps may be negatively associated with postoperative complications, though this study was not powered to draw any further conclusions. However, the device used in this study was not optimal with approximately 60% of the 30-day postoperative period captured. Further, this was in the setting of simplified device management that did not require subjects to sync the device with a phone or electronically transfer data to the study site.

Two unpublished studies have investigated the use of wearables in cystectomy patients, each with a different focus. Preliminary results from the first 30 patients of a UK study assessing the role of wearables in cystectomy patients found 26 of 30 (86.7%) patients complied with using the device for 7 days postoperatively. The study also sought to correlate number of steps with the 30-second sit-to-stand test and EQ-5D-5L standardized health and mobility questionnaire. The median daily step count was 5498 over the first 7 days postoperatively and did not correlate with the sit-to-stand test or EQ-5D-5L.[8] It is unknown how compliance was defined in this study, but it does shed light on potentially obtainable compliance rates. Though this study is still ongoing, it demonstrates the uniqueness of data obtained from wearables and the challenge of reconciling their results with known standards.

A pilot study from University of Southern California used wearables in 21 patients to track steps, daily calories burned, and sleep characteristics before, during hospitalization, and after cystectomy. Patients were found to average 4806 daily steps preoperatively; this is notably higher than our study which only averaged 1517 daily steps up to 2 weeks postoperatively. Average sleep was found to be 5.3 hours per day preoperatively and 4.9 hours postoperatively, less than the 8 hours median in our study. They found that reduced daily step count was associated with delay in return of bowel function.[9] The use of sleep monitoring represented a novel postoperative variable though its clinical implications remain unknown.

It is worth noting in both ours and the University of Southern California study, increased step count was associated with better outcomes (return of bowel function, fewer postoperative events). A potential concern with standard wearables is the sensitivity for the type of steps that postoperative patients make, which may be shuffled or subtler than what standard wearables are tuned in to identify. No studies to date have validated the accuracy of these devices in the postoperative setting.

Current wearables require their user to maintain a Bluetooth connection to a smartphone. According to a recent pew study, only 46% of people over the age of 65 own a smartphone.[10] As this is a key age of the cystectomy population, we were concerned that this would significantly limit and potentially bias research involving wearables. We therefore designed our study to be independent of smartphones by using wearables that hold around 10 days’ worth of data.
of information and having the patients exchange their device every 10 days. It’s likely this 10-day cycle that resulted in the trimodal distribution of compliance seen in Figure 2.

The ideal device for future studies would require minimal user involvement, last 30 to 60 days on a single charge, accurately detect postoperative movements, and reliably transmit data back to the

Figure 2. (A) Percent compliance per postop day, (B) mean heart rate by postop day, and (C) mean steps by postop day.
care team. Though not performed in this study due to the emphasis on the feasibility of postoperative monitoring with activity trackers, having the patient wear the device preoperatively would provide baseline performance data, and allow for improved prognostic information and enhanced postoperative monitoring.

Limitations of this study include the feasibility nature of the design and small sample size, which prevent statistical significance of secondary outcomes. Compliance was also potentially limited by the specific wearable device chosen for the study and may not be translatable to other wearables. In our study, poor device compliance further limited the ability to analyze secondary outcomes and associations with complications. The nonrandomized nature of this feasibility trial may have led to a measurement bias, as patients may alter their normal activity behaviors due to being monitored. Further studies will importantly need to randomize patients to wearing versus not wearing activity trackers to account for the potential effect of this bias.

5. Conclusions

Patients undergoing radical cystectomy for bladder cancer stand to benefit from close postoperative monitoring. Current wearables are capable of recording postoperative steps and heart rate, though given the low compliance and limited usable data in our study, we believe they are not well suited for this task. Potentially low compliance will require special consideration when estimating study size to adequately power future trials. As this study was designed as a feasibility trial, it is underpowered to demonstrate significance with activity tracking and outcomes, therefore it remains to be determined if increased daily steps noted in ours and other studies are protective of postoperative complications or indicative of a healthier patient. Further work will need to be done to better understand the role wearables can play in postoperative monitoring.

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Statement of ethics

Subjects have given their written informed consent and the study protocol was approved by our committee on human research. IRB Approved Protocol 00094674. All procedures performed in this study involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Table 2
Summary stratified by event status.

| Variable                       | All subjects (n = 19) | Event (n = 4) | No event (n = 15) | p     |
|--------------------------------|----------------------|--------------|------------------|-------|
| Average heart rate, median (IQR) | 78.2 (73.3–90)       | 88 (83–92.4) | 76.3 (72.4–88.1) | 0.22  |
| Minimum heart rate, median (IQR) | 63.4 (56.9–74.7)     | 70.6 (65.7–76) | 60 (55.5–73.8)  | 0.22  |
| Maximum heart rate, median (IQR) | 122 (112.7–128.5)    | 115.4 (111.8–117.4) | 124 (112.7–131.3) | 0.25  |
| Daily step count, median (IQR) | 2,358 (1,707–4,289)  | 2,125 (1,856–3,168) | 2,358 (1,855–4,289) | 0.81  |
| Hours of sleep, median (IQR)   | 8 (7.2–8.7)          | 7.4 (6.2–8.3) | 8 (7.5–8.7)      | 0.47  |

IQR = interquartile range.

Conflict of interest statement

The authors have no conflict of interest to declare.

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Author contributions

None.

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