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Use of a wrist-mounted device for continuous outpatient physiologic monitoring after transsphenoidal surgery: a pilot study

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Abstract

Purpose Patients who undergo transsphenoidal surgery can experience hormonal, electrolyte, and fluid disturbances in the postoperative period leading to outpatient readmissions for medical management. Our goal was to determine whether use of a wrist-mounted physiologic tracking device is feasible in this setting and whether changes or trends in these parameters after discharge can help predict aberrant physiology in these patients.

Methods Wrist-mounted physiologic tracking devices that transmit data via Bluetooth to a mobile device were used to monitor patients. Preoperative baseline data and postoperative data were aggregated daily to compare within-patient and between-patient trends.

Results Of 11 patients enrolled in the study, 1 was readmitted for symptomatic hyponatremia. Device data completeness ranged from 78 to 93% with the exception of oxygen saturation (25% completeness). The patient with hyponatremia had a significantly lower baseline level of activity compared with other patients. Nonreadmitted patient activity variables (steps, calories, and distance) decreased by 48–52% after the operation ($P < 0.001$). The activity variables for the patient with hyponatremia were statistically unchanged after the operation; however, the patient did experience a significant decrease in heart rate compared with baseline.

Conclusion Deployment of a wrist-based physiologic tracking device is feasible for surgical patients in elective clinical practice. Overall, the device was associated with good patient adherence and high patient satisfaction. Patient activity significantly decreased after surgery. A significant decrease in heart rate was detected in a patient with hyponatremia who required readmission, which reflects the known intravascular volume expansion in this state.

Keywords Hyponatremia · Outpatient · Physiologic monitoring · Pituitary adenoma · Transsphenoidal surgery

Abbreviations

bpm	Beats per minute
brpm	Breaths per minute
hrv	Heart rate variation
SIADH	Syndrome of inappropriate antidiuretic hormone secretion
SpO_2	Oxygen saturation

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Introduction

Although widespread in the consumer market, noninvasive personal activity and physiologic tracking has not been well evaluated among postsurgical patients. The early postoperative period after discharge is a vulnerable time for patients. Studies in this area have examined patient activity and postsurgical outcomes. For example, in a study of more than 500,000 patients in the National Surgical Quality Improvement Program database, functional status was one of the strongest predictors of readmission to the hospital within 30 days [1]. The first study in the literature of postoperative activity monitoring was performed by the cardiothoracic surgery department at the Mayo Clinic (Rochester, MN) using the ankle-mounted Fitbit device (Fitbit, Inc, San Francisco, CA) [2]. Among elderly patients undergoing cardiac surgery, Cook et al. [2] found a significant relationship between the number of steps taken in the early recovery period, length of stay, and disposition. However, this study was limited to the initial inpatient period and did not track patients after discharge from the hospital.

Although a number of devices have been validated in comparative studies [3–7], there are currently no studies describing surgeon-initiated tracking of postoperative patient activity after discharge from the hospital. It is not known whether intervention on the basis of data from these devices can improve patient outcomes, nor whether other metrics beyond physical activity (e.g., blood pressure, heart rate, and oxygen saturation) can also be used effectively to predict outpatient complications leading to readmission.

Patients who undergo transsphenoidal procedures for pituitary lesions are at risk for disorders of electrolytes and fluid balance caused by manipulation of the pituitary gland. We and others have demonstrated that the most common reason for unplanned readmission to the hospital among these patients is hyponatremia caused by syndrome of inappropriate antidiuretic hormone secretion (SIADH) [8]. We hypothesize that physiologic tracking in the outpatient setting can reveal changes in physiologic parameters that reflect these complications leading to readmission. The goal of this study was to perform a pilot evaluation of the technical feasibility, adherence rates, and patient satisfaction associated with outpatient physiologic tracking while also exploring physiologic changes for further study.

Methods

Eligible patients and screening procedures

Eligible patients were at least 18 years of age undergoing elective transsphenoidal surgery for functioning and nonfunctioning pituitary adenomas with Knosp grade 0–3 tumors. Pregnancy, previous transsphenoidal surgery, and out-of-state residence were exclusions. Eligible patients were identified in the outpatient clinics by the study nurse and screened for eligibility between March and September of 2017. Written and oral informed consent was obtained during the preoperative office visit. The study was approved by the St. Joseph's Hospital and Medical Center Institutional Review Board. The study is reported according to STROBE guidelines [9].

Data acquisition and analysis

The wristband device was obtained from Wavelet Health (wavelethealth.com) and synced to the patients' smartphones via a Bluetooth connection. Tracked physiologic parameters included steps, calories, distance, heart rate, heart rate variation, respiration rate, and oxygen saturation. After instruction on the use of the device, patients wore the device to obtain baseline physiologic data before surgery. Data were uploaded to secure servers for aggregation. Default settings on the devices included collection of all variables every 20 min. All variables were summarized per 24-h period for further analysis. Patients with missing preoperative or postoperative data or reported malfunction of the device or smartphone application were excluded from further analysis.

Patient device satisfaction was evaluated using an experience survey of questions scored on a five-point Likert scale that included overall device satisfaction (1 = unsatisfied, 2 = somewhat unsatisfied, 3 = neither satisfied nor unsatisfied, 4 = somewhat satisfied, 5 = satisfied) and how bothersome the device was (1 = not at all bothersome, 5 = very bothersome). We also asked questions requesting the patient's estimate of days per week and hours per day worn. The survey was administered at the first postoperative outpatient clinic visit conducted within 2 weeks of surgery, and it also included open-ended opportunity for feedback.

We determined that five patients were needed to detect a two-sided difference of 20% in a preoperative compared with postoperative variable value with a type I error rate of 5% and standard deviation one-tenth of the mean at a power of 0.8. We performed the preliminary analysis when the number of patients surpassed this threshold, and one patient in the cohort was readmitted for hyponatremia. Univariate nonparametric statistical tests were two-tailed and adjusted for multiple comparisons using the Holm–Bonferroni method. A P value < 0.05 was considered to be significant. For hierarchical cluster analysis, each postoperative physiologic variable for each patient was analyzed with a linear regression model. The slope from this model was used to describe the variable trend over time in the postoperative time period for each variable. This resulted in a patient–variable trend matrix that was analyzed with hierarchical clustering using Ward's minimum variance method and the Lance–Williams dissimilarity update formula. Oxygen saturation was excluded from the cluster analysis because this variable was not captured for the hyponatremic patient. All data analysis was performed with R, version 3.4.2 (R Foundation).

Results

Patient adherence and data quality

Eleven patients were enrolled in this pilot study. Four patients were excluded because of failure of data transfer from the devices to the cloud-based storage platform, leaving seven patients in the final analysis. Demographic and clinical characteristics of the patients are presented in Table 1. Preoperative baseline data were tracked for a mean (SD) of 4.4 (3.7) days, and there was good adherence, ranging from 89 to 100% (Table 2). Overall completeness of

Table 1 Demographic and clinical characteristics of patients enrolled in a study of a wrist-mounted device for continuous physiologic monitoring of outpatients who have undergone transsphenoidal surgery

Patient	Age (years)	Sex	Clinical syndrome	Presentation	Length of stay (days)
1[a]	30	F	Cushing disease	Amenorrhea, weight gain, hirsutism	2
2	37	F	Cushing disease	Headache, galactorrhea, fatigue, weight gain, facial hirsutism	2
3	37	M	Rathke cleft cyst	Headache, fatigue	2
4	43	F	Acromegaly	Headache	2
5	59	M	Nonfunctioning pituitary adenoma	Fatigue, hypogonadism	2
6	41	M	Nonfunctioning pituitary adenoma	Incidental	1
7	26	F	Cushing disease	Headache, weight gain, irregular menses	2

[a]This patient was readmitted to the hospital with hyponatremia

Table 2 Preoperative and postoperative daily use of a wrist-mounted device for continuous physiologic monitoring of outpatients who have undergone transsphenoidal surgery

Patient	Preoperative adherence (%)	Preoperative days tracked	Postoperative adherence (%)	Postoperative days tracked
1[a]	88.89	9	100.00	6
2	100.00	1	84.61	13
3	100.00	2	100.00	5
4	90.00	10	100.00	6
5	100.00	2	81.81	11
6	100.00	2	91.67	6
7	100.00	5	84.50	8
Overall, mean (SD)	97 (5)	4.4 (3.7)	90 (10)	7.9 (3)

[a]This patient was readmitted to the hospital with hyponatremia

preoperative and postoperative variables ranged from a mean (SD) of 93% (16%) for heart beats per minute to 25% (34%) for oxygen saturation (Table 3). In aggregate, data volume was highest on preoperative days 2–1 and postoperative days 4–6 (Fig. 1). Patient-reported data indicated that the device was worn for a mean (SD) of 6.1 (1.6) days per week and 20.6 (5.0) hours per day.

Patient satisfaction

Patient-reported satisfaction on a five-point Likert scale was a mean (SD) of 3.6 (1.9). Mean (SD) patient-reported levels of how much the device bothered the patient were 2.1 (1.9). Complaints from patients included difficulty securing the wrist strap, difficulty charging the device, and difficulty pairing the device with the smartphone. During the study exit interview, patients reported that they were largely enthusiastic to embrace the technology and contribute to the research.

Trends in physiologic findings before and after surgery

There were clear general trends in activity noted after surgery compared with before surgery. Among the daily average measures of activity, calories burned, distance traveled, and

Table 3 Completeness of physiologic data among patients enrolled in a study of a wrist-mounted device for continuous physiologic monitoring of outpatients who have undergone transsphenoidal surgery

Patient	Variable (%)						
	Calories	Steps	Distance	bpm	SpO_2	brpm	hrv
1[a]	86	86	86	*57*	*7*	*71*	*50*
2	100	100	100	100	*8*	85	*15*
3	83	83	83	100	*17*	100	100
4	93	93	93	100	*7*	100	100
5	83	83	83	92	*8*	83	83
6	100	100	100	100	*25*	100	100
7	100	100	100	100	100	100	100
Overall, mean (SD)	92 (8)	92 (8)	92 (8)	93 (16)	*25 (34)*	91 (12)	78 (33)

Values < 80% are presented in italic typeface

bpm beats per minute, *brpm*, breaths per minute, *hrv* heart rate variation, SpO_2 oxygen saturation

[a]This patient was readmitted to the hospital with hyponatremia

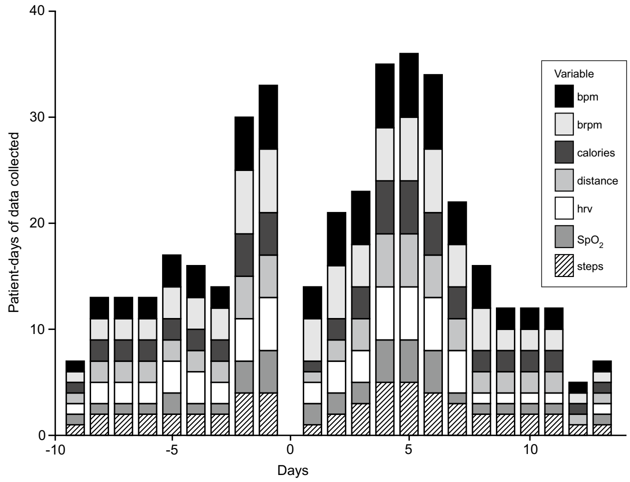

Fig. 1 Histogram of daily data collected, by variable. The *x*-axis indicates days relative to the day of the operation (0), with numbers <0 indicating preoperative days and numbers >0 indicating postoperative days. *bpm* beats per minute, *brpm* breaths per minute, *hrv* heart rate variation, SpO_2 oxygen saturation. Reproduced with permission from Barrow Neurological Institute, Phoenix, Arizona

steps taken decreased by 45% ($P<0.001$), 44% ($P=0.005$), and 45% ($P=0.001$), respectively, compared with before surgery. Daily mean oxygen saturation also significantly decreased, from 93.7% before the operation to 91.8% after the operation ($P=0.04$). Other measures of cardiorespiratory function, including mean daily heart rate ($P=0.59$), heart rate variation ($P=0.92$), and breaths per minute ($P=0.28$) were statistically unchanged. These findings are nearly identical to those in the results seen for patients who were not readmitted.

Physiologic findings in a patient with severe delayed hyponatremia

One patient with Cushing disease who had undergone subtotal hypophysectomy was readmitted on postoperative day 8 due to severe hyponatremia (sodium level, 119 mmol/L) secondary to SIADH. This provided us the opportunity to compare the recorded physiologic parameters of this patient with those of the six patients with normonatremia (Table 4). The preoperative and postoperative periods were analyzed separately. In both the preoperative and postoperative periods, compared with normonatremic patients, the hyponatremic patient had a statistically lower activity level as determined by daily mean (SD) distance traveled (1696 [960] vs. 482 [301] m before surgery, $P=0.004$) and steps taken (4401 [2266] vs. 2412 [1505] steps before surgery, $P=0.05$). Before undergoing the operation, compared with normonatremic patients, the hyponatremic patient also had a higher mean (SD) daily heart rate (74 [13] vs. 87 [7] bpm, $P=0.04$). During the postoperative period, compared with the patients with normonatremia, the hyponatremic

Table 4 Comparison of physiologic parameters of six patients with normonatremia versus one patient with hyponatremia before and after transsphenoidal surgery

Variable	Normonatremia, mean (SD) ($n=6$)	Hyponatremia, mean (SD) ($n=1$)	*P*	Difference in mean values[a] (%)
Before surgery				
Calories	138.39 (70.30)	91.61 (55.29)	0.14	−34
Distance	1695.66 (959.87)	482.44 (301.14)	**0.004**	−72
Steps	4400.50 (2265.86)	2411.86 (1505.32)	**0.047**	−45
bpm	74.26 (13.31)	86.60 (7.23)	**0.04**	17
brpm	16.74 (2.58)	14.71 (4.03)	0.12	−12
hrv	62.94 (29.04)	44.99 (18.57)	0.20	−29
SpO_2	93.67 (2.58)	NA	NA	NA
After surgery				
Calories	72.53 (44.78)	38.09 (16.76)	0.10	−47
Distance	819.28 (582.71)	194.24 (88.68)	**0.02**	−76
Steps	2280.61 (1439.46)	970.60 (442.32)	0.05	−57
bpm	79.46 (18.94)	64.33 (17.01)	0.18	−19
brpm	17.32 (3.81)	14.33 (3.06)	0.19	−17
hrv	60.21 (21.99)	35.46 (4.36)	0.13	−41
SpO_2	91.78 (2.91)	91.00 (NA)	NA	−1

Boldface type indicates statistical significance

bpm beats per minute, *brpm* breaths per minute, *hrv* heart rate variation, *NA* not available, SpO_2 oxygen saturation

[a]Percentage difference between the mean value for patients with normonatremia, who were not readmitted to the hospital, and the mean value for the patient with hyponatremia, who was readmitted

patient maintained a significantly lower level of mean daily activity (819 [583] vs. 194 [89] m, $P = 0.02$; 2281 [1439] vs. 971 [442] steps, $P = 0.05$); however, there was no statistically significant difference in heart rate, breaths per minute, or heart rate variation. Data collected on oxygen saturation were incomplete for the hyponatremic patient, and thus an analysis of this variable was not performed.

We then examined within-group changes in tracked variables before and after surgery (Table 5). Among patients who were not readmitted, measures of activity were significantly lower in the postoperative period, including calories burned during activity (48% decrease, $P < 0.001$), distance traveled (52% decrease, $P < 0.001$), and steps taken (48% decrease, $P < 0.001$). There were no significantly different changes in heart rate, breaths per minute, or heart rate variation. In contrast, for the hyponatremic patient, the only variable that significantly differed before and after surgery was heart rate, which decreased 26% relative to the patient's own preoperative baseline ($P = 0.04$) (Fig. 2). On the basis of data recording timestamps, this decrease in heart rate was determined to be statistically significant 1 day prior to readmission. This patient was not receiving β-blocker medication. The hyponatremic patient achieved biochemical remission of hypercortisolism, as did two other patients in our cohort who had Cushing disease. However, the nonhyponatremic patients did not experience a change in outpatient heart rate. This supports the heart

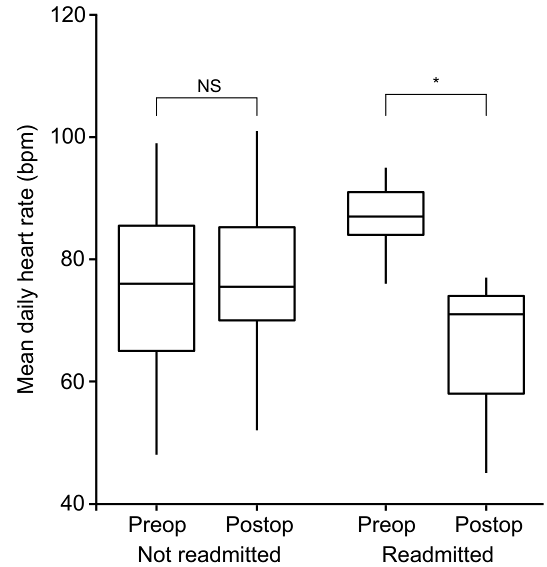

Fig. 2 Box plot of preoperative (Preop) and postoperative (Postop) mean daily heart rate in beats per minute (bpm) for patients who were not readmitted ($n = 6$) compared with one readmitted patient with hyponatremia due to syndrome of inappropriate antidiuretic hormone secretion. The middle horizontal line indicates the mean, the box indicates the interquartile range, and the whiskers indicate the maximum and minimum values. Asterisk indicates statistically significant difference ($P < 0.05$). *NS* not significant. Reproduced with permission from Barrow Neurological Institute, Phoenix, Arizona

Table 5 Comparison of physiologic parameters before versus after transsphenoidal surgery for six patients with normonatremia and one patient with hyponatremia analyzed separately

Variable	Before surgery, mean (SD)	After surgery, mean (SD)	P	Difference in mean values[a] (%)
Not readmitted ($n = 6$)				
Calories	138.39 (70.30)	72.53 (44.78)	**<0.001**	−47.59
Distance	1695.66 (959.87)	819.28 (582.71)	**<0.001**	−51.68
Steps	4400.50 (2265.86)	2280.61 (1439.46)	**<0.001**	−48.17
bpm	74.26 (13.31)	79.46 (18.94)	0.24	7.00
brpm	16.74 (2.58)	17.32 (3.81)	0.51	3.46
hrv	62.94 (29.04)	60.21 (21.99)	0.69	−4.34
SpO_2	93.67 (2.58)	91.78 (2.91)	**0.049**	−2.02
Readmitted for hyponatremia ($n = 1$)				
Calories	91.61 (55.29)	38.09 (16.76)	0.07	−58.42
Distance	482.44 (301.14)	194.24 (88.68)	0.07	−59.74
Steps	2411.86 (1505.32)	970.60 (442.32)	0.07	−59.76
bpm	86.60 (7.23)	64.33 (17.01)	**0.04**	−25.72
brpm	14.71 (4.03)	14.33 (3.06)	0.89	−2.58
hrv	44.99 (18.57)	35.46 (4.36)	0.53	−21.18
SpO_2	NA	NA	NA	NA

Boldface type indicates statistical significance

bpm beats per minute, *brpm* breaths per minute, *hrv* heart rate variation, *NA* not available, *SpO_2* oxygen saturation

[a]Percentage difference between the mean value before surgery and the mean value after surgery

rate change being associated with sodium abnormalities as opposed to decreased systemic cortisol.

Cluster analysis of postoperative physiologic trends

We next examined how the overall trends in all of the tracked physiologic parameters of the patients after surgery might be used to distinguish the patient with hyponatremia. Postoperative data for each variable for each patient were analyzed with linear regression to establish a stable, increasing, or decreasing trend of that variable over time. This matrix of patient–variable trends was then evaluated with a clustering model, which demonstrated that the pattern of physiologic variable changes for the readmitted patient was separately clustered (Fig. 3). As seen in the heat map representation of this clustering model, all of the tracked variables for the readmitted patient demonstrated a downward trend over time. This is in contrast to the remainder of the patients, who had an overall increasing trend in at least three of the six tracked variables included in the cluster analysis.

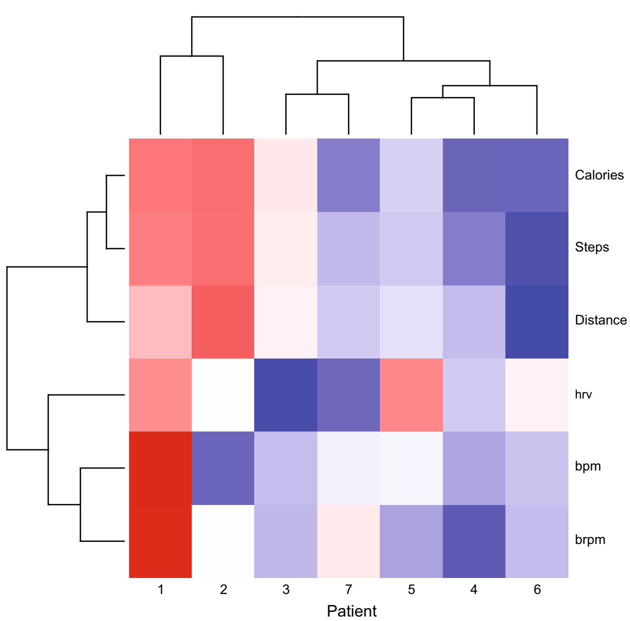

Fig. 3 Heat map of unsupervised, hierarchically clustered physiologic trends during the postoperative recovery period. Brackets indicate hierarchical clustering. Columns represent distinct patients, with each box representative of the trend of the physiologic variable by linear regression slope. Patient numbers correspond to those in the tables. Patient 1 was readmitted to the hospital with hyponatremia. Red and blue indicate decreasing and increasing trend, respectively, for the specified variable. *bpm* beats per minute, *brpm* breaths per minute, *hrv* heart rate variation. Reproduced with permission from Barrow Neurological Institute, Phoenix, Arizona

Discussion

In this study, patients with planned transsphenoidal surgery wore a wrist-mounted biometric tracking device that recorded numerous physiologic parameters before and after surgery, including measures of activity and cardiorespiratory function. Because these patients can experience endocrine and other physiologic changes after surgery that can result in morbidity and readmission to the hospital, they are an excellent population of patients in which to scrutinize this technology for potential applications in improving preoperative evaluation and postoperative care.

The goals of the study were to determine whether this technology could be deployed effectively, determine the barriers (both technological and patient-related) to use of consumer-grade tracking devices in a medical setting, assess patient satisfaction, and conduct preliminary analyses of the recorded physiologic parameters. Overall, there was good patient satisfaction and adherence. Patients were enthusiastic to embrace this technology. Overall, we found that this technology is feasible for deployment in routine surgical practice.

We also explored the changes in physiologic parameters that occur in these patients after surgery. One notable result of the study is that one patient developed severe hyponatremia after surgery. This allowed us to study the physiology of this patient relative to that of patients who had uncomplicated postoperative courses and therefore learn more about how these devices might be applied in patient care.

We observe that the readmitted patient had lower levels of physical activity before and after surgery, which fits with general clinical intuition and evidence that patients with poorer levels of conditioning are at higher risk of complications and readmission [1]. This patient was also obese secondary to Cushing disease, and both conditions put her at risk for postoperative complications. The within-patient analysis indicated that the readmitted patient experienced a significant decrease in heart rate after surgery. All other patients had heart rates that were statistically unchanged after surgery compared with baseline. Given that the cause for readmission of the patient was hyponatremia secondary to SIADH, the water retention associated with this condition would be expected to expand intravascular volume with a compensatory decrease in heart rate to maintain homeostasis in blood pressure. This demonstrates the potential of physiologic tracking to reveal the complications that occur in these patients in the outpatient setting.

We also aimed to determine whether time-dependent changes in these variables taken in aggregate, which could perhaps be thought of as a postoperative physiologic trend "fingerprint" or "physiome" of each patient, differed in the readmitted patient. We found that this patient's data naturally clustered separately from data for the patients who were not readmitted, which suggests that, with more data, we may be able to define overall high-risk postoperative physiologic trends clusters that can be used to direct postoperative care resources to prevent readmission.

Strengths of this study include use of preoperative data for postoperative comparison, good patient adherence in wearing the device, and a device platform capable of secure and centralized data aggregation. However, significant barriers to using this modality to study patients exist. The recruitment of a larger number of patients is necessary to establish population-wide baselines if, for example, preoperative risk is to be used to set goal activity levels for patients to achieve before surgery. In addition, as we found during this study, each device may have unique technical issues. In discussion with the device manufacturer, we verified that oxygen saturation tracking is susceptible to artifact with motion and not fully clinically validated.

Future directions include the study of a larger cohort to determine the differences in patients with complications, including both patients who require hospital readmission and those who require more intensive outpatient management and might benefit from targeted supportive interventions. In combination with patient characteristics that most surgeons routinely assess regarding risk (e.g., age, comorbid conditions, and vital signs), a preoperative "physiologic assessment" using remote trackers has great potential to supplement decision-making regarding surgical risk.

Conclusions

We found that deployment of a wrist-based physiologic tracking device is feasible for surgical patients in elective clinical practice. Overall, patient activity decreased significantly after the operation as determined by calories burned, steps taken, and distance traveled. We also found a significant decrease in oxygen saturation after surgery. In our pilot cohort, one patient was readmitted with severe hyponatremia secondary to SIADH. This patient had significantly lower levels of activity relative to other patients and experienced a significant decrease in heart rate after surgery, reflecting the known intravascular volume expansion associated with this condition. The use of wrist-based physiologic tracking devices represents a potentially valuable modality to monitor outpatient health status and improve care delivery in surgical practice.

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Compliance with ethical standards

Conflict of interest Dr. Little is an investor in Kogent and has received stock options in Spiway. Dr. Nakaji has stock ownership in GT Medical Technologies and stock options in SpiWay. The other authors declare that they have no conflict of interest.

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