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Effects of an activity tracker with feedback on physical activity in women after midline laparotomy: A randomized controlled trial

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Abstract

Purpose: To investigate whether the use of an activity tracker with feedback increases physical activity and is safe in patients who underwent a midline laparotomy for gynecologic disorders.

Methods: Patients who were planned to undergo a midline laparotomy for gynecologic diseases wore an activity tracker at baseline and from postoperative days 1–6. Patients in the experimental arm could monitor their step counts and were encouraged to achieve the individualized step-count goal daily. In contrast, patients in the control arm did not monitor their step-counts and received the usual encouragement for ambulation. The primary endpoint was the percentage of the average step-count at postoperative days 4–5 divided by the baseline activity count.

Results: Seventy-three patients were randomized; 63 patients underwent a surgery and wore an activity tracker; 53 patients were evaluable for primary endpoint. The activity recovery rate was significantly higher in the experimental arm compared to the control arm (71% vs 41%, $p < 0.01$). However, the study arm was not significantly associated with the activity recovery rate in multivariate analysis. The brief pain inventory score, brief fatigue inventory score, day of first flatus, day of soft blend diet initiation, ileus incidence, and length of postoperative hospital stay were similar between arms. The incidence of wound dehiscence and other adverse events were similar between arms. There were no grade 3 of 4 adverse events.

Conclusion: The use of an activity tracker with feedback is safe and may increase physical activity in patients who have undergone major gynecologic surgery.

Key words: exercise, fitness trackers, gynecologic surgical procedures, laparotomy, recovery of function.

Introduction

Physical activity reflects functional status and is associated with health outcomes in many conditions. For example, lower levels of physical activity have been associated with a longer hospital stay in elderly inpatients.[1] Health outcomes can be improved by increasing physical activity. For example, physical exercise has been shown to reduce the readmission rate in patients with coronary heart disease,[2] and physical exercise improves obesity and quality of life in breast cancer survivors.[3]

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Low physical activity levels in the perioperative period are associated with increased complication rates and prolonged hospital stay. For example, a low physical activity level in the postoperative period was reported to be associated with pulmonary embolism and deep vein thrombosis in patients who underwent heart surgery.[4,5] The time to ambulation after hip fracture surgery was related to delirium, pneumonia, and prolonged hospital stay,[6] and a low postoperative physical activity level was associated with prolonged hospital stay in patients who underwent coronary artery surgery.[7]

To improve surgical outcomes, several studies have examined the effect of exercise therapy in diverse settings. For example, inpatient exercise therapy reduced hospital stay in colon cancer patients.[8] Pre- and early post-rehabilitation, including intensive mobilization, reduced the length of hospital stay in patients who underwent spinal surgery.[9] However, exercise therapy requires resources. For example, in one trial, the exercise therapy comprised a 15-min exercise session under therapist supervision twice a day,[8] while in another trial, an intensified exercise program, protein supplements, and balanced pain therapy were used.[9] Therefore, the adoption of exercise therapies in routine practice is challenging.

Simpler methods such as the use of an activity tracker were reported to increase physical activity and decrease body mass index and blood pressure mainly in outpatient settings.[10] The use of an activity tracker with feedback also accelerated recovery in women who underwent day-case laparoscopic cholecystectomy,[11] and self-monitoring of physical activity using an activity tracker increased physical activity in hospitalized cardiac patients.[12] However, there are few studies examining the effect of activity tracker use in inpatients who have undergone major surgery, and therefore, it is unclear whether they are safe and effective in these patients. For example, unsupervised ambulation in surgical inpatients could result in falls.

We investigated whether activity tracker use, with feedback, increased physical activity and was safe in patients who underwent a midline laparotomy for gynecologic diseases.

Materials and Methods

This was a single-center, randomized, open-label trial comparing the effect of using an activity tracker with feedback with usual care, on physical activity in patients who underwent a midline laparotomy for gynecologic diseases. After the institutional review board approved the protocol (Seoul National University Bundang Hospital IRB, No. E-1311/225-002) and registered at www.clinicaltrials.gov (NCT02344095), patients were enrolled in a tertiary hospital in Republic of Korea from January 2014 to August 2015. All subjects gave informed consent. The inclusion criterion was a planned midline laparotomy for gynecologic disease. The major exclusion criteria were conditions in which physical activity should be restricted, the patient being unable to ambulate independently, anticipated intensive care unit admission, and anticipated discharge before postoperative day 5.

Before the patients were admitted for surgery, they were requested to wear an activity tracker (Lifegram, LA11M-BS, LG) on the wrist for 2 days to determine the baseline activity that was calculated by averaging the step-counts for two complete days. When only one complete day count was measured, we used this as the baseline activity. After the baseline activity was measured, patients were randomized into the experimental and control arms in a 1:1 ratio using block randomization. Stratification factors were age (<=60 vs >60) and indication for surgery (confirmed or suspicious cancer vs not cancer). Randomization and notification of result were performed by the statistics center of our institute.

Patients in both trial arms wore an activity tracker from the morning of postoperative day 1 to the morning of postoperative day 6. Patients in the experimental arm self-monitored their step-counts via the activity tracker and were encouraged to achieve the individualized step-count goal daily. The goal on postoperative day 1 was 5% of baseline activity. For example, a patient with a baseline activity of 10 000 was encouraged to walk 500 steps or more on postoperative day 1. If the patient achieved this, the goal became the next level. The goals were set at 5%, 15%, 30%, 50%, 80%, 120%, 170%, and 230% of baseline activity and patients were encouraged to achieve these daily. Patients were allowed to surpass several levels in a day. In contrast, patients in the control arm wore an activity tracker but could not monitor their step counts because the screen of the activity tracker was blinded. They received the usual encouragement for ambulation but no goals were set.

The primary endpoint was the activity recovery rate at postoperative days 4–5, which is the percentage of the average step count on postoperative days 4 and 5 divided by the baseline activity. For example, when baseline activity is 10 000 and step counts at

postoperative days 4 and 5 are 3000 and 5000, the activity recovery rate is 40%. In some cases, only one complete day of step counts was measured on postoperative days 4–5 because the patient was discharged at postoperative day 5. In these cases, we used the one complete day step count as the average step count of postoperative days 4 and 5. The secondary endpoints were pain, measured with the brief pain inventory (BPI) at postoperative days 2 and 5; fatigue, measured with the brief fatigue inventory (BFI) on postoperative day 5; day of passing first flatus; day of initiation of a soft blend diet; ileus incidence, and postoperative hospital stay. Safety endpoints were the incidence and grade of wound dehiscence and other adverse events. The grade was determined according to the Common Terminology Criteria for Adverse Events (CTCAE), version 4.0.

Based on previous studies,[10,13] the activity recovery rates in the experimental and control arms were estimated as 36% and 30%, respectively. The standard deviation of activity recovery rate was assumed as 8%. With alpha error 0.05, power 80%, drop-out rate 10%, and two-sided test, the sample size was determined as 64.

For analysis, two cohorts were defined. The safety cohort was defined as patients who underwent midline laparotomy and wore an activity tracker for any duration. Baseline characteristics, surgery characteristics, and safety endpoints were measured in the safety cohort. The efficacy cohort was defined as patients who wore an activity tracker until postoperative day 5 and whose activity recovery rates were calculated. Efficacy endpoints were evaluated in the efficacy cohort.

To compare variables between arms, the student's *t*-test, the Wilcoxon rank-sum test and Fisher's exact test were used according to the type of variables and normality. All analyses were performed using R (version 3.6.1 [5 July, 2019]). This study is being reported in line with Consolidated Standards of Reporting Trials (CONSORT) Guidelines.

Results

Seventy-three patients were randomized but 63 patients received surgery and wore an activity tracker (safety cohort). Ten patients were dropped due to early discharge, therefore, the remaining 53 patients made up the efficacy cohort (Figure 1). All baseline and surgery characteristics were balanced between the experimental and control arms except the American Society of Anesthesiologists (ASA) score which was lower in the experimental arm (Table 1).

The baseline activity levels were similar between the experimental and control arms. However, activity levels at postoperative days 4–5 tended to be higher in the experimental arm. Therefore, the activity recovery rate was significantly higher in the experimental than in the control arm (71% vs 41%, p-value <0.01) (Table 2). However, in the unplanned multivariate logistic regression analysis including the ASA score and study arm, the activity recovery rate was associated with the ASA score (1 [ref] vs 2 or 3, coefficient $= -40$, $p = 0.04$) but not with the study arm (control arm [ref] vs experimental arm, coefficient $= -2$, $p = 0.90$).

The BPI score on postoperative days 2 and 5, the BFI score at postoperative day 5, the day of first flatus, day of soft blend diet initiation, ileus incidence, and postoperative hospital stay were similar between the study arms (Table 2).

The incidence of wound dehiscence and other adverse events were similar between the arms. There were no adverse events of grade 3 or higher (Table 3). In addition, venous thromboembolism did not occur.

Discussion

The use of an activity tracker with feedback is safe and may increase physical activity in patients who have undergone major surgery for gynecological conditions. The difference in activity recovery rate between the experimental and control arms was substantial, but the ASA score was not balanced between both arms. In addition, the multivariate analysis including study arm and ASA score showed that the activity recovery rate was associated with the ASA score but not with the study arm. Therefore, our findings should be interpreted with caution. In future studies investigating the physical activity in surgery patients, the effect of the ASA score should be controlled.

Activity tracker use with feedback increased physical activity in outpatient settings.[10] However, the effect varied according to specific situations. For example, in patients who underwent bariatric surgery, the use of an activity tracker with exercise counseling increased physical activity. However, using an activity tracker without exercise counseling did not increase physical activity.[14] In another study,

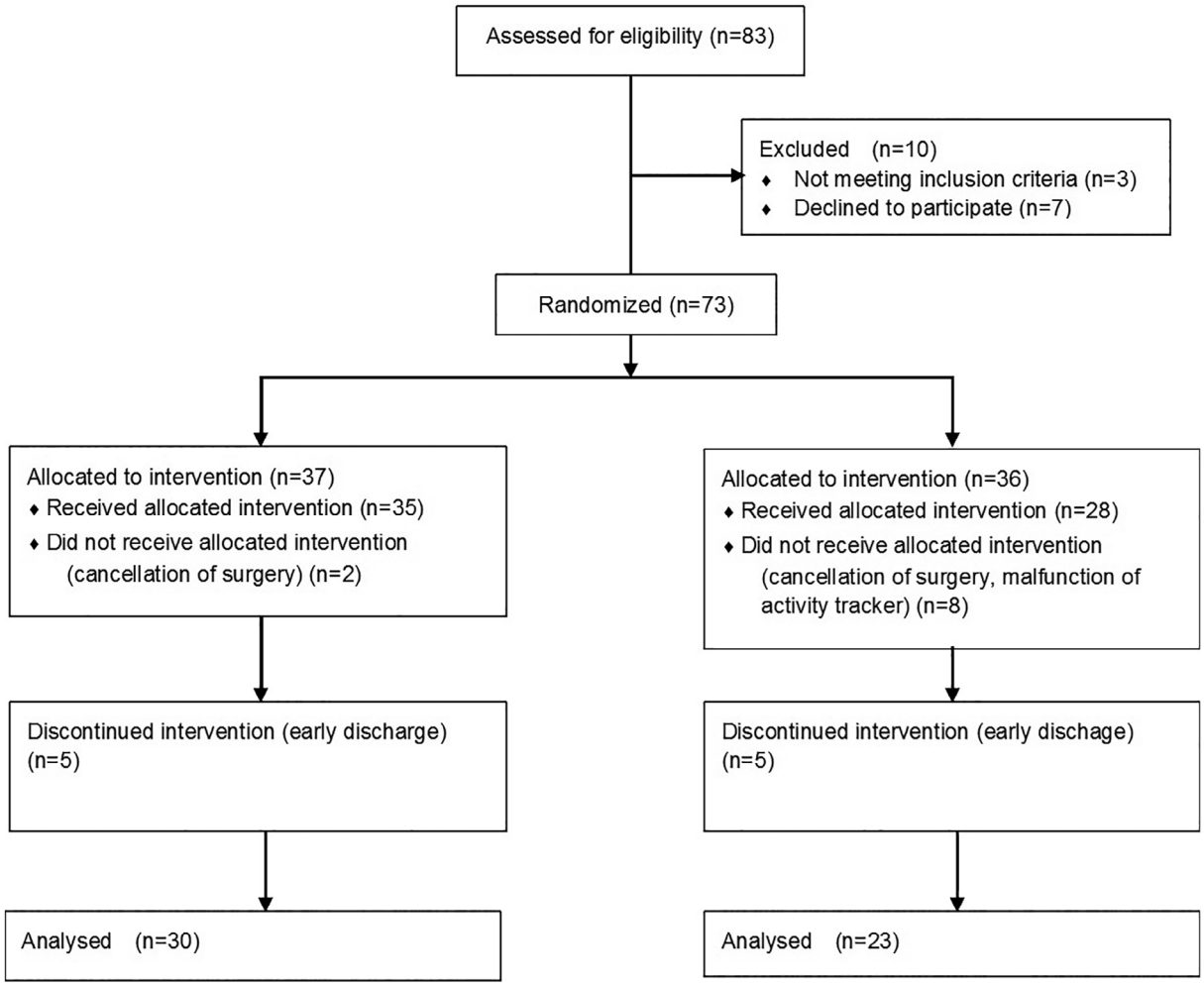

Figure 1 Patient numbers at each stage of the study

Table 1 Baseline and surgery characteristics

	Experimental arm $n = 35$	Control arm $n = 28$	p-value
Age, mean ± SD (years)	52.5 ± 10.4	55.2 ± 11.9	0.34
Height, mean ± SD (cm)	156.7 ± 5.7	156.0 ± 7.0	0.66
Weight, mean ± SD (kg)	56.6 ± 8.7	60.5 ± 10.3	0.10
ASA score, *n* (%)			0.02
1	19 (54)	7 (25)	
2	16 (46)	19 (68)	
3	0 (0)	2 (7)	
Indication for surgery, *n* (%)			0.74
Confirmed or suspicious cancer	30 (86)	23 (82)	
Not cancer	5 (14)	5 (18)	
Surgery time (min), median (range)	165 (55–675)	153 (25–615)	0.36
Incision length, mean ± SD (cm)[a]	19.3 ± 5.7	19.1 ± 5.3	0.92

Abbreviation: ASA, American Society of Anesthesiologists. and [a]Based on 43 patients due to missing data.

Table 2 Efficacy endpoints

	Experimental arm $n = 30$	Control arm $n = 23$	p-value
Activity (step count)			
Baseline, median (range)	6481 (1201–18 338)	6209 (630–18 548)	0.68
Postoperative days 4–5, median (range)	3806 (380–12 938)	2002 (89–7758)	0.09
Recovery rate, median (range), %	71 (4–300)	41 (1–278)	<0.01
BPI at postoperative day 2			
Worst in the last 24 h, median (range)	8 (5–10)	7 (4–10)	0.21
Least in the last 24 h, median (range)	3 (0–10)	2 (1–5)	0.24
Average, median (range)	5 (3–10)	5 (2–8)	0.08
Right now, mean ± SD	5.1 ± 2.4	5.1 ± 2.0	0.94
BPI at postoperative day 5			
Worst in the last 24 h, median (range)	7 (2–9)	5 (2–10)	0.33
Least in the last 24 h, median (range)	3 (0–6)	2 (0–4)	0.13
Average, mean ± SD	4.8 ± 1.9	3.8 ± 1.7	0.07
Right now, mean ± SD	4.0 ± 1.8	3.0 ± 1.8	0.07
BFI at postoperative day 5			
Right now, median (range)	5 (0–9)	5 (0–9)	0.31
Usual during past 24 h, median (range)	5 (0–8)	5 (0–8)	0.11
Worst during past 24 h, median (range)	7 (3–10)	7 (1–10)	0.62
Flatus, postoperative day, median (range)	4 (1 – >5)	3 (2 – >5)	0.75
Soft blend diet initiation, postoperative day, median (range)	3 (1 – >5)	3 (1 – >5)	0.76
Ileus, n (%)	2 (7)	2 (9)	1.00
Length of stay, (days), median (range)[a]	7 (4–58)	6 (4–26)	0.12

Abbreviations: BFI, Brief Fatigue Inventory; BPI, Brief Pain Inventory. and [a]Based on 60 patients including those who were discharged early.

Table 3 Safety endpoints

	Experimental arm $n = 35$	Control arm $n = 28$	p-value
Wound dehiscence, n (%)[a]	5 (14)	2 (7)	0.46
Patients with adverse events except wound pain, fatigue, ileus and wound dehiscence, n (%)	3 (9)	4 (14)	0.70
Fever, Gr 1	1	1	
Localized edema, Gr 1	1	0	
Seroma, Gr 1	1	1	
Seroma, Gr 2	0	2	
Urinary retention, Gr 1	0	1	
Urticaria, Gr 2	0	1	

[a]Based on 62 patients due to missing data of a patient in the control arm.

activity tracker use with a smartphone application did not increase physical activity in breast cancer survivors.[15] Studies of the effect of using an activity tracker with feedback on physical activity in an inpatient setting are rare and studies on surgical inpatients are extremely rare. In one randomized trial, the use of an activity tracker with ambulation goal-setting did not increase the physical activity in gynecologic surgical patients. However, the hospital stay was less than 2 days, and 12% of the patients were discharged without any physical activity.[16] In patients who underwent major abdominal visceral surgery, the use of an activity tracker increased the physical activity in the laparoscopic surgery group but not in open surgery group.[17] To our knowledge, the present study is the first to suggest that an activity tracker with feedback is safe to use and may increase physical activity in inpatients who underwent gynecologic open surgery.

The present study has several limitations. A major limitation is the imbalance of the ASA score between arms, which made the results difficult to interpret. Second, the absence of baseline measurements of BPI and BFI scores also makes comparisons difficult. Third, the short duration of observation and the small sample make this study underpowered for detecting the changes in rare and long-term adverse events such as incisional hernia.

In conclusion, the use of an activity tracker with feedback is safe and may increase physical activity in patients who have undergone major surgery for gynecological diseases. However, our findings should be interpreted with caution because of an imbalance of ASA scores between arms.

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Conflict of Interest

None declared.

Author Contributions

JN: acquisition of data, drafting of the manuscript, critical revision of the manuscript. KK: conception and design, acquisition of data, analysis and interpretation of data, drafting of the manuscript, critical revision of the manuscript, statistical analysis, obtaining funding. YBK: acquisition of data, critical revision of the manuscript. DHS: acquisition of data, critical revision of the manuscript. EJY: conception and design, critical revision of the manuscript. HH: conception and design, critical revision of the manuscript. administrative technical or material support. SY: conception and design, critical revision of the manuscript, administrative technical or material support.

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