Ambulation Orderlies and Recovery After Cardiac Surgery: A Pilot Randomized Controlled Trial

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ABSTRACT

Background: One potential strategy to increasing physical activity after surgery is to use an ambulation orderly (AO), a dedicated employee who assures frequent patient walking. However, the impact of an AO on physical and functional recovery from surgery is unknown.

Methods: We randomized postoperative cardiac surgical patients to receive either the AO or usual care. We measured average daily step count, changes in 6-min walk test (6MWT) distance, and changes in functional independence (Barthel Index). Our primary goal was to test protocols, measure variability in activity, and establish effect sizes.

Results: Thirty-six patients were randomized (18 per group, 45% bypass surgery). Overall, patients exhibited significant recovery of physical function from baseline to discharge in the 6MWT (from 83 to 172 meters, $p < 0.001$) and showed improvement in independent function (Barthel Index, 67 to 87, $p < 0.001$). Moreover, each additional barrier to ambulation (supplemental oxygen, intravenous poles/fluid, walkers, urinary catheters, and chest tubes) reduced average daily step count by 330 steps/barrier, $p = 0.04$. However, the AO intervention resulted in only a small difference in average daily step counts (2718 versus 2541 steps/d, Cohen's $d = 0.16$, 608 patients needed for larger trial), which we attributed to several trial factors that likely weakened the AO intervention.

Conclusion: In this pilot study, we observed significant in-hospital physical and functional recovery from surgery, but the addition of an AO made only marginal differences in daily step counts. Future studies should consider stepped-wedge or cluster trial designs to increase intervention effectiveness.

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INTRODUCTION

The risks of prolonged bed rest among hospitalized patients are well known and include cardiovascular deconditioning, bone and muscle loss, and compression ulcers (1,16). Similarly, the benefits of ambulation include a reduced hospital length of stay (LOS), lower risk of delirium, and lower incidence of deep venous thrombosis (6,8). Despite these facts, achieving sufficient ambulation is difficult to achieve for most hospitalized patients, particularly among surgical patients who must deal with postoperative pain, surgical drains, and other temporary medical devices that inherently restrict ambulation (2,4,17). Furthermore, patients are commonly placed on bed rest due to concerns about falls and the safety of ambulation (5). As a result, physical inactivity represents a sizable challenge for surgeons and hospitals as they work to limit unnecessary bed rest and support safe ambulation among all their patients.

While there are many reasons for poor mobility, the most commonly cited barrier to improving ambulation by physicians and nurses is lack of time and dedicated staff (3,7). To directly address this barrier, our institution hired additional staff members (ambulation orderly, AO) in May 2013 on the postoperative cardiovascular nursing unit. These employees are responsible for ambulating patients frequently, up to 4 times per day. Our prior research found that, the institution of our AO program was associated with a 1.3-d shorter hospital LOS and a reduced risk of falls (11). Although these results are promising, they could have been confounded due to other institutional trends or occurred though a mechanism other than increased ambulation.

Consequently, while the concept of an AO intuitively makes sense and has strong face validity, empirical prospective randomized evidence is needed before such a program could be advocated for widespread implementation. We therefore undertook a pilot study to evaluate our AO program among postoperative patients with recent cardiac surgery. Our goal was to evaluate our methods, measures, and outcomes and to estimate effect sizes in preparation for a larger trial. We hypothesized that AOs would hasten physical and functional recovery from surgery.

MATERIALS AND METHODS

We performed a randomized controlled pilot of AO-directed ambulation (intervention) compared to usual care (UC, nurse-directed ambulation) on our 32-bed postoperative cardiovascular surgical ward at Baystate Medical Center in Springfield, Massachusetts, between February and June of 2015. Patients gave written informed consent within 4 h after transfer from the cardiac intensive care unit to the postoperative floor. This trial was registered at clinicaltrials.gov with unique identifier NCT02375282 and was approved by the Baystate Institutional Board Review, number BH14-69.

Patients were eligible to participate if they were age ≥18 years and had just undergone coronary artery bypass graft surgery, valve surgery, or a combination of these 2 procedures. We required that patients were ambulatory prior to their hospitalization, cognitively capable of giving informed consent and following study procedures, and could communicate in English. We excluded patients with an expected ward LOS of ≤2 d and patients without thoracotomy, such as patients with transcutaneous aortic valve replacements.

Baseline Assessment

After signing informed consent, all patients performed a baseline 6-min walk test (6MWT), according to American Thoracic Society guidelines on the postoperative ward (9). Each patient reported dyspnea and modified Borg ratings of perceived exertion scores at peak exercise (13). Heart rate and oxygen saturation were measured at baseline and at the end of the 6MWT. Most patients required at least 1 assistant (such as a nurse, nurses' aide, or cardiac rehabilitation staff) in addition to the study staff to complete the baseline 6MWT. Wheelchairs were available throughout the 6MWT, and patients rested as much as necessary during the test.

As part of the 6MWT, we tallied the number of temporary medical instruments the patient was using in order to accomplish the 6MWT safely. We deemed these instruments as "barriers" to ambulation because they uniformly required staff assistance to prepare the patient for ambulation. We considered walkers, supplemental oxygen via nasal cannula with oxygen cylinder, urinary catheters and drains, chest tubes and drains, transcutaneous temporary pacer wires with external pacer box, and intravenous (IV) infusions with IV poles to each be barriers to spontaneous ambulation.

After the 6MWT, patients wore a research-grade accelerometer (Actigaph, GT3X+ Pensacola, FL) on the wrist for the remainder of their hospitalization to measure physical activity, as previously described and validated (12). The patient's nurse rated the patient's functional independence using the Barthel Index, which is a validated tool for assessing function status of institutionalized patients (10,15). It includes items on feeding, bathing, grooming, dressing, bowel and bladder continence, toilet use, transfers, mobility, and stairs. It ranges from 0 to 100, from completely dependent to completely independent.

Randomization and Blinding

After completing baseline assessments, patients were randomized to either nurse-directed ambulation (UC) or to AO-directed ambulation (intervention.) Randomization was performed in a 1:1 pattern using a permuted block design to assure group balance throughout the trial. Sequence generation was created using random computer generation (done by P.V.). The randomization log was administered by research associates not involved in the study so that all study authors and outcome assessors were blinded to group assignment. After randomization, these research associates informed both the patient's nurse and the AOs of the study assignment.

Additionally, patients were blinded to study assignment. At the time of consent, patients were informed they would work with a team to improve their physical and functional capacity. They were told this team could include physical

therapists, nurses, nurses' aides, inpatient cardiac rehabilitation staff, and/or an AO, but were not specifically told that there was a random chance that an AO would be assigned to work with them. Such incomplete disclosure is allowable by Office of Human Research Protection guidelines in behavior health interventions as long as there is close oversight, clear justification, and eventual complete disclosure to patients. Accordingly, all patients were ultimately informed of the full study purpose, hypothesis, and their study assignment in a mailed letter within 6 weeks of hospital discharge.

Usual Care and Ambulation Intervention

Usual care was provided by hospital staff on the designated 32-bed cardiovascular postoperative floor. Throughout the trial, this floor was staffed by 6–8 nurses and 3–4 patient care technicians during daytime hours. Nurses and nurses' aides (in both groups) were instructed to walk with patients as they normally would and not limit their contact or walking with patients in either intervention or control groups. No other specific instruction was given to nursing staff. Although not measured in this study, UC in the nursing group historically included less than 1 bout of ambulation with either the nurse or nurses' aide during the 12-h shift. Additionally, all patients in both groups walked daily with inpatient cardiac rehabilitation and additionally with physical therapy if judged necessary.

In the intervention group, an AO was on duty 7 d/week during daytime hours. Under the direction of nursing and inpatient cardiac rehabilitation staff members, they assured safe ambulation and handled all medical equipment needed for the patient to walk up to 4 times daily. Although no specific exercise prescription was given, each patient ambulated to fatigue for between 3 and 10 min, as tolerated by the patient. The exact frequency and intensity of the AO intervention depended on the needs of the patient, such that mostly immobile patients received more visits than did the nearly independent patients. Consequently, patients early in the hospitalization course were visited more frequently than patients who were closer to hospital discharge, and when a patient was ambulating frequently and safely, the AO no longer made visits.

Outcome Measurements

In the 24 h prior to the anticipated hospital discharge, we repeated the 6MWT, the Barthel Index, and collected the accelerometer. The 2 main outcomes were the change in walking distance between the baseline and final 6MWT and the step counts as measured by the accelerometer between the AO and nursing groups. Prespecified secondary outcomes included the average slope of progression in daily step counts (step improvement/d), average daily energy expenditure, total steps on study day 3, the change in 6MWT vital signs from baseline to discharge, and the improvement in the Barthel Index. Finally, we evaluated the LOS and included the total hospital LOS, the surgical LOS (from surgery to discharge), and the ward LOS (from arrival on postsurgical ward to discharge).

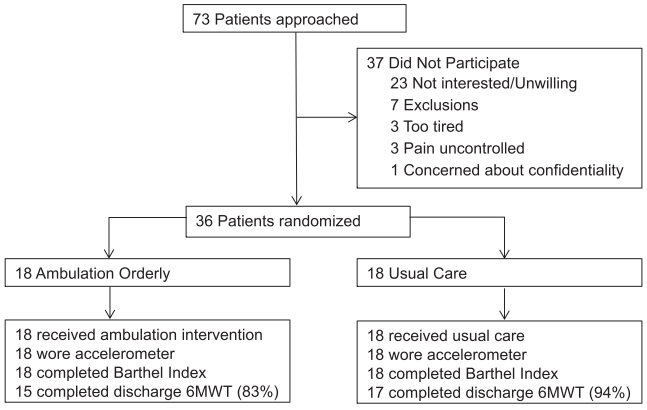

FIGURE 1. Consort diagram of patient recruitment and retention.

To better understand variability in ambulation patterns, we further evaluated improvements in the 6MWT, the Barthel Index, and the change in 6MWT vital signs and effort ratings among all patients, regardless of group assignment. We assessed the number of steps on each hospital day, the number of bouts of exercise lasting ≥3 min on each hospital day, and the relationship between ambulation barriers and total average daily step counts.

Statistical Analysis

All analyses were done according to intention-to-treat principles with patients analyzed in the group to which they were randomized. Baseline characteristics were compared between groups using proportions for categorical data, means and standard deviations for normally distributed continuous variables, and medians and interquartile ranges for skewed variables. As this was a pilot study, the main objective was to estimate feasibility, effect size, and variability in the intervention. Since estimates of effect size and variability were unknown, a formal test of the hypothesis of group differences was premature, and power calculations were not undertaken. Instead, effect size was determined by calculating standard effect size, Cohen's d, measuring power, and estimating the number of patients needed in a future trial. P values are reported to support interpretation of effect size estimation.

To evaluate physical recovery, we compared baseline to discharge changes in outcomes among the combined group, using paired t tests. To evaluate the daily progression in steps/d, we used linear regression and a time × group interaction variable to determine the slope of improvement by hospitalization day and the impact of group assignment, respectively. All calculations were performed on JMP version 12.0.1 (SAS Institute, Cary, NC).

RESULTS

We approached 73 eligible patients, of which 36 (49%) agreed to participate and were randomized to either the AO group or the UC group (Figure 1). The most common cause for not participating was lack of interest in the study. All patients wore and returned the accelerometer, and their nurses completed the Barthel index, but 4 (11%) patients were

TABLE 1. Baseline patient characteristics.

Characteristic	AO, N = 18	UC, N = 18	P value
Age (years ± SD)	62 ± 13	69 ± 8	0.053
Male sex	72%	78%	0.70
Race			0.11
Black	6%	0%	
Hispanic	11%	0%	
White	83%	100%	
Surgical procedure			0.06
CABG	39%	50%	
CABG + valve	6%	28%	
Valve	56%	22%	
Cardiac risk factors			
Hypertension	78%	83%	0.67
Diabetes mellitus	28%	22%	0.70
Hyperlipidemia	72%	94%	0.06
Smoking			0.33
Current	17%	17%	
Former	39%	61%	
Never	44%	22%	
Body mass index (kg/m^2 ± SD)	30 ± 4	29 ± 4	0.37
Ejection fraction (% ± SD)	57 ± 14	52 ± 16	0.31
Past cardiac history			
Prior myocardial infarction	22%	0%	0.01
Prior percutaneous coronary intervention	22%	0%	0.01
Prior cardiac surgery	11%	11%	1.00
Prior heart failure	17%	22%	0.67
Prior stroke	11%	17%	0.63
Additional comorbidities			
Peripheral vascular disease	6%	11%	0.54
Chronic obstructive pulmonary disease	11%	0%	0.09
Osteoarthritis	17%	22%	0.67
Atrial fibrillation	22%	22%	1.00
Chronic kidney disease	17%	28%	0.42

CABG = coronary artery bypass graft; SD = standard deviation; AO = ambulation orderly; UC = usual care

discharged before completing a repeat 6MWT. Overall, there were some differences in baseline patient characteristics by group, with the AO group being younger, more likely to have had valve surgery, or have a history of prior myocardial infarction or percutaneous coronary intervention (Table 1).

When evaluated as a combined group, patients walked 83 ± 84 meters in the 6MWT and were moderately functional (Barthel Index of 67 ± 16). Over the course of their hospitalization from baseline to discharge, patients improved their 6MWT by 87 meters, their step count by 1569 steps, and their Barthel Index by 20 points (all $p < 0.001$, Table 2). On a per-day basis, this correlated to an improvement in step count of 256 ± 91 steps/d, $p = 0.005$. At baseline, the average number of ambulation barriers was 1.6 ± 1.1 and decreased to 0.7 ± 0.7 at the time of discharge. Each additional baseline ambulation barrier was associated with 330 fewer steps/d, $p = 0.04$ (Figure 2) and 40.7 fewer meters/barrier in the 6MWT, $p = 0.005$.

There was little difference by group in either of the 2 main outcomes of average daily step count or 6MWT distance improvement (Table 3 and Figure 3). Similarly, there was little difference in other physical activity outcomes, except possibly on day 1 when step count and 3-min bouts of exercise were modestly higher at 393 steps and 3 bouts,

TABLE 2. Longitudinal outcomes for combined cohort.

Measure	Baseline	Discharge	Difference	P value[a]
Daily step count	1490 ± 973	3058 ± 1982	1569 ± 2089	<0.001
Barthel Index	67 ± 16	87 ± 15	20 ± 15	<0.001
6-min walk parameters				
Distance (meters)	83 ± 84	172 ± 89	87 ± 69	<0.001
Heart rate change	+ 12 ± 15	+ 15 ± 19	3 ± 3.6	0.40
O_2 saturation change	- 0.2 ± 4.0	- 0.8 ± 2.8	- 0.7 ± 0.9	0.47
Dyspnea rating	2.4 ± 2.1	2.2 ± 1.2	- 0.1 ± 0.6	0.96
Borg rating of perceived exertion	11.3 ± 3.1	11.3 ± 2.5	- 0.2 ± 0.4	0.48

[a]From pair t tests.

respectively. Notably, total, surgical, and ward LOS were 1–2 d shorter in the AO group, but this seems likely to be due to differences in baseline group characteristics.

The standardized effect size for the AO intervention on average daily step count was low (Cohen's d = 0.16, 89 steps). Given the effect size and variability observed, we estimate that power to detect a statistical difference between groups was only 7.5% for average daily step count, and a future trial would require a total of 608 patients to find a statistically significant result.

DISCUSSION

In this pilot double-blind randomized controlled trial among patients on a postoperative ward following cardiac surgery, we found that our procedures were feasible and that performing a 6MWT on postoperative day 2 or 3 was possible even when patients had multiple medical instruments that inhibited ambulation. We also demonstrated the important role that medical barriers played in limiting ambulation and noted substantial in-hospital improvements in both physical activity and functional status. However, we found that patients assigned to the AO intervention had only marginally increased levels of average daily step counts when compared to UC, and 6MWT distance improvement was essentially unchanged between groups. Secondary outcomes similarly showed only minimal changes with the AO intervention.

Several important trial features potentially affect the interpretation of our results. First, although both patients and study staff were blinded, nursing staff was not blinded to group assignment. We suspect this led to a strong Hawthorn effect whereby nurses increased their ambulation efforts with patients who were not assigned to the AO. Indeed, several nurses reported making extra efforts to assure their UC patients were ambulated regularly. Although it was unknown to what degree this happened across the entire group, this factor alone could have made a major impact and biased our results towards the null. Second, less than half of the approached patients consented to participate in this trial, and this may have resulted in our recruiting a healthier population that was more able to ambulate and less likely to benefit from an AO. Indeed, functional status was relatively high, our trial population's surgical LOS was shorter than our institutional norms [at median of 6.5 d versus 7.5 d (11)], and patients walked more than 2,000 steps/d, a value higher than expected for a hospitalized surgical population (14). Third, we did not track how often the AO visited patients because we assumed that measuring ambulation (3-min bouts of exercise) with the accelerometer would be sufficient. However, this limited our ability to judge the strength, timing, or frequency of the intervention, and this prevented us assuring that a quality intervention actually occurred. Fourth, because the AO program had already been implemented for 2 years at the time of the trial, there was already a strong culture of early ambulation among the nurses and physicians on this floor, and this probably resulted in more ambulation in both groups, which probably weakened the AO intervention. Lastly, about half way through the trial, our surgical group restructured their rounding responsibilities, and the primary surgeon who was newly assigned to round on the postoperative floor began insisting that nursing staff ambulate patients who were participating in our study more

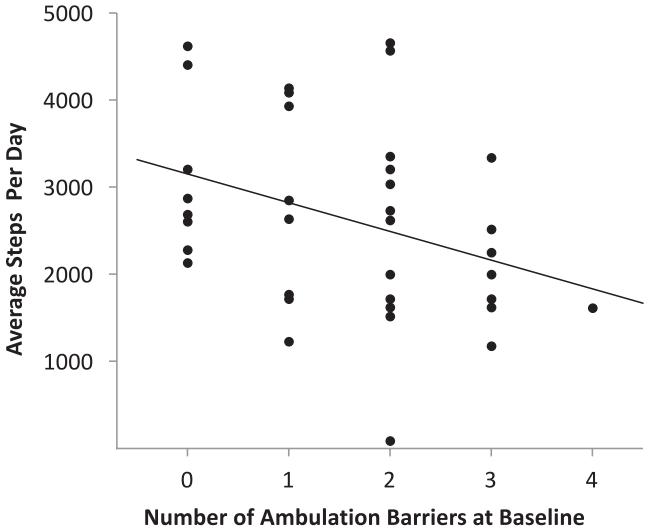

FIGURE 2. Impact of ambulation barriers on daily step count. As seen, each additional barrier was associated with a lower daily step count by an average of 330 steps/d. $R^2 = 0.11$, $p = 0.04$.

TABLE 3. Outcomes by group.

Outcomes	Ambulation Orderly, N = 18	Usual Care, N = 18	P value
Main outcomes			
Average daily steps (steps)	2718 ± 1205	2541 ± 1012	0.63
6-min walk distance improvement (m)	82 ± 73	91 ± 65	0.71
Additional outcomes			
Barthel Index improvement	20.6 ± 3.6	19.9 ± 3.6	0.89
Daily energy expenditure (calories)	435 ± 254	358 ± 141	0.27
Physical activity by days prior to discharge			
Steps (5 d prior to d/c), n = 6	2074 ± 2800	911 ± 188	0.78
Steps (4 d prior to d/c), n = 9	2202 ± 735	2193 ± 1273	0.98
Steps (3 d prior to d/c), n = 21	2064 ± 1746	1816 ± 1410	0.73
Steps (2 d prior to d/c), n = 32	2610 ± 1479	2255 ± 844	0.43
Steps (1 d prior to d/c), n = 36	3195 ± 1905	2941 ± 1687	0.76
Steps (discharge), n = 36	2825 ± 1540	3002 ± 2366	0.79
Physical activity outcomes by enrollment day			
Steps (day 1), n = 36	1686 ± 1104	1293 ± 804	0.23
Steps (day 2), n = 36	3217 ± 2008	2819 ± 1189	0.48
Steps (day 3), n = 32	2703 ± 1476	3214 ± 2065	0.42
Steps (day 4), n = 21	3296 ± 1295	2808 ± 1757	0.47
Recovery slope (improved steps/d)	225 ± 140	265 ± 122	0.69
3-min bouts of exercise			
3-min bouts of exercise (day 1)	6.1 ± 6.3	3.1 ± 4.1	0.11
3-min bouts of exercise (day 2)	8.1 ± 8.8	6.9 ± 9.9	0.54
3-min bouts of exercise (day 3)	6.7 ± 8.7	7.6 ± 6.0	0.27
3-min bouts of exercise (day 4)	7.4 ± 6.4	6.8 ± 5.6	0.93
Average number of 3-min bouts of exercise/d	7.4 ± 6.5	6.2 ± 4.6	0.37
LOS, median (IQR)			
Total LOS	7 (6, 10.25)	9.5 (5.75, 13.25)	0.16
Surgical LOS	5.5 (4.75, 7)	7 (5.75, 10.5)	0.06
Ward LOS	3 (2.75 to 4)	4 (3, 5.25)	0.18

LOS = length of stay; IQR = interquartile range; d/c = discharge

frequently than was their usual routine. This contamination was not anticipated during trial planning and was not discovered until after trial completion. We are unsure how this problem affected our results, but if this surgeon was effective, we believe this would bias our results toward the null. Given these limitations, it seems possible that, under different circumstances, in sicker populations, and with nurses who were blinded to patient assignment, or on wards unaccustomed to the presence of an AO, our AO intervention would have made a larger difference in increasing physical activity and functional recovery.

Future trials of AO interventions should address ways to increase the frequency and intensity of the AO visits and maintaining full team buy-in. These trials may also do well to focus their efforts on sicker patients with more barriers to ambulation, such as patients in the intensive care units or patients earlier in the course of their postoperative recovery when multiple medical devices are still needed for proper medical care. They should consider enrolling patients prior to surgery. Furthermore, we strongly believe that any future trials of AOs would best be done at the unit or hospital level, rather than at the patient level to avoid intervention contamination as we experienced. Thus, a traditional cluster randomized controlled trial or a stepped wedge design seems well suited to this research topic and would likely avoid the majority of the issues we encountered in our pilot.

One key study finding that intuitively makes sense but has not been previously quantitated is the important role of ambulation barriers in impairing mobility. As demonstrated in our study, each additional barrier to ambulation was

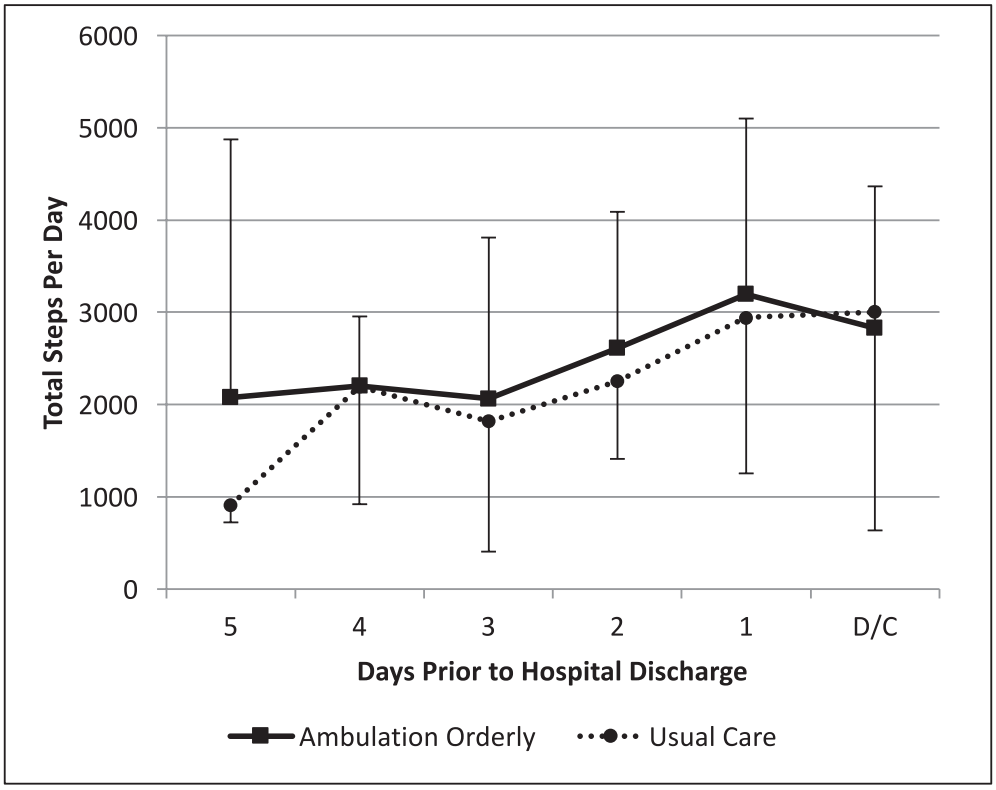

FIGURE 3. Step progression by group. As seen, the average participant increased their average total daily step count by 256 ± 91 steps/d, p = 0.005, but little difference was observed between groups, and there was large variability.

associated with substantially lower step counts, such that patients with 3 or 4 barriers averaged 750 steps fewer than patients with 2 or fewer ambulation barriers. While we suspect this finding is a result of the inherent immobility caused by these barriers, we also believe these barriers are markers of greater illness severity and predisposition to increased sedentary behavior. Although we could not determine the exact causation of the lower step counts in patients with greater barriers, there appears to be an imperative to reduce unnecessary temporary medical devices but also assure that ambulation efforts are focused on those patients with a greater number of barriers who are at risk for the consequences of prolonged bed rest and immobility. By so doing, patients will be more able to ambulate spontaneously, patients with greater ambulation assistance needs will be identified, and the harmful consequences of sedentary behavior will be avoided.

CONCLUSIONS

In this double-blind pilot trial of an AO in a postoperative cardiac surgical ward, we found that the addition of an AO made little difference in daily ambulation or physical recovery from surgery. Any future trial would require either much larger sample sizes or a more effective intervention. We also demonstrated the key role of ambulation barriers in reducing daily step counts and found that patients had substantial recovery in their daily physical activity levels and functional independence, regardless of group assignment.

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Disclosures
None for all authors

Author Contributions
Drs. Pack, Visintainer, Headley, Engelman, Lagu, and Lindenauer each assisted with study design, concept, and interpretation of results. Ms. Woodbury, Riley, and Miller each helped collect data and interpret results. Drs. Pack and Visintainer performed the statistical analysis. Dr. Pack drafted the manuscript, and all authors critically reviewed the manuscript and approved the final version.