Digital tracking of patients undergoing Radical Cystectomy for Bladder cancer: Daily step counts before and after surgery within the iROC randomised controlled trial

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Abstract

Background: Efforts to improve recovery after Radical Cystectomy (RC) are needed.

Objectives: Investigate wrist-worn wearable activity trackers in RC participants.

Design, Setting and Participants: Observational cohort study within iROC Randomized trial.

Interventions: Patients undergoing RC at 9 cancer centers wore wrist-based trackers for 7 days at intervals before and after surgery.

Outcome Measurements and Statistical Analysis: Step counts were compared to participant and operative features, and recovery outcomes.

Results and Limitations: 284/308 (92.2%) participants returned digital activity data at Baseline (median 17 days (IQR: 8-32) before RC) and Post-operatively (5 (5-6) days), Weeks 5 (43 (38-43) days), 12 (94 (87-106) days) and 26 (192 (181-205) days) after RC. Compliance was affected by time from surgery and a COVID-19 pandemic lockdown (return rates fell to 0-7%, chi sq. $p<0.001$). Step counts dropped after surgery (mean of 28% Baseline), before recovering at 5 (71% Baseline) and 12 (95% Baseline) weeks (all ANOVA $p<0.001$). Baseline step counts were not associated with post-operative recovery or death. Patients with extended hospital stays had reduced post-operative step counts, with a difference of 2.2 days (95% CI: 0.856 to 3.482 days) between the lowest third and highest two thirds, linear regression analysis ($p < 0.001$). Additionally, they spent less time out of hospital within 90 days of RC (80.3 vs 74.3 days, $p = 0.013$). Lower Step counts at 5, 12 and 26 weeks were seen in those seeking medical help and needing readmission (ANOVA $p \leq 0.002$).

Conclusions: Baseline step counts were not associated with recovery. Lower post-operative step counts were associated with longer hospital lengths of stay and post-discharge readmissions. Studies are required to determine whether low step counts can identify patients at risk of developing complications.

Patient summary: Post-operative step counts appear a promising tool to identify patients in the community needing medical help or re-admission. More work is needed to understand which measures are most useful and how best to collect them.

Trial registration: ISRCTN Identifier: ISRCTN13680280; ClinicalTrials.gov Identifier: NCT03049410

Introduction

Bladder cancer (BC) is a common malignancy and one of the most expensive human cancers to manage [1]. Risk factors include smoking, pollution, diesel fumes, occupational carcinogens, age and sex [2]. Around half of BCs arise following cigarette exposure [3] and more than a third of disability-adjusted life years due to BC are attributable to smoking [4]. Lifestyle surveys reveal most affected individuals have one or more competing long term condition [5], are obese or overweight, and self-declare insufficient daily exercise levels [6]. Whilst Enhanced Recovery After Surgery (ERAS) pathways facilitate rehabilitation after Radical Cystectomy (RC) [7][8], this procedure is a major undertaking in this co-morbid population, many of whom have received neoadjuvant chemotherapy [9], and so complications are common [10]. Early post-operative mobilization is an important component of ERAS [11] and various attempts have been used to encourage and monitor compliance with this [12, 13].

Wearable activity trackers offer the potential to improve outcomes after surgery through either incentivization of mobilization [14] or the identification of patients deviating from expected recoveries [15, 16]. For example, Daskivich et al. reported a direct association between walking more steps on the first day after major surgery and shorter hospital length of stays, when measured using a wearable tracker in 100 participants [17]. Panda et al. used a smartphone uploaded app to measure walking levels in 62 participants recovering from surgery and found mean exertional levels were significantly reduced in those who were readmitted, developed a complication or died [18]. Mylius et al. identified links between pre-operative moderate to vigorous physical activity (MVPA) levels and recovery from hepato-pancreato-biliary cancer surgery [19], suggesting that absolute step count alone may not be enough. These reports complement further studies [20-22] and suggest the association between digitally measured steps counts and recovery from surgery necessitates further exploration. Here we describe our findings of monitoring daily steps counts in participants undergoing RC with a randomized trial comparing open and robotic surgery [23].

Methods

Participants

The randomised controlled iROC trial recruited patients from 9 centers in the United Kingdom from March 2017 to March 2020 [23, 24]. The primary objective was to investigate the impact robotic or open surgery on patient recovery. Eligible patients were adults, with nonmetastatic urothelial, squamous, adenocarcinoma, or variant bladder cancer. Of 338 randomised patients, 317 underwent radical cystectomy (as detailed elsewhere [23, 24]). All participating centres used Enhanced Recovery After Surgery (ERAS) programmes as standard of care.

Digital Tracking

Participants were given a Misfit Shine (Misfit, Fossil Group Inc, USA) wrist work activity tracker and instructed on its use by research nurses. They were asked to wear the device for a 7-day period and return it in person at the next clinic visit or by post. Data were collected at Baseline (pre-operative), post-operative (from day 5) and Weeks 5, 12 and 26 after RC. Post-operative devices were collected directly whilst participants were still in hospital. Step counts were extracted and loaded on the trial database for analysis.

Endurance testing and Quality of life

For endurance testing, a 30 Second chair to stand (CTS) test was performed [24]. This the number of times the patient can stand from sitting in a 30-second interval. This was counted in the outpatient's clinic at the same timepoints as for step count collection (Baseline, Post-op (on day 5), Week 5, Week 12 and Week 26). To measure overall health-related Quality of Life (HRQoL), we also collected the EQ5D-5L questionnaire at these timepoints.

Statistical analysis

The analysis of any association between step counts and recovery was a secondary analysis in the IROC protocol. Step counts were allocated to time interval using the date of their collection and date of RC. To exclude participants not wearing the tracker or unreliable use, we only included patients who recorded ≥3 days data with ≥100 steps/day in this analysis. Patient and recovery metrics were compared with mean (average) daily steps counts, maximum steps in a single day and total counts over a week (only for those with 7 consecutive days of data). Outcomes included post-operative complications (Adverse Events) as recorded by each hospital's trial team, post-discharge readmission to hospital, or visit to their community medical practitioner (GP) or nearest Emergency Room (accident and Emergency), length of stay (LOS) following surgery and Days Alive out of Hospital within 90 days of surgery (DAOH90, which was the primary outcome for the randomized controlled trial). Comparisons were made using the Chi squared test (categorical values) and Students T test or ANOVA tests (continuous variables). Time to event data was plotted using the Kaplan-Meier method and compared using a Log rank test. Pearson's correlation coefficient was used determine any association between two continuous variables. Linear regression was used to analyse relationships between activity levels and LOS or DAOH90. Separate models were tested to include participant demographics with Baseline or Post-operative activity data, Baseline CTS or Baseline EQ5D SAH. All tests were two sided and a P value of 0.05 taken to be of significance. Analyses were performed within Statistical Package for the Social Sciences (Vsn. 29.0. SPSS Inc., IBM Corp., Armonk, NY, USA) or Prism (Vsn. 9.0 GraphPad Software, LLC).

Results

Cohort and Compliance with activity tracking

In total, 308 participants (typical for RC, table 1) underwent surgery and were eligible for activity tracking. Of these, 284 (92.2%) returned digital activity data from one or more time period (supplementary figure 1). Responders appeared broadly representative of the entire population, with only participants with a higher ECOG performance status (Chi squared p=0.01) or undergoing neobladder reconstruction (p=0.02) being more likely to return activity data than the others (supplementary table 1). Most participants returned 7 days of data (78-88%), although compliance (7 consecutive days) fell with time (67% Baseline to 41% at 26 Weeks, supplementary table 2). Compliance was dramatically affected by the COVID pandemic. The UK government imposed the first national lockdown midway through follow up (23rd March 2020) and tracker returns rates dropped from 51-68% before lockdown to 0-7% after, chi sq. p<0.001 (supplementary figure 2).

Baseline activity levels

Baseline activity data was collected at a median of 17 days (IQR: 8-32) before RC. Across the whole cohort, the average daily, maximum daily and total weekly Baseline step counts were

6,378 (st. dev. 3,024), 9,516 (4,727) and 42,119 (22,089), respectively. Baseline step counts varied with various participant demographics (such as sex, ECOG performance status, smoking status and eGFR, supplementary table 3) and were associated with Baseline CTS score (supplementary table 4, Pearson's $p<0.001$) and Quality of Life (EQ5D-5L Self Assessed Health today (SAH) Scores, $p<0.001$).

Activity levels over time

Post-operative activity data was collected i). immediately Post-operatively (median of 5 days (IQR (5-6)) after RC), and ii). around Weeks 5 (43 days (38-43)), iii). 12 (94 days (87-106)) and iv). 26 (192 days (181-205)) after RC (supplementary figure 3). Step counts (daily averages shown in Table 2), dropped dramatically after surgery (to an average 28% of Baseline), before recovering at 5 Weeks (71% of Baseline) and nearly reaching Baseline (95%) by 12 weeks (all ANOVA $p<0.001$). Reductions in step counts were greatest in oldest patients, those with renal impairment and with reduced ECOG-PS (ANOVA $p<0.03$). We stratified activity levels into tertiles for analysis (figure 1). Participants who were more active at Baseline, walked significantly more steps at 5 and 12 weeks after surgery (ANOVA $p<0.05$). Participants with higher Baseline CTS scores also walked more steps at Baseline and 26 weeks ($p<0.033$). Differences were also seen according to participant age and ECOG performance status, but not by surgical approach.

In hospital recovery with respect to Baseline and Post-operative Activity Levels

Post-operative complications were recorded in 124 participants (151 separate diagnosis). Older age (Chi square $p=0.03$) and lower Baseline CTS scores ($p=0.05$) were associated with the presence of post-operative complications. Baseline step counts were not associated with the presence, number or type of complications (e.g. complications associated with immobility) or death within 90 days (supplementary table 5), while baseline CTS was associated with a difference in post-operative cardiovascular ($p=0.03$) and death ($p=0.023$) events between the lowest third and highest two third tertiles. Linear regression revealed neither LOS (B=0.1 (95%CI: -0.289 to 0.522) days per 1,000 steps, $p=0.57$, figure 2a) nor DAOH90 (converted to log DAOH90, B=0.02 (-0.023 to 0.055, $p=0.4$)) varied with Baseline step count. In the post-operative period, average daily step counts were associated with hospital length of stay and DAOH90 (Linear regression $p=0.013$). With regards to LOS, the difference was around 2.2 days (95%CI: 0.856 to 3.482 days) between the lowest third and highest two third tertiles (figure 2b). This equates to participants staying 1.1 more days (in LOS) for every 1,000 fewer steps they walked (linear regression B=1.104 (95CI; 0.340-1.868), p=0.004). Post-operative step counts were mostly not associated with the presence, number or type of complications (supplementary table 5).

Recovery after discharge

Activity levels after discharge varied with post-operative recovery and community medical demands (figure 3). At both 5 and 12 weeks, participants with one or more complication had lower step counts (ANOVA p<0.009) than those without. Within 26 weeks of discharge, 220/272 participants sought medical help either from their GP (176 participants), Emergency Room (A&E, n=160) or a hospital. Those seeking help had lower step counts at five weeks than those who did not see a physician (average steps 5,684 (st. dev. 3062) for no help vs. 4,465 (2,479) for 1-4 visits and 4,123 (2,331) for more 5+ visits, ANOVA p=0.03). In total, 87/272 patients were re-admitted (64 once, 19 twice and 4 three times) to hospital. Step counts at 5, 12 and 26 weeks were lower in those with readmission (ANOVA p<0.014). This appeared to be in a dose dependant manner, with fewer steps in those with more readmissions (figure 3c). Consequently, DAOH90 varied significantly with Week 5 step counts (73.5 ± 15.4 (lowest 1/3) vs.78.5 ± 7.6 (mid 1/3) and 79.6 ± 7.5 (highest), ANOVA p=0.002), frequency of medical help (ANOVA p<0.001) and readmissions rate (p<0.001, figure 3d).

Discussion

Step counts from wearable trackers collect physiological measures which are different to traditional observations, but their utility in surgical care remains unclear. We report the first large study detailing step counts from wearable devices in a contemporary, multicentre cystectomy population. We build upon smaller single centre studies reporting feasibility [20-22],[25] and financial incentives on activity levels [26]. A recent review identified only 3% of reports in this rapidly emerging field come from Urology [27] and so it is important to add high quality contemporary data to the literature. Our findings complement and contradict prior studies and point to areas of future research that are needed.

Firstly, we found activity trackers were acceptable to participants, regardless of age and sex (although we did not assess technology confidence or educational level). Compliance dropped with the COVID-19 pandemic lockdown and with time from RC. The latter reflects either falling levels of interest or rising levels of fatigue, and so work is needed to understand patient's perceptions of the benefits (and risks) of activity tracking and how to build the value of this approach [27]. A balance is needed between privacy concerns and the opportunity for earlier discharge and recovery at home [28]. Data from the National Surgical Quality Improvement Program show that early discharge is safe (and presumably preferable) for a many patients in this context [29].

Secondly, we did not see a relationship between Baseline (i.e. screening or pre-operative) step counts and post-operative complications or hospital length of stay. This observation contradicts smaller reports in colorectal surgery, which show that patients with the lowest step counts have significantly longer lengths of stay and higher complication rates [20],[30], in hepatobiliary surgery in which the most vigorously active patients had faster functional recovery [19], and in lung resection [21]. Within our cohort, Baseline activity levels were mostly not associated with participant demographics, although they did reflect stamina (CTS test) and HRQOL (EQ5D-5L SAH, supplementary tables 3 and 4). The contradiction with prior data might reflect specific demands of different surgical recoveries, that we collected only steps per day (rather than vigour of exercise, speed of walking, geolocation or duration of exercise), that our larger, multicentre study revealed the real-world impact of these devices, or the findings are population specific. With regards to the latter, the RC cohort can be selected (as less fit patients can have radiotherapy) and so step counts in our cohort (mean 6377/day) were greater than those in pneumonectomy (3888/day)[21] and colorectal resection (4569/day)[20] cohorts, and most participants were ECOG-PS 0 and 1. Future studies should collect more detailed activity data [31] from a broader range of participants, compare with respect to baseline activity levels and fully integrate into Prehabilitation regimens.

Thirdly, higher step counts in the first week after surgery were associated with shorter length of stays and higher step counts after discharge (in Week's 5, 12, and 26) were associated with lower requirements for medical care (either community doctor visits or hospital readmissions). These findings are consistent with prior data [16, 17], supporting the potential for this technology to identify patients suitable for early discharge or those in the community needed extra support. Robinson et al. identified a decrease in daily steps of more than 50% for two consecutive days as a potential trigger for intervention [32]. However, various reviews have highlighted limitations in the evidence that prevent current implementation [15, 27] (e.g. research grade or commercial devices, algorithm updates, skewed reporting, high risk of bias, and data security concerns).

This study has several limitations. Firstly, we only collected daily step counts. It may be that MVPA is a better measure or that step counts should be annotated by geolocation, duration, terrain and weather. It might also be that pain scores and analgesic use could inform step count interpretation. Secondly, we did not collect other physiological measures (such as heart rate or blood oxygen levels). The trial was designed in 2016, when technology readiness was lower amongst the patient population and smartphones were less prevalent. Since then, smartphones have become ubiquitous, accelerated considerably due to the COVID-19 pandemic and the widespread use of many consumer devices to collect health data (such as heart rate, pulse oximetry, sleep, temperature variability etc). Due to continuous pairing with smartphone devices, real-time continuous monitoring is now possible. Future studies should test the value of continuous modern wearable devices in measuring peri-operative outcomes following major surgery [33], adherence to ERAS pathways, as well as improving outcomes using prehabilitation and rehabilitation programmes. Thirdly, we did not understand the technological confidence of our cohort or their educational, social deprivation levels, or the impact of the COVID-19 pandemic on activity behaviours. It is likely this will affect extrapolation into the next study (when targeting those at highest risk of complications). With regards to data collection, compliance was significantly impacted by the COVID-19 lockdown. This was due to multiple factors, such as change of follow-up from in-person to telephone clinics (and so devices could not be collected), delays with the UK postal system due to staff illness and demand, and that research staff were diverted into clinical care of COVID-19 patients. Finally, the study was underpowered to determine differences between the role of step counts in open and robotic RC recovery.

Conclusions

Most participants were welcoming of digital tracking technology. Post-operative step counts appear a promising tool to identify patients in the community who may need medical help or re-admission to hospital. More work is needed to understand which measures are most useful, how best to collect them and how to integrate within rehabilitation (ERAS) pathways.

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		Male		Female		
		n	%	n	%	P value
Age (mean ± St. Dev.)		69.2	8.09	67.12	9.02	
Age category	30-55 yrs	10	4.5%	6	10.7%	0.23
	55-65 yrs	51	22.8%	17	30.4%	
	65-75 yrs	112	50.0%	21	37.5%	
	75-80 yrs	36	16.1%	9	16.1%	
	80+ yrs	15	6.7%	3	5.4%	
BMI (mean ± St. Dev.)		28.14	9.86	27.71	7.19	
BMI category	<18.5 kg/m2	4	1.8%	1	1.8%	**0.01**
	18.5-24.9 kg/m2	56	24.9%	23	40.4%	
	25-30 kg/m2	114	50.7%	17	29.8%	
	30+ kg/m2	51	22.7%	16	28.1%	
Smoking status	Current	28	12.4%	5	8.8%	**0.01**
	Ever	141	62.4%	30	52.6%	
	Never	57	25.2%	22	38.6%	
Smoking years (mean ± St. Dev.)		29	15	32	14	
ECOG Performance status	0	174	80.6%	40	71.4%	
	1	35	16.2%	15	26.8%	
	2	4	1.9%	1	1.8%	
	3	3	1.4%	0	0.0%	
eGFR (mean ± St. Dev.)		75	20	76	16	
eGFR Category	<50 mls/min	20	9.0%	5	9.4%	0.90
	50-80 mls/min	101	45.7%	21	39.6%	
	80-90 mls/min	34	15.4%	10	18.9%	
	>90 mls/min	66	29.9%	17	32.1%	
Hemoglobin (mean ± St. Dev.)		13.55	1.79	12.4	1.42	**<0.001**
Anemic Prior to RC	Hb≥ 12 g/dl	184	82.1%	38	67.9%	**0.02**
	Hb<12 g/dl	40	17.9%	18	32.1%	
Baseline CTS (mean ± St. Dev.)		14	4	14	4	
Baseline EQ5D SAH (mean ± St. Dev.)		80	16	75	20	**<0.001**
Length of stay (mean ± St. Dev.)		11	8	12	8	0.33
DAOH90 (mean ± St. Dev.)		77	13	75	14	0.42
Reconstruction	Neobladder	29	12.8%	6	10.5%	0.45
	ileal conduit	198	87.2%	51	89.5%	
Route of RC	iRARC	119	52.4%	29	50.9%	0.10
	Open RC	108	47.6%	28	49.1%	
Total		227	79.9%	57	20.1%	

Abbreviations: RC = Radical Cystectomy; iRARC = Intracorporeal Robot Assisted Radical Cystectomy; BMI = Body Mass Index; CTS = 30 second Chair to stand test; EQ5D SAH = Today's Self assessed Quality of lIfe using the 0-100 score within the EQ5D tool; DAOH90 = Days alive and Out of Hospital within 90 days of Radical Cystectomy.
P values represent those from Chi squared test for categorical and ANOVA for continuous variables.

Table 1. Participants who underwent a Radical Cystectomy and recorded ≥3 days step counts in one or more time window.

		Post-operative				Week 5				Week 12				Week 26			
		Mean	St. dev.	% baseline	ANOVA	Mean	St. dev.	% baseline	ANOVA	Mean	St. dev.	% baseline	ANOVA	Mean	St. dev.	% baseline	ANOVA
Sex	Male	1855	1329	29%	0.59	4653	2406	72%	0.40	6066	2768	93%	0.47	5975	2895	92%	0.70
	Female	1676	1279	29%		4453	3211	76%		5934	3411	101%		6655	3809	113%	
Age category	30-55 yrs	2414	1647	37%	0.45	6016	3195	92%	**0.007**	6460	3158	98%	0.18	9511	7792	145%	**0.003**
	55-65 yrs	1914	1357	31%		5010	2549	81%		6792	3191	110%		7200	3232	117%	
	65-75 yrs	1720	1198	25%		4747	2589	70%		6071	2732	89%		6018	2694	89%	
	75-80 yrs	1792	1520	31%		3743	2255	64%		4940	2935	85%		4687	3045	81%	
	80+ yrs	1498	936	28%		2684	2077	51%		5478	2693	104%		3974	1714	75%	
BMI category	<18.5 kg/m2	1765	1092	28%	0.81	5050	2390	80%	0.16	6363	1719	101%	0.09	6805	1048	108%	0.52
	18.5-24.9 kg/m2	2031	1579	30%		5213	2837	76%		6630	3081	97%		6997	3674	102%	
	25-30 kg/m2	1829	1229	29%		4447	2596	71%		5548	2797	88%		5870	2900	93%	
	30+ kg/m2	1535	1176	26%		3950	1839	66%		6068	3002	101%		5601	2769	93%	
ECOG Performance status	0	1858	1352	28%	0.74	4854	2546	73%	**0.02**	6228	2883	94%	0.20	6482	3086	98%	**0.01**
	1	1629	1119	30%		3731	2477	68%		5779	3002	106%		4934	2629	91%	
	2	2016	1246	33%		2789	1606	46%		3180	1804	52%		2153	2310	35%	
	3	1040	.	15%		.	.			9074	.	131%		10341	.	149%	
ileal conduit	Neobladder	1643	1237	29%	0.98	5015	2268	89%	0.92	5024	2421	89%	0.27	5142	2534	92%	0.28
	ileal conduit	1782	1432	28%		4313	2585	69%		6025	3021	96%		5836	2823	93%	
Route of RC	iRARC	1946	1069	28%	0.24	5109	2681	73%	0.59	6378	2914	91%	0.54	6856	3553	98%	0.30
	Open RC	1528	1105	23%		3345	1985	51%		4069	2145	62%		4096	2506	63%	
Smoking status	Current	1603	1239	26%	0.60	4316	2197	70%	0.17	6217	3097	100%	0.28	6310	2686	102%	0.11
	Ever	1888	1335	23%		5320	3183	66%		6273	2994	78%		6413	3391	80%	
	Never	2251	1438	39%		5132	2684	90%		6178	2772	108%		6260	3572	110%	
Anemic Prior to RC	Hb≥ 12 g/dl	1738	1302	27%	0.12	4600	2512	72%	0.85	5769	2786	91%	**0.03**	5779	3081	91%	**0.03**
	Hb<12 g/dl	2079	1363	33%		4518	2743	71%		7020	3335	110%		7300	2756	115%	
eGFR Category	<50 mls/min	1809	1430	26%	**0.02**	4661	2779	67%	**0.02**	6676	2948	96%	**0.05**	6908	4852	99%	0.08
	50-80 mls/min	1814	1303	29%		4603	2565	73%		5937	2930	94%		5995	2787	95%	
	80-90 mls/min	1922	1327	30%		4701	2515	73%		5913	3099	92%		5829	2781	91%	
	>90 mls/min	1686	1300	27%		4503	2682	71%		6180	2728	98%		6431	3396	102%	

Table 2. Average step counts from weeks 1 (post-operative, from n=210 participants), 5 (n=197), 12 (n=169) and 26 (n=134) after RC, with respect to participant demographics.

Figures Legends

Figure 1. Average daily step from Baseline to 26 weeks after Radical Cystectomy according to patient and operative features. a). Step counts varied according to Baseline average daily step counts (stratified into low, mid and highest tertiles) and b). according to Baseline Chair to Stand (CTS) test counts (stratified into low, mid and highest tertiles). Little difference was seen according to c). route of surgery (open or complete intracorporeal robot assisted (RARC)) and d). reconstructive choice (Neobladder reconstruction (Neobl.) or Ileal Conduit (IC)). e). Older participants and those with f). lower ECOG performance status walked fewer steps in the recovery periods than younger or higher performance status participants. Participant numbers are shown in brackets next to each class.

Figure 2. Time to hospital discharge according to Average daily step counts. Average daily step counts (stratified into lowest, mid and highest tertiles) at a). Baseline and b). in the first Post-operative week, with respect to Length of Stay. Linear regression models incorporating participant demographics revealed no association with Baseline step count values, whilst participants with lower Post-operative counts had longer Length of Stays when compared to participants with higher step counts. The difference was around 2.2 days (95%CI: 0.856 to 3.482 days) between the lowest third and highest two thirds tertiles, which equates to participants staying 1.1 more days (in LOS) for every 1,000 fewer steps they walked (linear regression B=1.104 (95CI; 0.340-1.868), p=0.004).

Figure 3. Recovery after Radical Cystectomy with respect to step counts and days alive out of hospital (DAOH90). Average daily step counts were lower at 5 and 12 weeks in participants who developed a complication (Adverse Event (AE)) after RC or b). required readmission (ReAdm.) to hospital, when compared to those without these events (None/Not). c). Incremental episodes of readmission (0, 1, 2 to 3 times) were associated with lower step counts, and this reached significance at 5 weeks. Consequently, d). time out of hospital (DAOH90) varied with Week 5 step counts, and the need for/amount of medical input (either GP, A&E or hospital) and hospital readmission.

Author contributions:

Drs Catto, Khetrapal and Kelly had full access to all the data in this study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Catto, Khetrapal, Kelly and Brew-Graves

Acquisition, analysis, or interpretation of data: Khetrapal, Kelly and Catto

Drafting of the manuscript: Catto, Khetrapal, Brew-Graves, Williams and Kelly

intellectual content: Khetrapal, Kelly and Catto

Obtained funding: Catto, Kelly, and Brew-Graves

Administrative, technical, or material support: Williams

Conflicts of interest/Disclaimers:

James Catto has received reimbursement for consultancy from Astra Zeneca, Ipsen, Ferring, Roche, and Janssen; speaker fees from BMS, MSD, Janssen, Astellas, Nucleix, and Roche; honoraria for membership of advisory boards for Ferring, Roche, Gilead, Photocure, BMS, QED therapeutics and Janssen; and research funding from Roche. The remaining authors declare no conflicts of interest with this work.

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Appendix 1: The iROC study team

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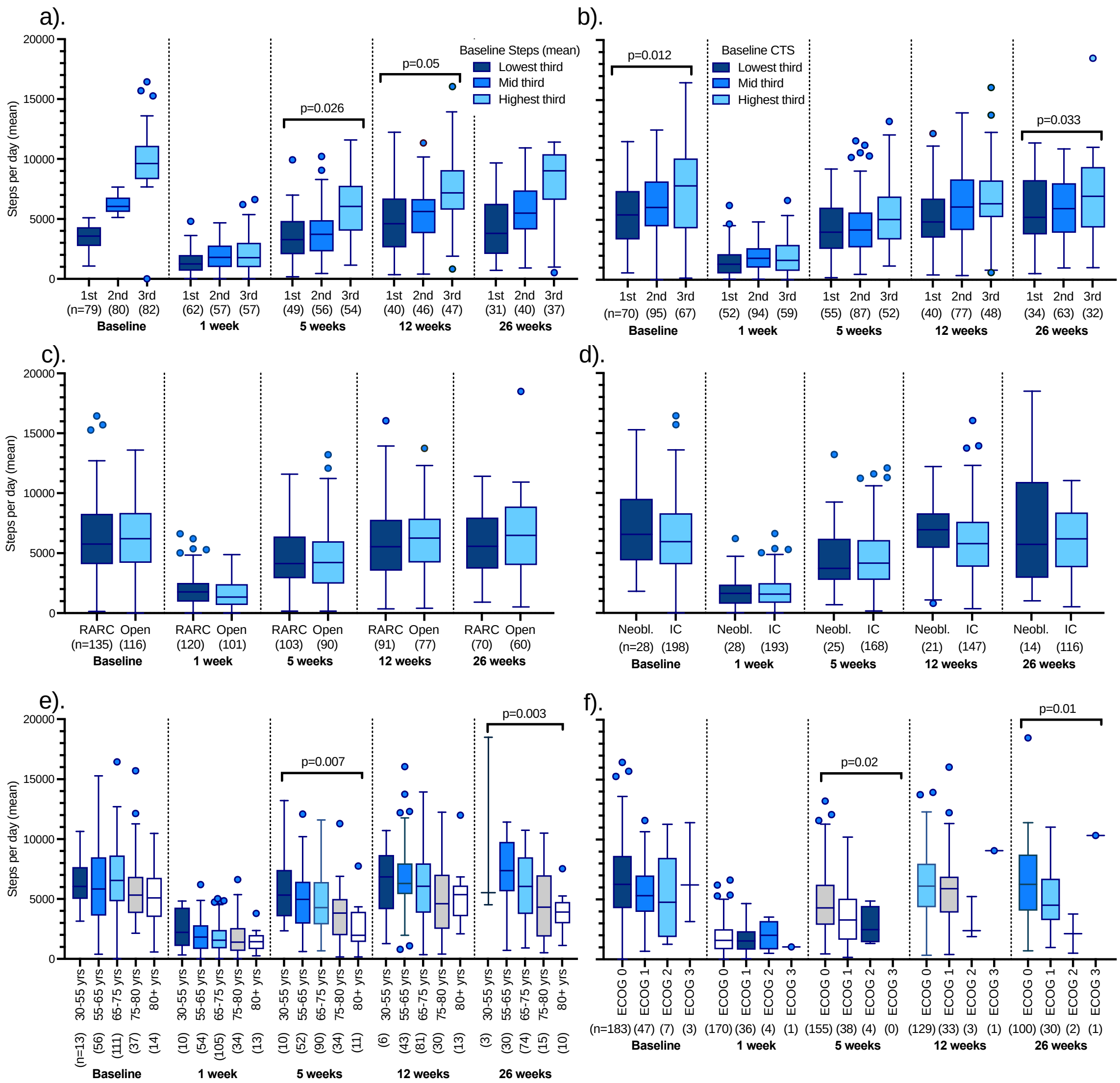

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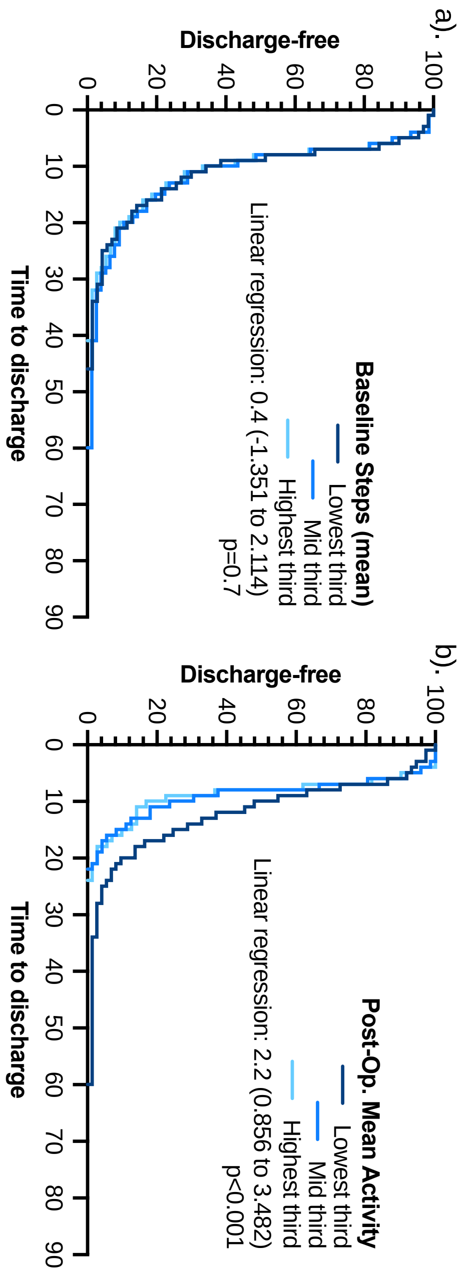

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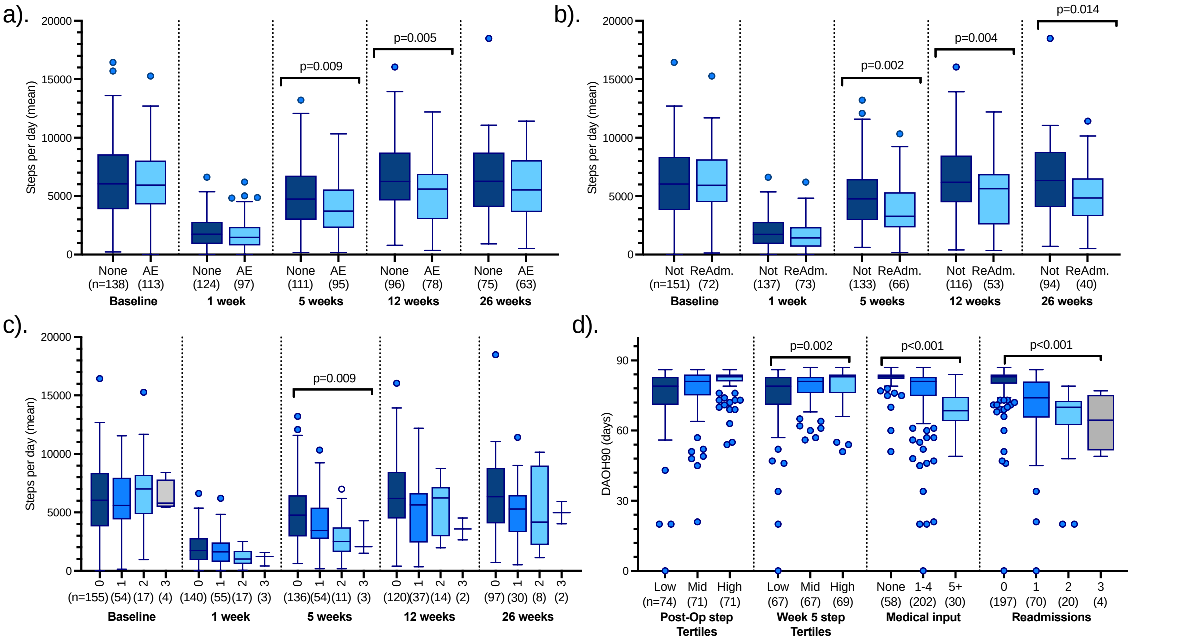

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