Time to readiness for discharge is a valid and reliable measure of short-term recovery after colorectal surgery

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Abstract

Background: Short-term recovery after colorectal surgery has been traditionally investigated through length of stay (LOS); however, this measure is influenced by several confounding factors. This study aimed to investigate the construct validity and reliability of assessing the time to achieve standardised discharge criteria (Time to Readiness for Discharge - TRD) as a measure of short-term recovery. In a secondary analysis, we compared sample size requirements for RCTs using TRD or length of stay (LOS) as outcome measures. **Methods:** Seventy patients participated in the construct validity study and 21 patients participated in the reliability study. TRD was defined as the number of days to achieve discharge criteria previously defined by consensus. Construct validity was investigated by testing the hypotheses that TRD is: longer in patients undergoing open surgery; (2) longer in patients with severe comorbities (ASA Score $\geq$ 3); (3) longer in elderly patients ($\geq$80 years); (4) longer in patients developing complications; (5) longer in patients undergoing emergency surgery and (6) shorter than LOS. Reliability was calculated by comparing measures of TRD by two independent assessors. **Results:** Five of the six hypotheses were supported by the data ($p<0.05$). Interobserver reliability was excellent ($ICC_{2.1}$ = 0.99). Sample size estimations showed that RCTs using TRD as an outcome measure require approximately 23% less participants compared to RCTs using LOS. **Conclusion:** The results of this research support the construct-validity and reliability of TRD as a measure of short-term recovery. Using TRD as an alternative to LOS may reduce sample size requirements in future RCTs.

Introduction

Postoperative recovery is a nebulous concept. There is no universally accepted definition of recovery and there are few validated tests or indices to measure this construct.[1] Studies involving inpatient surgery often classify the process of recovery in two phases: 'short-term recovery', i.e. the period of recovery between surgery and hospital discharge and 'long-term recovery', i.e. the period of recovery from hospital discharge until return to work and/or normal daily activities.[2-3] Hospital length of stay (LOS) is a common endpoint of short-term recovery in surgical studies. The validity of this measure, however, is controversial as LOS is influenced by personal and organizational factors that are not related to the construct. These include health care systems, hospital culture, surgeon's preferences, patient's expectations and availability of postoperative support. [1, 4]

An alternative measure of short-term recovery may be obtained by assessing the time to achieve hospital discharge criteria. For the purpose of this study, this measure will be referred to as 'Time to Readiness for Discharge' (TRD). Rather than indicating the exact number of days patients stay in hospital after surgery, TRD indicates the number of days patients take to achieve the stage of recovery when they no longer require inpatient treatment and are considered ready to leave the hospital. As only factors related to physiological recovery are taken into account in the assessment, this measure may be a more appropriate index of short-term recovery than LOS.[4] The concept of TRD is not new to the literature as several authors have previously assessed time to achieve discharge criteria to indicate short-term recovery.[5-12] These authors, however, applied this outcome measure in a non-standardised manner (i.e. using different criteria to determine readiness for discharge), making it difficult to compare results across studies. In addition, there is a lack of research investigating the psychometric properties of TRD so that this outcome measure can be recommended for use in research.

In the present study, we used a set of standardized discharge criteria recently defined by international consensus[13] to determine TRD in a cohort of patients undergoing colorectal surgery. Our primary aim was to assess the construct validity and reliability of TRD as a measure of short-term postoperative recovery. Secondarily, we used data from this cohort to estimate and compare sample size requirements for randomized controlled trials (RCTs) using TRD or LOS as outcome measures.

Methods

Participants

Adult patients (> 18 years) undergoing open or laparoscopic colorectal surgery in a tertiary public hospital in Melbourne, Australia, were considered for inclusion in the study. We excluded patients undergoing surgery via transanal, transsacral or perineal approaches, surgery after trauma or surgery to other organs in addition to colorectal surgery. Ethical approval for the study was obtained from the Western Health Low Risk Human Research Ethics Panel (QA 2010.25).

Procedures

Four surgeons with extensive experience in laparoscopic and open colorectal surgery performed all operations. Bowel preparation was used in patients undergoing left sided or rectal resection. A nasogastric tube was not used. Drain tubes were used only below the peritoneal reflection. Postoperative fluids and electrolytes were given according to clinical requirement. Clear liquids and carbohydrate drinks were offered on postoperative day (POD) 1. Solid food was given after the first flatus occurred, and meals were served at the bedside. Analgesic requirements were assessed daily by the hospital's pain management team. Postoperative analgesia was multimodal with the majority of patients receiving patient-controlled analgesia and transitioned to oral analgesics after diet was tolerated. Patients were encouraged to sit out of bed from POD 1 by the medical and nursing staff and mobilized as remaining tubes and catheters permitted.

For this study, readiness for discharge was considered to have been achieved when patients fulfilled all five discharge criteria defined by consensus (Table 1).[13] An assessor independent to the colorectal surgery team and therefore to decisions regarding patient management and discharge (Assessor 1) was responsible for recording the achievement of criteria using a standardized assessment form (Appendix 1). Discharge criteria were evaluated during the morning ward rounds from POD 1. TRD was calculated by subtracting the date of surgery from the date when patients achieved readiness for discharge. The clinical team was unaware of the study purpose, ensuring discharge decisions were not influenced by the proposed discharge criteria.

Demographic data (age, sex, preoperative diagnosis, ASA Score) and surgical outcome data (type of surgery, surgical access, surgery duration, complications and readmissions) were obtained from medical records. Intraoperative and postoperative complications were registered according to the criteria outlined by Lang et al (2001).[14] and classified according the Clavien-Dindo criteria.[15]

Reasons for patients staying in hospital after discharge criteria had been achieved were analysed through a qualitative thematic analysis of discharge planning notes. These notes were taken by Assessor 1 during the colorectal surgery ward rounds. The thematic analyses involved: (1) transcribing of the notes into an excel spreadsheet; (2) coding the data by highlighting each important element of the transcripts; (3) identifying of themes based on patterns observed in the codes and (4) reviewing the themes for refinement.[16] Patient medical records were reviewed if there was a significant discrepancy between TRD and LOS (>1day).

Measurement of Construct Validity

Our aim was to assess the construct validity of TRD by testing the following hypothesis:

(1) TRD is longer in patients undergoing open in comparison with laparoscopic colorectal surgery.

(2) TRD is shorter than actual hospital length of stay.

(3) TRD is longer in patients with severe comorbidities (ASA $\geq$ 3) in comparison with those with less severe comorbidities (ASA < 3).

(4) TRD is longer in elderly patients ($\geq$80 years old) in comparison with younger patients (<80 years old).

(5) TRD is longer in patients developing postoperative complications in comparison with those not developing complications.

(6) TRD is longer in patients undergoing emergency in comparison with those undergoing elective surgery.

The sample size calculation for this validity study was based upon a comparison of TRD in open versus laparoscopic colorectal surgery. We used a formula for unequal sample sizes[17] as the proportion of patients undergoing laparoscopic colorectal surgery in our institution was approximately 75%. With α=0.05 and β=0.20, considering a standard deviation of 2.4 days[5, 7,

[9] and an assumed dropout rate of 10%, a sample of 72 patients was considered sufficient to detect a difference of two days between groups.

Measurement of Reliability

We assessed interobserver reliability in a subgroup of patients who were evaluated by a second assessor (Assessor 2). Assessors 1 and 2 collected data independently, were blinded to each other's evaluations and were asked not to discuss their findings until the completion of the study. It was hypothesised that the reliability between these assessors would be excellent ($ICC_{2.1} \geq 0.75$).

Sample size requirements for the reliability study were calculated based on using an intraclass correlation coefficient (ICC).[18] With two assessors evaluating the outcome measure TRD, expecting a reliability of 0.9 and a dropout rate of 10%, a sample of 21 patients would be sufficient to detect a minimally acceptable reliability of 0.7.

Statistical analyses

Validity and reliability studies

Statistical analyses of the data were performed using SPSS software version 17.0 (Chicago, Illinois, USA). Data regarding TRD were treated as non-normally distributed as per analysis of skewness and kurtosis. Hypotheses 1, 3, 4, 5, 6 and 7 were tested using Mann Whitney U test and hypothesis 2 was tested using Wilcoxon Signed Rank test. Reliability between the two assessors evaluating TRD was calculated using the intraclass correlation coefficient ($ICC_{2,1}$), including the 95% confidence interval.[19] The degree of reliability was defined based on following criteria: > 0.75 = excellent reliability; 0.75 – 0.40 = fair to good; < 0.40 = poor.[20] Absolute reliability was calculated using the standard error of measurement ($SE_{measure} = SD\sqrt{1 - ICC}$).

Calculation of sample size requirements for hypothetical RCTs using TRD or LOS as outcome measures of short-term recovery

As a secondary aim of this study, we used variability estimates (standard deviations) of data obtained from this cohort to calculate the minimum sample size needed to conduct adequately powered RCTs comparing the effect of different interventions on LOS and TRD. This analysis followed the principles described by Wittes (2002).[21] Sample sizes were calculated based on the assumption that a hypothetical RCT should be able to detect a relative difference of one or two days in LOS or TRD.[6, 22-24] All calculations were based on a single-centre trial with no dropouts. α was set at 0.05 to control for type I error (false-positive result) and β at 0.20 to control for type II error (false-negative result). A two-sided testing was assumed. All sample size calculations were performed using IBM® SPSS® SamplePower.

Results

Seventy-two patients undergoing colorectal surgery were recruited from November 2010 to April 2011. As two patients were lost to follow up (one transferred to tertiary private hospital and one transferred into care of another team), a cohort of 70 patients were included in the analysis. Data for the reliability study were collected from 20 consecutive patients from this cohort, between February and March 2011. Demographic, operative and postoperative outcome data are described in Table 2. Data on time to achieve each discharge criterion, TRD and LOS are presented in Table 3. Thirty-five patients (50%) remained in hospital after TRD were achieved. Most of these patients (43%) were not discharged because the surgical team judged they required further time in hospital (Table 4). Specific reasons included waiting for patients to improve their general condition (27%) spend more time out of bed (20%), or pass stool (7%).

Five of the six hypotheses were supported by the data (Table 5). TRD was longer in patients undergoing open surgery (Hypothesis 1) ($p=0.01$) and shorter than LOS (Hypothesis 2) ($p<0.001$). TRD was also longer in patients with lower preoperative physical status (Hypothesis 3) ($p=0.001$), in those developing postoperative complications (Hypothesis 5) ($p<0.001$) and in patients undergoing emergency colorectal surgery (Hypothesis 6) ($p=0.01$). One hypothesis was not supported (Hypothesis 4) as TRD was found to be similar in elderly ($\geq$80 years old) and younger patients (<80 years old) ($p=0.60$).

Interobserver reliability between the two assessors evaluating TRD was excellent ($ICC_{2.1}$ = 0.99; 95% CI = 0.97-0.99). Standard error of measurement was 0.34. This indicates that, when different assessors evaluate TRD, a variation of $\pm$0.34 days can be expected with 68% confidence and a variation of $\pm$0.68 days can be expected with 95% confidence.

The standard deviations of the measures TRD and LOS were 3.45 and 3.95 respectively. Sample size estimates considering these standard deviations are presented in Table 6. Because TRD is a more precise measure (i.e. with lower standard deviation), RCTs using TRD require approximately 23% less participants to become adequately powered regardless of the effect size being assumed.

Discussion

The results of this research support the construct-validity and reliability of TRD as a measure of short-term recovery after colorectal surgery. Moreover, our results showed that using the TRD as an alternative to LOS reduces data variability (i.e. standard deviation) and, as a result, may reduce sample size requirements for RCTs assessing strategies to enhance postoperative recovery. Hence, the use of this outcome measure as an alternative to LOS may reduce research costs, decrease study duration and increase feasibility of full implementation of RCTs. Assessment of TRD is simple, practical and inexpensive. It requires a minimal amount of training and modification to clinical routine as it involves information that is commonly recorded in medical charts.

From a clinical perspective, our results suggest that the use of standardized discharge has the potential to improve the efficiency of postoperative care by decreasing medically unnecessary hospital stays. Fifty percent of the patients included in the analysis stayed in hospital after discharge criteria were achieved. This may reflect uneasiness of clinicians in discharging patients or aggressiveness of the discharge criteria proposed. This result is supported by studies by Maessen et al,[4, 25] where around 65% of prolonged hospital stays were considered clinically inappropriate. Although there are social, organizational and psychological factors that will invariably influence discharge decisions,[13] our results showed that 43% of hospital stays beyond short-term recovery can potentially be avoided by the use of specific discharge criteria. The use of standardized discharge criteria by surgical units may also be a useful tool to audit clinical practice and identify systemic issues affecting lengths of stay. [13]

The median difference between LOS and TRD found in our validity study was one day. In previous literature, this difference varied from 0 to 3 days.[5, 7-12] Differences in discharge criteria and health care environments may be the reason for this variation. Our results are also in agreement with previous research suggesting that patients undergoing open[26] or emergency surgery[27-28], with high ASA scores,[29-31] or developing postoperative complications[29-30] have slower short-term recovery.

The only hypothesis rejected in the validity study was the one stating that elderly patients (≥80 year old) have longer TRD compared to younger patients (<80 year old). Age alone may be a surrogate marker of LOS and postoperative recovery. In one of the largest cohort studies aimed at assessing recovery outcomes after colorectal surgery (n= 1035), Hendry et al (2009)[31] identified age over 80 years old as an independent predictor of prolonged time to mobilization and prolonged LOS. Our sample included only 10 patients >80 and therefore may not have been adequately powered for the comparison.

An excellent level of reliability was observed when two independent assessors measured TRD. This is reassuring that discharge criteria agreed by consensus have endpoints that are well defined and easy to assess.[13] The use of the same standardized assessment form by both assessors may also have facilitated agreement. The reliability study involved a medical (surgical registrar) and a non-medical assessor (physiotherapist), suggesting that health-care professionals from different disciplines can reliably evaluate TRD.

We were not using a full ERAS protocol at the hospital at the time of measurement. Therefore, LOS, TRD, and time to achieve each discharge criterion observed in our study were comparable to studies performed within a 'traditional care' setting but not to studies using ERAS protocols. The average LOS observed in our study was seven days compared to approximately five days in the ERAS literature.[32-33] Time to achieve discharge criteria in ERAS studies varied from three to five days[10-12] compared to six days in our study. Time to pass flatus and time to tolerate solid food was also longer in the current study in comparison to studies using ERAS (3 vs 2 days and 5 vs. 1-3 days, respectively).[10-12, 23] Although participants in our study were encouraged to mobilize from POD 1, they took an average of five days to achieve discharge criteria regarding mobilization and self-care (i.e. ability to sit up, walk, go to the toilet, dress, shower and climb stairs if needed at home). In ERAS studies the time to achieve similar criteria (e.g. mobilization as preoperative) was approximately three days.[23, 31, 34-35] This difference may be explained by the use of different protocols of early mobilization. While we did not use a standardized program to guide patient mobilization during the hospitalization period, studies using full ERAS protocols encouraged patients to stay out of bed for up to eight hours and perform up to six walks on the ward per day.[31, 34, 36-39] The time to mobilization observed in our cohort is comparable to other Australian studies where patient mobilization was not standardized.[40]

The current era of evidence-based medicine raises the need for valid and reliable methods to measure if a new treatment is better than a previously accepted one. Although widely used as a measure of short-term recovery, LOS is influenced by patient and organizational factors that do not reflect recovery and invariably add variance to the measure. As the influence of these factors will vary across hospitals and health care systems, even when studies are concordant in demonstrating a LOS benefit for a given treatment, it is difficult to assess the relative magnitude of treatment effects among studies and compare their results. The choice between LOS and TRD may have little influence on the results of studies assessing interventions with a substantial effect size (e.g. ERAS vs. standard care); however, excessive variance will increase the probability of a negative result (type II error) or considerably increase sample size requirements in studies involving interventions with smaller effect sizes. The need for more precise estimates of short-term recovery rises, for example, in studies aimed at understanding the relative contribution of different components of ERAS. The controversial results observed in RCTs investigating the effect of laparoscopic surgery,[23, 39, 41] epidural analgesia,[24, 42] optimized fluid therapy[43-44] and preoperative carbohydrate loading[45-46] might in part be explained by inadequate outcome measurement and differences in statistical power across different studies. In addition to TRD, the use validated performance-based measures of recovery (e.g. six-minute walk test[47]) and patient-reported recovery measures (e.g. Surgical Recovery Scale[48]) may also overcome the limitations involved in the assessment of LOS. Investment in developing better outcome measures of postoperative recovery may be a more cost-effective strategy to improve research quality than simply increasing sample sizes.

In the last decade, numerous studies in colorectal surgery have evaluated TRD as an index of short-term recovery.[5-12] Although this provides evidence of face validity (i.e. researchers believe that TRD measures recovery), our study is the first to formally assess the psychometric properties of this measure. A major strength of our study was its prospective use of standardized criteria agreed by international consensus.[13] This ensures that these criteria have face and content validity within an international context and, therefore, can be reproduced in future research. Data collection was contemporaneous and standardized. Consecutive patients undergoing a wide variety of colorectal surgery procedures were included to avoid sampling bias. We performed a priori sample size calculations to ensure adequate statistical power.

A limitation of this study was that patient's postoperative care was not standardized using an ERAS program, which is currently considered as gold-standard care after colorectal surgery.[32-33] A survey study by Kahokehr et al,[49] published in 2010, suggested that the uptake of ERAS programs in Australia and New Zealand has been slow. Although some components of ERAS were already in use in the institution (e.g. early mobilisation, removal of nasogastric tube in the operating room), some interventions considered important to enhance recovery, such as epidural analgesia and early oral intake, were not routinely implemented. It is possible that patients would have taken less time to achieve discharge criteria if an ERAS program had been fully applied. Evaluation of discharge criteria was made once a day during the colorectal surgery morning ward rounds. Assessments at shorter intervals (e.g. every 12 hours, or in the morning and afternoon) could have produced more precise results in regards to the day of achievement of criteria. In regards to the sample size estimates presented in this study, it is important to note that these estimates do not intend to guide sample size decisions for future RCTs assessing TRD. The intention of presenting these data was to provide a proof-of-concept of the potential sample size reductions by using TRD as an alternative to LOS.

Our study provides avenues for future research. Establishing the psychometric properties and usefulness of a measurement tool is a continuous process of investigation and development. Therefore, we encourage the reproduction of our protocol in external settings, especially in units using ERAS programmes. Our results suggest that the use of standardized discharge criteria in clinical practice has the potential to reduce medically unnecessary hospital stays. This finding encourages future studies to confirm the safety and benefits of this approach to patient discharge.

Conclusion

This cohort study involving an Australian sample of patients undergoing colorectal surgery treated in a traditional care environment supports the construct validity and reliability of TRD as a measure of short-term recovery. Using this outcome measure as an alternative to LOS has the potential to reduce sample size requirements in future RCTs. This has the potential to increase research efficiency and decrease research costs.

References

1. Carli F, Mayo N. Editorial I: Measuring the outcome of surgical procedures: what are the challenges? Br J Anaesth 2001;87:531-3.
2. MacKay G, Ihedioha U, McConnachie A, Serpell M, Molloy RG, O'Dwyer PJ. Laparoscopic colonic resection in fast-track patients does not enhance short-term recovery after elective surgery. Colorectal Dis 2007;9:368-72.
3. King PM, Blazeby JM, Ewings P, Kennedy RH. Detailed evaluation of functional recovery following laparoscopic or open surgery for colorectal cancer within an enhanced recovery programme. Int J Colorectal Dis 2008;23:795-800.
4. Maessen JM, Dejong CH, Kessels AG, von Meyenfeldt MF. Length of stay: an inappropriate readout of the success of enhanced recovery programs. World J Surg 2008;32:971-5.
5. Carli F, Mayo N, Klubien K, Schricker T, Trudel J, Belliveau P. Epidural analgesia enhances functional exercise capacity and health-related quality of life after colonic surgery: results of a randomized trial. Anesthesiology 2002;97:540-9.
6. Herroeder S, Pecher S, Schonherr ME, et al. Systemic lidocaine shortens length of hospital stay after colorectal surgery: A double-blinded, randomized, placebo-controlled trial. Ann Surg 2007;246:192-200.
7. MacKay G, Fearon K, McConnachie A, Serpell MG, Molloy RG, O'Dwyer PJ. Randomized clinical trial of the effect of postoperative intravenous fluid restriction on recovery after elective colorectal surgery. Br J Surg 2006;93:1469-74.
8. Noblett SE, Snowden C, Shenton B, Horgan A. Randomized clinical trial assessing the effect of Doppler-optimized fluid management on outcome after elective colorectal resection. Br J Surg 2006;93:1069-76.
9. Wakeling HG, McFall MR, Jenkins CS, et al. Intraoperative oesophageal Doppler guided fluid management shortens postoperative hospital stay after major bowel surgery. Br J Anaesth 2005;95:634-42.
10. Challand C, Struthers R, Sneyd JR, et al. Randomized controlled trial of intraoperative goal-directed fluid therapy in aerobically fit and unfit patients having major colorectal surgery. Br J Anaesth 2012;108:53-62.
11. Kahokehr A, Sammour T, Shoshtari KZ, Taylor M, Hill AG. Intraperitoneal local anesthetic improves recovery after colon resection: a double-blinded randomized controlled trial. Ann Surg 2011;254:28-38.
12. Levy BF, Scott MJ, Fawcett W, Fry C, Rockall TA. Randomized clinical trial of epidural, spinal or patient-controlled analgesia for patients undergoing laparoscopic colorectal surgery. Br J Surg 2011;98:1068-78.
13. Fiore JFJ, Bialocerkowski A, Browning L, Faragher IG, Denehy L. Criteria to Determine Readiness for Hospital Discharge Following Colorectal Surgery: An International Consensus Using the Delphi Technique. Dis Colon Rectum 2012;55:416-23

14. Lang M, Niskanen M, Miettinen P, Alhava E, Takala J. Outcome and resource utilization in gastroenterological surgery. Br J Surg 2001;88:1006-14.

15. Dindo D, Demartines N, Clavien PA. Classification of surgical complications - A new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205-13.

16. Braun V, Clarke V. Using thematic analysis in psychology. Qual Res Psychol 2006:77-101.

17. Machin D, Campbell M, Tan S, Tan S. Sample Size Tables for Clinical Studies. 3 ed: Blackwell Science; 2008.

18. Walter SD, Eliasziw M, Donner A. Sample size and optimal designs for reliability studies. Stat Med 1998;17:101-10.

19. Atkinson G, Nevill AM. Statistical Methods For Assessing Measurement Error (Reliability) in Variables Relevant to Sports Medicine. Sports Med 1998;26:217-38.

20. Shrout PE, Fleiss JL. Intraclass Correlations : Uses in Assessing. Rater Reliability. Psychol Bull 1979;86:420-8.

21. Wittes J. Sample Size Calculations for Randomized Controlled Trials. Epidemiol Rev 2002;24:39-53.

22. Gatt M, Anderson ADG, Reddy BS, Hayward-Sampson P, Tring IC, MacFie J. Randomized clinical trial of multimodal optimization of surgical care in patients undergoing major colonic resection. Br J Surg 2005;92:1354-62.

23. Vlug MS, Wind J, Hollmann MW, et al. Laparoscopy in Combination with Fast Track Multimodal Management is the Best Perioperative Strategy in Patients Undergoing Colonic Surgery A Randomized Clinical Trial (LAFA-study). Ann Surg 2011;254:868-75.

24. Zutshi M, Delaney CP, Senagore AJ, et al. Randomized controlled trial comparing the controlled rehabilitation with early ambulation and diet pathway versus the controlled rehabilitation with early ambulation and diet with preemptive epidural anesthesia/analgesia after laparotomy and intestinal resection. Am J Surg 2005;189:268-72.

25. Maessen J, Dejong CHC, Hausel J, et al. A protocol is not enough to implement an enhanced recovery programme for colorectal resection. Br J Surg 2007;94:224-31.

26. Schwenk W, Haase O, Neudecker Jens J, M¸ller Joachim M. Short term benefits for laparoscopic colorectal resection. Cochrane Database of Systematic Reviews 2008:CD003145.

27. Jestin P, Nilsson J, Heurgren M, Påhlman L, Glimelius B, Gunnarsson U. Emergency surgery for colonic cancer in a defined population. Br J Surg 2005;92:94-100.

28. Coco C, Verbo A, Manno A, et al. Impact of Emergency Surgery in the Outcome of Rectal and Left Colon Carcinoma. World J Surg 2005;29:1458-64.

29. Schmelzer TM, Mostafa G, Lincourt AE, et al. Factors affecting length of stay following colonic resection. J Surg Res 2008;146:195-201.

30. Rickard MJFX, Dent OF, Sinclair G, Chapuis PH, Bokey EL. Background and perioperative risk factors for prolonged hospital stay after resection of colorectal cancer. ANZ J Surg 2004;74:4-9.

31. Hendry PO, Hausel J, Nygren J, et al. Determinants of outcome after colorectal resection within an enhanced recovery programme. Br J Surg 2009;96:197-205.

32. Adamina M, Kehlet H, Tomlinson GA, Senagore AJ, Delaney CP. Enhanced recovery pathways optimize health outcomes and resource utilization: A meta-analysis of randomized controlled trials in colorectal surgery. Surgery 2010;149:830-40.

33. Varadhan KK, Neal KR, Dejong CHC, Fearon KCH, Ljungqvist O, Lobo DN. The enhanced recovery after surgery (ERAS) pathway for patients undergoing major elective open colorectal surgery: a meta-analysis of randomized controlled trials. Clin Nutr 2010;29:434-40.

34. Boulind CE, Yeo M, Burkill C, et al. Factors predicting deviation from an enhanced recovery programme and delayed discharge after laparoscopic colorectal surgery. Colorectal Dis 2011;14:e103-10.

35. Vlug MS, Bartels SAL, Wind J, et al. Which fast track elements predict early recovery after colon cancer surgery? Colorectal Dis 2012;14:1001-8.

36. Basse L, Hjort Jakobsen D, Billesbolle P, Werner M, Kehlet H. A clinical pathway to accelerate recovery after colonic resection. Ann Surg 2000;232:51-7.

37. Henriksen MG, Jensen MB, Hansen HV, Jespersen TW, Hessov I. Enforced mobilization, early oral feeding, and balanced analgesia improve convalescence after colorectal surgery. Nutrition 2002;18:147-52.

38. Holte K, Foss NB, Andersen J, et al. Liberal or restrictive fluid administration in fast-track colonic surgery: a randomized, double-blind study. Br J Anaesth 2007;99:500-8.

39. King PM, Blazeby JM, Ewings P, et al. Randomized clinical trial comparing laparoscopic and open surgery for colorectal cancer within an enhanced recovery programme. Br J Surg 2006;93:300-8.

40. Browning L, Denehy L, Scholes RL. The quantity of early upright mobilisation performed following upper abdominal surgery is low: an observational study. Aust J Physiother 2007;53:47-52.

41. Basse L, Jakobsen DH, Bardram L, et al. Functional recovery after open versus laparoscopic colonic resection: a randomized, blinded study. Ann Surg 2005;241:416-23.

42. Marret E, Remy C, Bonnet F. Meta-analysis of epidural analgesia versus parenteral opioid analgesia after colorectal surgery. Br J Surg 2007;94:665-73.

43. Bundgaard-Nielsen M, Secher NH, Kehlet H. 'Liberal' vs. 'restrictive' perioperative fluid therapy: a critical assessment of the evidence. Acta Anaesthesiol Scand 2009;53:843-51.

44. Srinivasa S, Taylor MHG, Sammour T, Kahokehr AA, Hill AG. Oesophageal Doppler-guided fluid administration in colorectal surgery: critical appraisal of published clinical trials. Acta Anaesthesiol Scand 2010;55:4-13.

45. Noblett SE, Watson DS, Huong H, Davison B, Hainsworth PJ, Horgan AF. Pre-operative oral carbohydrate loading in colorectal surgery: a randomized controlled trial. Colorectal Dis 2006;8:563-9.

46. Mathur S, Plank LD, McCall JL, et al. Randomized controlled trial of preoperative oral carbohydrate treatment in major abdominal surgery. Br J Surg 2010;97:485-94.

47. Moriello C, Mayo NE, Feldman L, Carli F. Validating the Six-Minute Walk Test as a Measure of Recovery After Elective Colon Resection Surgery. Arch Phys Med Rehabil 2008;89:1083-9.

48. Paddison JS, Sammour T, Kahokehr A, Zargar-Shoshtari K, Hill AG. Development and Validation of the Surgical Recovery Scale (SRS). J Surg Res 2011;167:e85-e91.

49. Kahokehr A, Robertson P, Sammour T, Soop M, Hill AG. Perioperative care: a survey of New Zealand and Australian colorectal surgeons. Colorectal Dis 2010;13:1308-13.

Table 1. Criteria to determine readiness for hospital discharge following colorectal surgery*

Criteria	**Endpoints to determine when criteria should be considered to have been achieved**
Tolerance of oral intake	Patient should be able to tolerate at least one solid meal without nausea, vomiting, bloating or worsening abdominal pain. Patient should drink liquids actively (ideally > 800-1000 ml/day) and not require intravenous fluids infusion to maintain hydration
Recovery of lower gastrointestinal function	Patient should have passed flatus
Adequate pain control with oral analgesia	Patient should be able to rest and mobilise (sit up and walk, unless unable preoperatively) without significant pain (i.e. patient reports pain is controlled or pain score ≤ 4 on a scale from 0 to 10) while taking oral analgesics
Ability to mobilise and self-care	Patient should be able to sit up, walk and perform activities of daily living (e.g. go to the toilet, dress, shower and climb stairs if needed at home) unless unable preoperatively

Clinical examination and laboratory tests show no evidence of complications or untreated medical problems	Oral temperature should be normal
	Pulse, blood pressure and respiratory rate should be stable and consistent with preoperative levels
	Serum haemoglobin concentration should be stable, within acceptable levels
	Patient should be able to empty the bladder without difficulty or match preoperative level of bladder function

When the criteria described above are fulfilled, the patient is considered to have reached short-term postoperative recovery and should be considered ready for discharge. Discharge may take place as soon as the patient has adequate post-discharge support (family at home, nursing or rehabilitation facility) and is willing to leave hospital. If the patient had a stoma constructed, he or his family should have received training on stoma care or had outpatient training arranged.

*Fiore, J. F. J., Bialocerkowski, A., Browning, L., Faragher, I. G., & Denehy, L. (2012). Criteria to Determine Readiness for Hospital Discharge Following Colorectal Surgery: An International Consensus Using the Delphi Technique. *Dis Colon Rectum, 55*(4), 416-423.

Table 2. Demographic, operative and postoperative outcome data

Age, years	65.9±12.0

Gender (Male/Female)	40 (57)/30 (43)
BMI, kg/m^2	27.8±4.9
ASA Score (I/II/III/IV)	8 (11)/38 (54)/22 (31)/2 (3)
Diagnosis (cancer/benign disease)	47 (67)/23 (33)
Surgery urgency (elective/emergency)	57 (81)/13 (19)
Surgical access	
Laparoscopic	38 (54)
Open	24 (34)
Other (reversal of temporary colostomy/ileostomy)	8 (11)
Type of surgery	
Right colonic resection (ileocectomy to extended right hemicolectomy)	20 (29)
Left colonic resection (left hemicolectomy to high anterior resection)	21 (30)
Subtotal/total colectomy	4 (6)
Rectal resection (low anterior resection to abdominoperineal resection)	14 (20)
Colostomy	3 (4)
Reversal of temporary colostomy/ileostomy	8(10)
Formation of stoma (yes/no)	23 (33)/47(67)
Surgery duration, minutes	180.5±76.9
Postoperative analgesia (PCA/epidural)	67 (96)/3 (4)
Postoperative complications	24 (34)
Minor (Clavien-Dindo Grade I and II)	18 (26)
Major (Clavien-Dindo Grade ≥ III)	6 (8)
Discharge destination (home/rehabilitation hospital or nursing home)	64 (91)/6 (9)
Unplanned readmission within 30 days	7 (10)

Results are expressed as n (%) or mean±SD. BMI = body mass index, ASA = American Society of Anesthesiologists, PCA = patient controlled analgesia.

Table 3. Time to achieve each discharge criterion, TRD and LOS

Tolerance of oral intake, days	5.0 (4.0-7.0)
Recovery of lower gastrointestinal function, days	3.0 (2.0-4.0)
Adequate pain control with oral analgesia, days	4.0 (4.0-6.0)
Ability to mobilise and self-care, days	5.0 (3.0-6.0)
No evidence of complications or untreated medical problems, days	4.0 (3.0-7.0)
TRD, days	6.0 (4.0-8.0)
LOS, days	7.0 (5.0-9.0)

Results are expressed as median (interquartile range), unless otherwise stated.

TRD = time to readiness for discharge, LOS = hospital length of stay

Table 4. Reasons for staying in hospital after short-term recovery had been achieved

Patient did not achieve sufficient recovery according to the surgeons' judgment (medical decision)	15 (43%)
Patient required training (or more training) to manage the stoma	7 (20%)
Absence of sufficient post-discharge support or planning	6 (17%)
Awaiting discharge by another medical team	4 (11%)
Awaiting scheduled procedure (normally performed as an outpatient)	2 (6%)
Patient not willing to discharge	1 (3%)

Table 5. Hypotheses tested to contribute evidence for construct validity of TRD as an outcome measure of short-term postoperative recovery.

Comparison	n	Median (IQR), days	Median difference (95% CI), days	p value
Open vs. Laparoscopic surgery	24 vs. 38*	6.0 (5.0-9.0) vs. 5.0 (4.0-7.0)	1.0 (0.0 – 2.0)	0.01†
TRD vs. LOS	70 (within group comparison)	6.0 (4.0-8.0) vs. 7.0 (5.0-9.0)	1.0 (0.0 – 1.0)	<0.001‡
Lower physical status (ASA ≥ 3) vs. Higher physical status (ASA <3)	24 vs. 36	7.0 (5.5-9.0) vs. 5.0 (4.0-7.0)	2.0 (1.0 – 3.0)	0.001†
Octogenarians (≥ 80yo) vs. Younger patients (< 80 yo)	10 vs. 60	6.5 (4.2-8.5) vs. 5.5 (4.0-7.2)	1.0 (-1.0 – 2.0)	0.6
Complications vs. No Complications	24 vs. 46	9.0 (6.0-11.5) vs. 5.0 (4.0-6.0)	4.0 (2.0 – 5.0)	<0.001†
Emergency vs. Elective surgery	13 vs. 57	8.0 (5.0-12.0) vs. 5.0 (4.0-7.0)	2.0 (0.0 – 5.0)	0.01†

vs. = versus, TRD = time to readiness for discharge, LOS = hospital length of stay, ASA = American Association of Anesthesiology Scale, IQR = interquartile range, CI = confidence interval

* Eight patients undergoing surgery for closure of stoma were excluded from this analysis.

† Mann Whitney U test

‡ Wilcoxon Signed Rank test

Table 6. Sample size estimates for studies using LOS and TRD as outcome measures of short-term recovery

Outcome measure	SD	n to detect a relative difference of ONE day	n to detect a relative difference of TWO days
LOS	3.95	490 (245 per arm)	124 (62 per arm)
TRD	3.45	376 (188 per arm)	96 (48 per arm)
Difference		114 (23%)	28 (22.5%)

TRD = time to readiness for discharge, LOS = hospital length of stay, SD = standard deviation