BJA

British Journal of Anaesthesia, 0 (0): 1–8 (2017)

doi: 10.1093/bja/aex250
Clinical Investigation

CLINICAL INVESTIGATION

Early mobilization programme improves functional capacity after major abdominal cancer surgery: a randomized controlled trial

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Abstract

Background: Major abdominal oncology surgery is associated with substantial postoperative loss of functional capacity, and exercise may be an effective intervention to improve outcomes. The aim of this study was to assess efficacy, feasibility and safety of a supervised postoperative exercise programme.
Methods: We performed a single-blind, parallel-arm, randomized trial in patients who underwent major abdominal oncology surgery in a tertiary university hospital. Patients were randomized to an early mobilization postoperative programme based on supervised aerobic exercise, resistance and flexibility training or to standard rehabilitation care. The primary outcome was inability to walk without human assistance at postoperative day 5 or hospital discharge.
Results: A total of 108 patients were enrolled, 54 into the early mobilization programme group and 54 into the standard rehabilitation care group. The incidence of the primary outcome was nine (16.7%) and 21 (38.9%), respectively (P=0.01), with an absolute risk reduction of 22.2% [95% confidence interval (CI) 5.9–38.6] and a number needed to treat of 5 (95% CI 3–17). All patients in the intervention group were able to follow at least partially the exercise programme, although the performance among them was rather heterogeneous. There were no differences between groups regarding clinical outcomes or complications related to the exercises.
Conclusions: An early postoperative mobilization programme based on supervised exercises seems to be safe and feasible and improves functional capacity in patients undergoing major elective abdominal oncology surgery. However, its impact on clinical outcomes is still unclear.
Clinical trial registration: NCT01693172.

Key words: rehabilitation; postoperative complications; neoplasms; early ambulation; exercise

Editorial decision: June 1, 2017; **Accepted:** July 4, 2017

Editor's key points

- Perioperative physical exercise is likely to improve postoperative outcomes, but clear evidence is lacking.
- This study found that an early postoperative mobilization programme was feasible in major cancer surgery patients.
- Early mobilization group was associated with better functional capacity, and perhaps better health-related quality of life with less postoperative fatigue.

Major abdominal oncology surgery is a prototype of surgical trauma that leads to a substantial loss of functional capacity, particularly in elderly patients. Full recovery to a preoperative state of independence may take weeks or even months.[1] Although surgery is the cornerstone of treatment to many intra-abdominal tumours, the decline in physical status caused by a surgical procedure can postpone the initiation of other adjuvant cancer therapies and impair the quality of life and patient outcomes.[2]

Early postoperative mobilization has been advocated for patients undergoing major surgery in order to improve functional capacity and to enhance recovery. However, few studies focused on demonstrating the benefits of postoperative exercise protocols implemented in patients after major surgical procedures.[3] Physical activity is associated with improvement in cardiopulmonary endurance, decreased fatigue symptoms, improved muscular strength and quality of life.[4 5] Despite potential benefits of a structured postoperative rehabilitation programme, there is still a lack of standardized postoperative rehabilitation protocols in current guidelines of perioperative care.[6]

The aim of this study was to assess the effect, feasibility and safety of an early postoperative mobilization programme on functional capacity, quality of life and clinical outcomes in patients undergoing major abdominal oncology surgery.

Methods

We performed a single-blind, parallel-arm, randomized trial in patients undergoing major abdominal oncology surgery in a single tertiary university hospital dedicated to cancer treatment. The study was conducted in accordance with the International Conference on Harmonization Good Clinical Practice and was approved by the local ethics committee (Comitê de Ética e Pesquisa da Faculdade de Medicina da Universidade de São Paulo, Brazil). Written informed consent was obtained from all patients or their legal surrogate. The study protocol was registered at ClinicalTrials.gov as NCT01693172.

Study population

We screened patients older than 18 yr scheduled to undergo elective major abdominal surgery for cancer treatment and managed perioperatively conforming to enhanced recovery principles as detailed in the Supplementary material. Major abdominal oncology surgery was defined as a procedure involving the gastrointestinal, gynaecological or urinary tract with an expected duration greater than 90 min. Exclusion criteria are detailed in the Supplementary material.

All patients were assessed for eligibility on the eve of surgery by a physician specialized in physical medicine and rehabilitation (physiatrist) who analysed the ability to walk without assistance, muscle strength and lack of neurological or cardiovascular condition, which would preclude exercise. Written informed consent was obtained.

Randomization

Eligible patients were randomly assigned in a 1:1 ratio to one of the two postoperative exercise programmes: an early postoperative programme based on supervised aerobic exercise, resistance and flexibility training or a standard rehabilitation care. The medical staff contacted the study randomization centre to register the patient and to be told which group the patient was allocated to. To avoid loss of concealment, the group to which the patient was allocated could only be accessed after registration in the study randomization centre. Allocation numbers were derived from a computer-generated non-blocked random number list prepared by the chief statistician, placed in opaque envelopes and opened sequentially to determine the treatment group of the patient. The patients, outcome adjudication committee and the investigators who classified outcomes and conducted the follow-up telephone assessments were blinded to the study-group assignments and had no access to the groups of treatment.

Assessment before exercises

Before and during the period of exercises, all patients included in the study were assessed daily by the physiotherapist regarding core stability, stability at orthostatic position, and upper and lower extremities grade of muscle strength. Core stability was defined as the ability of the patient to sit erected for at least 1 min. Stability at orthostatic position was defined as the ability of the patient to stand up (without support or swaying) for at least 1 min without development of symptoms of impending syncope (e.g. light-headedness, dizziness and nausea) or haemodynamic changes (heart rate increase >30 beats min^{-1} above supine baseline or by a systolic blood pressure decrease of >20 mm Hg). Muscle strength was graduated according the Muscle Strength Grading Scale (Grade 0 to 5).[7]

Treatment protocol

The early mobilization programme consisted of a set of exercises (core stability and orthostatic training, gait training, aerobic and resistance training) implemented according to the level of functionality or mobility of the patient (Fig. 1). The programme started from postoperative day (POD) 1 and lasted until hospital discharge with two sessions every day. A complete description of the treatment protocol is in the Supplementary material and in a concise form represented in Fig. 1.

Standard care

The standard rehabilitation care was composed of a set of exercises that started on POD 1 and continued until hospital discharge or walking independence. The programme was performed once a day and consisted of core control training, orthostatic training for patients with total core control and lower extremity muscle strength grade >3, gait training and passive or active range of motion exercises.

Outcome measures

The primary outcome was defined as the inability to cross the room or to walk the distance of 3 m without human assistance,