Validity and reproducibility of practical performance-based tests to estimate aerobic capacity in patients scheduled for elective colorectal surgery

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We aim to determine the validity of the steep ramp test as practical performance-based aerobic capacity test in patients undergoing elective colorectal resection by correlating the tests* scores with the ventilatory anaerobic threshold and oxygen…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal neoplasms malignant and unspecified
Study type	Observational non invasive

Summary

ID

NL-OMON55879

Source
ToetsingOnline

Brief title
Usefulness of practical tests to estimate preoperative aerobic fitness

Condition

- Gastrointestinal neoplasms malignant and unspecified

Synonym
bowel cancer, Colorectal cancer

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit Maastricht

Source(s) of monetary or material Support: Five4Five startsubsidie van het Kankeronderzoeksfonds Limburg (KOFL)

Intervention

Keyword: Abdominal surgery, Aerobic capacity, Preoperative risk stratification

Outcome measures

Primary outcome

The primary objective is to determine the criterion validity of the steep ramp test to estimate the ventilatory anaerobic threshold and oxygen uptake at peak exercise attained during maximal cardiopulmonary exercise testing in patients undergoing elective colorectal surgery, by evaluating the correlation of the primary outcome measure of the steep ramp test (achieved peak work rate) with the ventilatory anaerobic threshold and oxygen uptake at peak exercise as measured directly during cardiopulmonary exercise testing preoperatively in these patients.

Secondary outcome

The following secondary objective will be addressed for the purpose of obtaining more insight into the validity of the steep ramp test. The differences of scores of the steep ramp test between relevant patient subgroups will be tested to assess discriminative validity of the test.

Study description

Background summary

The primary treatment for colorectal cancer is surgical resection of the tumor. Undergoing major surgery is like running a marathon, and requires an optimal physical fitness of patients in order to cope with the surgical stress and

hospitalization. Preoperative aerobic capacity, measured during cardiopulmonary exercise testing, has been found to have a consistent positive relation with postoperative outcome in elective major intra-abdominal surgery (e.g. less morbidity, shorter length of hospital stay, and lower mortality). Hence, cardiopulmonary exercise testing can be used to identify patients with an increased risk for postoperative morbidity, an increased length of stay and/or an increased mortality risk. Preoperative exercise training of high-risk patients to improve their aerobic capacity (prehabilitation) is beneficial for preventing peri- and/or postoperative complications, reducing morbidity/mortality, and facilitating a swift return to an adequate performance of activities of daily living. However, performing cardiopulmonary exercise testing - requiring respiratory gas analysis measurements - is sometimes not feasible due to the expense, the need for special equipment, and the required trained staff. Therefore, the use of practical and inexpensive alternative performance-based aerobic capacity tests might increase the incorporation of objectively measured exercise capacity to estimate aerobic capacity for preoperative risk strati*cation. The steep ramp test and 3-minute step test might be useful, non-sophisticated, alternative performance-based tests, to estimate aerobic capacity as measured during cardiopulmonary exercise testing. This has not yet been investigated in patients opting for elective major intra-abdominal surgery, while accurate assessment of aerobic capacity in patients opting for major intra-abdominal surgery is crucial for identifying high-risk patients with a low aerobic capacity, as these patients might benefit from prehabilitation to decrease postoperative health- and functioning-related problems. Easy-to-perform performance-based aerobic capacity tests (steep ramp test and 3-minute step test) might thus be cost-efficient alternatives for more expensive and complicated laboratory aerobic capacity tests (cardiopulmonary exercise testing). These alternative tests are readily implementable in clinical oncology practice and can be invaluable for preoperative screening to guide individual patient management for the purpose of improving postoperative outcomes and prognosis.

Study objective

We aim to determine the validity of the steep ramp test as practical performance-based aerobic capacity test in patients undergoing elective colorectal resection by correlating the tests* scores with the ventilatory anaerobic threshold and oxygen uptake at peak exercise attained during maximal cardiopulmonary exercise testing on a cycle ergometer as gold standard test.

Study design

Cross-sectional study design. All patients will preoperatively perform the steep ramp test as part of usual care (regular hospital visit), whereafter only study participants will perform cardiopulmonary exercise testing in the context of the study (no extra study visit).

Study burden and risks

There will be no direct benefits for patients participating in this study. Patients gain insight in their physical fitness and as part of usual care will receive preoperative advice after the last study procedure about the importance of preoperative physical fitness and physical activity in relation to the risk for morbidity and recovery of physical functioning postoperatively. Moreover, in an extension of their regular care visit (preoperative assessment of physical fitness) of one hour at maximum, participants help to optimize perioperative care for future patients. Risks associated with participation are considered negligible. Exercise testing will be performed under controlled conditions and under the guidance of specifically trained employees and under supervision of a sport physician. All non-usual care measurements are non-invasive. Nevertheless, we realize that participation might be a burden for every patient.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a potential participant must meet all of the following criteria:
- patients, males and females, >18 years of age, newly diagnosed with colorectal cancer (stage I-IV);
- patients who undergo elective colorectal surgery at the Maastricht UMC+;
- patients without contraindications for exercise testing (physical activity readiness questionnaire);
- patients who gave informed consent to participate in this study.

Exclusion criteria

A potential participant who meets any of the following criteria will be excluded from participation in this study:
- patients undergoing acute (emergency) surgery;
- patients undergoing neoadjuvant therapy in the time between the usual preoperative screening of physical fitness (usual care) and the study visit;
- patients with a medical status that contraindicates exercise or exercise testing;
- patients with morbid obesity (body mass index >35 kg/m2);
- patients who are unable to perform exercise testing at a cycle ergometer (for cardiopulmonary exercise testing and the steep ramp test), as well as patients who are unable to perform the 3-minute step test;
- patients who are unable to cooperate with the testing procedures (e.g. insufficient understanding of the Dutch language).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	21-02-2020
Enrollment:	56
Type:	Actual

Ethics review

Approved WMO Date:	25-09-2019
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	04-06-2021
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	14-05-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL69473.068.19