Virtual Prehabilitation of Surgical Cancer Patients in Times of the Covid-19 Pandemic

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Table of Content

Study purpose and rationale

In light of the coronavirus (COVID -19) pandemic, the World Health Organization has warned of the possible loss of cancer surgery over the next 8 months and risk of death of many of these patients awaiting surgery dates. The pandemic has a major impact on everyday life of these patients, such as social distancing and physical isolation resulting in decline of physiological and psychological reserves. Lack of physical activity can lead to autonomic impairment and rapid loss of lean body mass and muscle strength (1). The psychological impact includes anxiety and depression, which in older people may contribute to cognitive decline or dementia. In addition, patients presenting for cancer surgery tend to have more comorbidities associated with reduced physical fitness and moderate-to-high levels of malnutrition. Such deterioration in health can progress even further, leading to cancer treatment-related complications and delayed surgical recovery (2). Interventions aimed to mitigate these side effects and engage patients to be resilient, while increasing their physiological fitness are crucial to improving clinical trajectories and are particularly relevant at this time given the current global pandemic (3).

Prehabilitation, a process of engaging patients to enhance their functional capacity before surgery with the aim to enhance tolerance to the physiological stress of surgery and recovery, has been shown to improve physical fitness, reduce length of hospital stay, improve health-related quality of life and reduce postoperative complications, with evidence of reducing healthcare costs. Prehabilitation has been shown to be more effective at improving exercise capacity than rehabilitation, moreover the benefits of prehabilitation are sustained postoperatively. Several studies from the Peri-Operative Program (POP) of the McGill University Health Centre (MUHC) on prehabilitation for cancer patients have shown improved recovery, earlier return to baseline functional capacity, reduced severity of complications, prolonged 5-year disease-free survival. This is a salient time to empower our participants in taking care of their health before and after surgery (4).

The Prehabilitation POP program of the MUHC includes personalized exercise training (aerobic, resistance, flexibility and balance), nutritional optimization and supplementation, emotional and psychological support, and behavioural changes (alcohol and smoking cessation) (5). The multidisciplinary POP team includes anesthesiologists, surgeons, internists, geriatricians, nutritionists, exercise physiologists, psychology-trained personnel, volunteers, graduate students. Over the last 10 years over 500 cancer patients have been included in several POP randomized controlled trials on the effect of home-based and supervised prehabilitation.

The present QI proposal has been set up in response to the reaction from our cancer patients enrolled in RCTs when we had made the decision on March 13th to close the Prehabilitation Clinic. Our participants were devastated when we informed them that the trials and the referrals from surgeons to the prehabilitation clinic were being paused. We continued to call them at home on a weekly basis and a majority of them continue to exercise, eat well and relax. A telephone line was opened to them in case they needed additional support. Our kinesiologists, nutritionists and psychosocial personnel have been able to provide support remotely. Support provided via telephone, however, has limitations: firstly, it limits the social component of seeing someone, as patients don't see the healthcare providers, and secondly, it is not feasible to recruit or to administer a prehabilitation through telephone-delivery, without seeing patients beforehand.

A recent study by Cherid et al.(2020 (6)), reported that elderly populations were increasingly knowledgeable in the use of technologies, with significant satisfaction from both patients and clinicians (7). Therefore, distanced delivery of health interventions with proper technological support to patients could enable prehabilitation staff to address the limitations previously

mentioned. The current study proposes the use of two technologies that have been discussed in the literature: a videoconferencing application and a training watch. Videoconferencing has proven to be effective in the delivery of rehabilitation after surgery (8) and have positive effects on patients' recovery. Videoconferencing has further proven to be feasible to deliver nutritional and psychological counseling (9,10). Additionally, with the technological advancements, trainings watch can now provide many tools to helps users be more aware of their daily habits in order to improve their lifestyle. Quantifying their sleep (11), relaxation time, physical activity (12) or inactivity (13) can help patients to obtain objectives.

There is a general concern that the backlog of cancer patients waiting for surgery during this period is going to increase and the general impact on patients isolated in their homes is going to cause potential physiological and psychological impairments. Therefore, we propose a distanced-delivered personalized home-based prehabilitation program to all cancer patients scheduled for surgery at the MUHC. The program will be delivered by qualified professionals, supported by technology provided by POP, to all cancer patients waiting for surgery, addressing the patients' risk factors in patients' pandemic reality perspective. Participant contacts will primarily occur virtually using technologies such as video conferencing and digital applications. This will enable us to continue to support people with cancer and deliver safe remote counseling by specialist healthcare providers in their own homes, whilst adhering to the Governmental guidelines on social distancing, self-isolation and shielding.

Aims & Hypothesis

1. To assess the feasibility of a distance-delivered prehabilitation program to oncologic surgical candidates in light of the current global pandemic.

2. To measure the effect of technology-supported prehabilitation on preoperative and postoperative functional capacity and clinical outcomes

3. To qualitatively investigate the impact of distance-delivery of prehabilitation on health-related quality of life, anxiety and depression, which may be exacerbated by the current global phenomenon.

It is hypothesized that distance-delivery of prehabilitation will be feasible if it provides comparative adherence and completion rates to internal data from pre-pandemic home-based programs of 71% (5)and 66% (ClinicalTrials.gov Identifier: NCT03361150), respectively.

Description of study population

Patients

Study Group: 100 patients on the waiting lists to undergo elective thoracic and abdominal surgery, initially at the Montreal General Hospital (MGH). Approximately 500 patients are operated at the MGH for lung, esophageal, stomach and colorectal cancer surgery per year.

Patients will be screened by the medical research team for health conditions that would prohibit participation in the program, at any moment prior to their surgery.

Inclusion criteria:

- Adults scheduled for elective cancer surgery that is delayed due to COVID-19 referred by a surgeon;
- Covered by the RAMQ

- Have medical clearance to exercise (as provided on the physician referral);
- Are able to understand English or French.

Sample Size

A convenient sample size of 100 cancer patients is based on the evaluation of adherence to the home-based virtual prehabilitation program. In a previous home-based study, we reported an adherence rate to prehabilitation of 78%; n = 38 (14) prior to surgery. We assume that the adherence rate in the present study will not be inferior because, despite being isolated at home, patients will have access to a video and a watch to encourage them to be active and engaged in the program. In consideration of Covid-19, we will start by enrolling 10-15 patients to determine which issues might be generated (problems with the internet, change in surgical wait list, drop out). As per our experience we expect 20% refusal to participate and 20% loss to follow-up.

Standards of Care & Hospital Procedures

MUHC Standard of Care During Pandemic

The standard of care is currently compromised given the global COVID-19 circumstances. As a result, the quality of care provided to surgical candidates is restricted.
Many surgeries have been postponed indefinitely, largely due to the restrictions imposed on allowed volume of surgeries performed per day. Currently, more than 100, 000 patients have been placed on surgical waitlists across the country(15). This number is expected to continue to rise with new patients diagnosed each day. As a result, many patients have been provided with an alternative neoadjuvant therapy, however, remain uncertain of when they will receive the curative surgery that they require.

Between diagnosis and surgery patients are encouraged not to visit the hospitals due to their compromised health status and the increased risk it might impose of potential exposures. Patients therefore have limited access to perioperative supportive care between diagnosis and surgical recovery.

Contrary to the pre-pandemic period, patients are not being seen by nurses and anesthetists in the pre-operative assessment clinic, and therefore do not receive the same quality of care preoperatively. Further, postoperatively, patients are confined to their rooms and not permitted to ambulate the corridors and visits by healthcare professionals are restricted.

In order to promote a safe hospital environment, patients are asked to come in the day before surgery to perform a precautionary test to identify if they are positive carriers of the COVID-19 virus. This beside the visit at the clinic when the surgeon will finalize the suitability for surgery.

Design and description of methodology

Quality Improvement (QI) study

This QI study will include one group of 100 patients who will receive distance-delivered support for all components of the home-based prehabilitation regimen in addition to 2 months of follow-up post-surgery. The program will include: exercise, nutrition, mental well-being and, if needed, smoking cessation. The technologies (a tablet and an active lifestyle watch) will be used to provide counselling, educate patients on lifestyle modifications and assess adherence remotely. Telephone calls will also be made on a weekly basis, if participants were unable to attend their video-conferencing counselling sessions.

Recruitment

Surgeons will mention that the study coordinator and the prehab team will contact and explain the nature of the study. If the patient is in agreement, he or she will then receive a phone call from a

prehabilitation team member to inquire about their interest in the project (discussion during which the project will be explained) and the available technologies (internet & technologies accessibility). Additionally, an appointment will be made for the drop-off of the required material and initial assessment (via videoconferencing). Baseline will be done within the following week. Two copies of the consent form will be signed during the initial assessment (if at the hospital) or during the the drop-off (if assessment done via videoconferencing), in a way that respects social distancing and other measures recommended by public health agencies and Centre de coordination des mesures d'urgence (CCMU) of the MUHC. The baseline evaluation is conducted by the physician, the kinesiologist & the nutritionist.

Evaluation process

Once the program has been explained to the patient and consent has been obtained by the prehabilitation team, together they will agree on a day in the following week for baseline evaluation. Baseline and subsequent evaluations will be conducted either in clinic, or over videoconference, depending on the evolving recommendations from the Public Health Authorities and CCMU of the MUHC. The duration of the evaluation will take approximately half an hour and will assess functional tasks such as, if possible, a patients' abilities to walk, stand up from a chair, in addition to answering several questionnaires. All components of the evaluation will be explained in advance to the patient, in order to assess level of comfort towards the tasks. If a patient does not feel comfortable executing any of the tasks, the latter task will not be done. The baseline evaluation will be followed by a 45 minutes technical workshop on the different pre-set applications and educational video content available on the tablet and the training watch, Polar watch (16). The patient will receive the multidisciplinary program following the initial evaluation up until surgery: the counseling with the healthcare providers will be done at home through the use of the tablet, and adherence to the different parts will be assessed with both survey and data from the Polar watch. Therefore, the patients will only have to come to the hospital for essential medical appointments. Patients will perform assessments at four time points, at baseline, 24 hours prior to surgery, in addition to 4- and 8-weeks after surgery.

Program Administered

The current project aims to improve the quality of care delivered to oncologic surgical candidates during the COVID-19 pandemic. The program for the current study will consist of two parts, the first being individual counselling with different healthcare professionals, the second component would be a home-based prehabilitation program.

The healthcare providers available for participants' respective needs include exercise physiologist, nutritionists and psychosocial personnel who would contact patients via phone, and a videoconferencing platform (Zoom(17)) if possible, facilitated by the use of the tablet.
Exercise physiologists will follow-up with patients regularly throughout the continuum of care (before and after their surgery(14)) and refer them to the relevant specialists as needed.
The patients will also have access to premade videos prepared by POP to provide additional support in their application of the preoperative recommendations: physical activity (aerobic, resistance, and flexibility), nutrition optimization (healthy eating, improving protein and energy intake, portion size, glycemic control), psychological exercises (breathing exercise, relaxation, imaging, visualization) and smoking cessations. These videos will be available to the patients on their tablet, in addition the exercises will be demonstrated in the booklets.

Exercise Recommended Program

As previously discussed, patients' mobility and capacity to undertake exercise will be evaluated before establishing the personalized exercise program. They will receive explanations of the program and their adherence to the latter will be monitored using a Polar watch. Patients will be instructed on how to perform aerobic exercise at home, by either walking or cycling initially at 50% of the calculated heart rate reserve for a cumulative minimum target of 30 minutes per day

(minimum bouts of 10 minutes), five times per week. Exercise volume or intensity will be increased in stepwise increments by 10% each week, if tolerable. Resistance training will also be encouraged, and patients will be asked to complete a series of 8 exercises targeting the major muscle groups three times per week. The exercises will be performed using bodyweight and/or elastic band until volitional fatigue. Patients will be asked to perform 8-12 repetitions of each exercise for a total of 2-3 sets.
Physical safety will be addressed by, firstly, before establishing recommendations exercises, evaluating the patient's functional capacities. This ensures the safety of every participant in their physical activity program done at home.

Nutritional Component: Supplementation and Follow-ups

The patients' nutritional status and dietary intake will be assessed by the nutritionist. The dietician will use basic anthropometrics and laboratories, in addition to a nutritional screening tool (PGS-GA) to help them assess a patient's dietary needs and extent of nutritional disparity. All patients will receive daily dietary supplements of whey protein. Special precautions will be considered if patients have specific medical conditions (e.g. diabetes). The supplementations will be given at the initial drop-off.
Nutritionist assessment and recommendation will be made through video-conferencing application within the first week of enrolment. Additional counselling sessions will be possible through videoconferencing, depending on patients' needs. Furthermore, to assess adherence to the nutritional recommendations, the patient will be instructed to take pictures of their food at once per week. These pictures will be sent to the dietician.

Psychological Component

Not surprisingly, patients recently diagnosed for cancer and awaiting major surgical resections often experience high levels of anxiety, depression and emotional distress. This can be further exacerbated when surgeries are delayed for reasons outside of their control. Since both anxiety and depression can influence patient motivation and willingness to adhere to clinical interventions, psychological strategies can be an important element in the cancer care continuum and help patients to cope with the stress of the disease and surgery. For this reason, patients will have access to a total of 1.5 hours of mental relaxation and coping mechanisms program within the first week of enrolment, using videoconferencing. However, given that patients experience varying degrees of emotional distress, more sessions will be provided as needed. In the first session with the psychologist trained personnel, the first hour will address the patient's anxieties, coping strategies, and post-operative expectations, with the goal of optimizing psychological well-being & ways of coping with surgery. The importance of the patient's active participation in the healing process will also be discussed. The last thirty minutes will be devoted to teaching relaxation techniques and breathing exercises. Patients will be given relaxation exercise recordings on the tablet to practice at home. Further, the adherence to the psychological well-being recommendations will be assessed through the Polar watch which will provide the information about frequency and duration of the home relaxation, deep breathing and positive thinking self-administered exercises, goal-based on discussion at the first counseling.

Lifestyle modification Component

Patients with smoking habits will be able to meet with a respiratory specialist through videoconferencing. The respiratory specialist establishes recommendations and will contact the physician for the recommended smoking cessation protocol. Moreover, the respiratory specialist will explain the use of the Inspiratory Muscles Trainer (IMT) to be done at home. The patient will be instructed to use the IMT every day, for a minimum of 2 series, each consisting of 30 breaths each. Weekly improvement will be assessed through the home-based videoconferencing.

Material for participants

In addition to the standard material provided in previous prehabilitation studies (booklet, nutritional supplement, relaxation recording, elastic band & IMT device), patients in this cohort will have access to two technological tools.

The two tools are used to assess adherence to the different parts of the program: 1. a Polar watch and 2. a tablet which will be loaned to them for the duration of the study with their respective chargers.

1. The Polar watch will allow them to monitor their heart rate, and physical activity volume and intensity during the aerobic and resistance training, in addition to daily activities. Then this information will be sent to the exercise physiologist. In addition, it provides a step counter which will help set goals for the patients and monitor the progress by the prehabilitation team.
2. The tablet will create a platform of communication between the patient and the multidisciplinary prehabilitation team. On the tablet provided with data (internet access), patient will have access to: a) reference videos about the different aspects of their prehabilitation program, b) videoconferencing and chat application to communicate with the family and healthcare professionals (zoom), c) a calendar to remind them of counseling appointments, d)a daily 3-questions survey concerning adherence, e) an application to track their physical activity progress, f) audio recordings for the relaxations and coping exercises, g) questionnaires and tools for baseline, preoperative assessment and post-operative follow-ups. We will contact the MUHC IT department to format the tablets (with their content and applications) in order to ensure that all material has the same settings with the right security settings applied.

Definition of endpoints

Feasibility and timeline

Approximately 500 thoracic and abdominal resections are performed annually at the Montreal General Hospital. If 75% of patients are eligible, and 75% of them agree to participate, we would enrol, approximately, 3 patients each week (30-45 weeks for enrolment). Thus, one year and half period is feasible for completion of this project.

Facilities available

The investigator is located at the Montreal General Hospital. The project will be run at the human performance laboratory in the Department of Anesthesia at the Montreal General Hospital. This lab is staffed by exercise physiologists, a nutritionist, research assistants and anesthesia fellows.

Measurements and study instruments

Outcome measures

All outcomes will be captured via patient chart review, self-report questionnaires, data collected from the Polar watch and digital surveys. Chart review outcomes include length of hospital stay, surgical and postoperative complications.

Primary outcome

The primary outcome of the current study is to assess the feasibility of distance-delivery of Prehabilitation to these high priority cancer patients using a digital platform. In order to ascertain if the program was feasible, the evaluation criteria included quantitative measures such as recruitment rate, adherence to program (self-reported measures and crude data from the polar), program completion rate, frequency of technological failures, adverse events, in addition to qualitative measures such as rational for refusal to participate, low compliance and drop-outs.

Secondary outcomes

Functional outcomes

A part of the secondary outcomes of the study include evaluating the impact of the program on patient functional capacity, assessed by a 30 second sit-to-stand, time-up and go (TUG), in addition to a 2- or 6-minute walk (18,19) test when possible. The above-mentioned assessments are used in a variety of clinical settings to quantify patient functional capacity and facilitates the identification of higher risk surgical candidates.

Nutritional and Metabolic Status

Nutritional status will be assessed at baseline, preoperatively and postoperatively. Several measures including body mass index (BMI), recent unintended weight loss over the preceding three months (> 10%), CRP, and serum albumin < 35 g^{-1} will be used to define poor nutritional status. The MUHC Abridged-Scored patient-generated subjective global assessment (PG-SGA) will also be used as a complementary nutritional assessment tool to identify patients at a high risk of malnutrition and monitor changes throughout the course of the perioperative period.

Sleep Quality

The current study will also investigate the impact of a multidisciplinary prehabilitation program on sleep duration and quality. The Polar watch will provide the research team with the approximate duration of sleep and patient's satisfaction of their sleep on a nightly basis. A supplementary questionnaire, the Pittsburgh Sleep Quality Index (PSQI), will be given to participants to obtain information on their quality of sleep.

Self-reported outcomes

In order to evaluate overall patient health status and health-related quality of life, they will be asked to complete self-reported questionnaires that measure: physical activity (Duke Activity Status Index; DASI), quality of life (EQ5D), the Hospital Anxiety and Depression Scale (HADS(20)), distress thermometer, the WHO Disability Assessment Schedule v2.0 (WHODAS), and the energy expenditure (CHAMPS)(21,22).

Surgical outcomes

Surgical outcomes information will be taken for patients' medical files. Postoperative complications will be recorded and scored using the Clavien-Dindo Classifications(CDC) and the comprehensive complication index (CCI) (23). 30-day mortality will assess the number of deaths within the first 30 days post-surgery. Length of intensive care stay will be assessed as the number of hours from arrival to the unit. Days with a chest tube will be assessed as the number of days and hours for the last day, if applicable. Length of Hospital Stay will be assessed as a number of post-operative hours until discharge.

Potential confounding variables

The current study will investigate a diverse patient population. A large degree of variability is to be expected in the observed functional and clinical outcomes. Several factors are known to affect patient prognosis and recovery, among them baseline BMI, smoking status, comorbidities (CCI), type of cancer, neoadjuvant therapies (type and duration) and duration of the prehabilitation program. Therefore, the current study will investigate the impact each factor on the reported outcomes.

Data analysis plan

All measures will be recorded at baseline (beginning of prehabilitation period; T0), within the 24 hours prior to surgery (end of prehabilitation period; T1) and further at 4- (T2) and 8-weeks (T3) follow-ups after surgery.

Descriptive analyses will be used to compare demographics, and baseline functional and pathological state. Mean and standard deviations will be reported when data is normally distributed, as parametric analyses will be selected

To assess feasibility, the recruitment, completion and adherence rates were computed. A one-sample one-sided z-test test will be performed on the adherence rate of participants with a set threshold of 71%, based on the internal historical data.

The change in functional outcomes, nutritional status, and self-reported outcomes parameters will be analyzed using paired z-test comparing means from pre- (T0) and post-tests (T1, T2 & T3). Addition analyses will include achieving the 80% adherence rate and dichotomous surgical, functional, nutritional, and self-reported variables (presented as percentages) to be compared using chi-square (or Fisher exact) testing.

To appraise the strengths of correlation at the different time points throughout the observation period, robust repeated measures modeling with linear mixed models will be applied, which accounts for the repeated nature of the continuous measurements (ANOVA).

These calculations will be performed using the PASW Statistics software version 24.0, with confidence interval and significance level preset at 95% and 0.05, respectively. (SPSS Inc, Chicago, Illinois).

Details on confidentiality

Confidentiality

The technologies used in this project, e.g. Zoom videoconferencing and Polar watch applications, use confidential information (email, name), patients will receive the material (tablet and watch) with already pre-set accounts from the IT department of the MUHC, coding their identity fully (where both name and email will be coded). Patients will be encouraged to read the Privacy Notices for both Polar and Zoom applications. Further, the Polar Ignite watch has a GPS which records location and distances travelled when activated during cardiopulmonary trainings sessions. This information will be disclosed to patients, as it may play a role in patients' willingness to participate.

Data Collection, Storage & Security, Handling and Record Keeping

The research coordinator (Bhagya Tahasildar, MD.) and PI (Francesco Carli) will assign identifiers to each study participant. These identification numbers (ID: PPP1 to PPP100) will not contain any Protected Health Information (PHI) (e.g., social security number, medical records number, etc.).
The information collected for the purpose of the research study will be kept strictly confidential and locked in a cupboard within a locked room in the Prehabilitation Clinic at MGH. All staff, including students, have signed a confidentiality agreement. The password-protected computer where data is entered is located in a locked room and not accessible to patients and external members of the hospital.

Since the tablets will be provided with an internet data and connection, the cookies will be disabled by the IT department of the MUHC. Additionally, patients will be asked to close their internet browser after each counselling appointment in order to maximize privacy and data protections.
All information (demographic, clinical, patient-reported questionnaires and adherence data) will be entered and managed in Redcap, a secure clinical trials management system. Data will be stripped of any identifying information (name, address) and each subject will be assigned a study number. All of the information obtained will be treated in a confidential manner.

Study investigators, approved staff, collaborators and local IRB will have access to review records for research, quality assurance, and data analysis.
Data collected before the moment where participants express their wish to stop participating, or where participants are lost in follow-up can be analyzed in a confidential manner, unless otherwise specified by the participants.

Following closure of the study, the principal investigator will maintain all study records in a safe and secure location for seven years, as specified by local regulations. The records will be accessible to allow for appropriate audit and investigations.

Statement on ethical considerations

The study will be submitted to the McGill University Health Centre Ethics Board for approval. Three studies on prehabilitation (see Background, above) were approved and completed by our team in our institution (McGill University Health Centre-Montreal General Hospital Research Ethics Committee REC#02-053, #09-284).

Other support
Our group has received a research grant from the MGH foundation and the Peri-Operative Program (POP) Foundation to support this project.

Registration
The proposal will be registered for Clinical Trials.

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