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SINGLE-CENTER, SINGLE-BLIND, RANDOMIZED CONTROLLED STUDY OF PREOPERATIVE REHABILITATION BUNDLE IN THE FRAIL AND ELDERLY UNDERGOING ABDOMINAL SURGERY – PHYSIOTHERAPY PROTOCOL

1. Physiotherapy Measurements at Baseline
   All subjects will have baseline measurements done at the Preoperative Evaluation Clinic and repeated on the morning of surgery, in the operating theatre.

   1.1. Respiratory Muscle Strength
   The assessment if respiratory muscle strength will be carried out as described by the 2006 American Thoracic Society (ATS) / European Respiratory Society (ERS) statement on Pulmonary Rehabilitation[1]. The respiratory muscle strength is assessed by measuring the maximum inspiratory (MIP) and maximum expiratory pressures (MEP) using a MicroRPM^{TM} respiratory pressure meter.

   The participant is placed in the sitting position and a nose clip is applied. He is then instructed about the maneuvers required for the test and told about the importance of preventing an air-leak around the seal. To measure the MIP, the patient is asked to exhale completely and inhale as deeply as possible. The largest negative pressure is then recorded as the MIP. To measure the MEP, the patient is asked to inhale completely and then exhale as forcefully as possible. The maximum recorded pressure is then recorded as the MEP. A total of three consecutive measurements are performed with 1-2 minutes of rest in between. The difference between the values should not exceed 10% for each repetition and the last value should not be the highest. For the analysis, the largest values will be used.

   1.2. Peak Cough Flow
   Peak cough flow (PCF) is an indirect way of measuring the airway resistance and it is an effort-dependent parameter. It will be measured using a Peak Flow Meter as previously described by Agrelli et al.[2] Three consecutive measurements will be obtained with 1-2 minutes of rest in between. For analysis, the highest value will be used**.**

2. Pre-op Physiotherapy Protocol
   2.1. Patients randomized to Intervention group will receive standard supportive education component (as per the control group) as well as an instruction session for the use of the Inspiratory Muscle Trainer (IMT) from a physiotherapist.

   2.2. Device – Each participant in the intervention arm will be issued a Threshold® IMT inspiratory muscle trainer (Threshold IMT, Respironics, Parsippany, New Jersey, USA) which they are instructed to use until the day of the surgery. The device contains a calibrated spring-loaded valve which provides a constant and pre-

determined training load during inspiration. The valve opens when the patient meets the set load during inspiration and expiration is unimpeded.

2.3. Initial prescription - The IMT protocol is modified from the program described by van Adrichem [3] and Hulzebos[4]. A load corresponding to 30% MIP will be used as the initial prescription. The participant then completes a 20-minute session at the pre-evaluation clinic under the supervision of a physician and a physiotherapist. The participant is then instructed to continue unsupervised IMT at home twice a day (each consisting of 20 minutes of continuous resistive inspiratory maneuvers) until the day of operation. The patients are also tasked to record their training duration, training intensity (in cmH_2O) and measure their exertion level using the Rate of Perceived Exertion (RPE) scale.[5]

2.4. TITRATION OF IMT LOAD - The patient's IMT prescription is modified as per the progression protocol described by Hulzebos[4] and Dronkers[6]. The optimal training load is set at a RPE of 6 (Moderate effort). If the RPE is lower than 5 after a training session, the inspiratory load will be increased by $2cmH_2O$ or by 5%. The threshold load is unchanged if the RPE is 5 or 6. If the RPE is 7 or higher, the inspiratory load will be decreased.

2.5. COMPLIANCE MEASURES - The participant's compliance to IMT will be measured using an exercise log. (Appendix D) Patients in the intervention arm will also be contacted by telephone on days 1, 4 and 7 of intervention to reinforce and evaluate the progress of their training.

2.6. CONTROL ARM - Patients in the control group will be advised to remain their usual activity level. They will receive standard supportive education concerning postoperative deep breathing exercises, incentive spirometry, coughing with wound support, DVT prophylaxis using anti-embolism stocking and the importance of early postoperative mobilization.

References

1. Nici L, Donner C, Wouters E, et al. American thoracic society/European respiratory society statement on pulmonary rehabilitation. *American journal of respiratory and critical care medicine* 2006;173(12):1390-413.

2. Agrelli TF, de Carvalho Ramos M, Guglielminetti R, et al. Preoperative ambulatory inspiratory muscle training in patients undergoing esophagectomy. A pilot study. *International surgery* 2012;97(3):198-202.

3. van Adrichem EJ, Meulenbroek RL, Plukker JT, et al. Comparison of two preoperative inspiratory muscle training programs to prevent pulmonary complications in patients undergoing esophagectomy: a randomized controlled pilot study. *Annals of surgical oncology* 2014;21(7):2353-60.

4. Hulzebos EH, Helders PJ, Favié NJ, et al. Preoperative intensive inspiratory muscle training to prevent postoperative pulmonary complications in high-risk patients undergoing CABG surgery: a randomized clinical trial. *Jama* 2006;296(15):1851-57.

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