Research Protocol

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Physiotherapy Section

Efficacy of Power Breathe Device versus Threshold Inspiratory Muscle Training Device on Inspiratory Muscle Strength in Upper Abdominal Surgery Patients: A Research Protocol

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ABSTRACT

Introduction: Surgery care is important in the treatment of a variety of disorders as well as the alleviation of human suffering. Surgery is essential for meeting basic healthcare needs all across the world, although to varying degrees depending on disease subtypes and epidemiological regions. Laparoscopic surgery is now widely established. Benefits of laparoscopic surgery include improved cosmetic results, reduced postoperative pain, and reduced length of hospital stay with patient satisfaction. Upper abdominal surgery initiates a series of physiological events that result in postoperative pulmonary complications such as increased morbidity, mortality, and hospitalisation. Preoperatively in abdominal surgeries, Inspiratory Muscle Training (IMT) devices have been used to reduce postoperative pulmonary complications as well as improve the quality of life of the patients.

Need of the study: Surgery is a crucial part of the healthcare system, and it has a direct impact on the respiratory system. With changes in postoperative pulmonary functions, there are limitations in lung volume and capacities such as total lung capacity, vital capacity, and tidal volume. Power breathe devices have been utilised preoperatively in abdominal procedures for inspiratory muscle training and to prevent postpulmonary complications. As a result, the purpose of this study is to see how the power breath device and the threshold IMT device affect inspiratory muscle strength in upper abdominal operations.

Aim: To compare the effect of a power breathe device versus a threshold inspiratory muscle training device on inspiratory muscle strength in patients who had upper abdominal surgery.

Materials and Methods: The present comparative research protocol is planned to be conducted on 60 patients with upper abdominal surgery with reduced inspiratory muscle strength. The expected study duration is of one year from 2022 to 2023. Total subjects will be randomly divided into two groups, Group-A will receive power breathe plus conventional physiotherapy five days per week and Group-B will receive threshold IMT plus conventional physiotherapy five days per week for period of two weeks. Before initiating the intervention, patients will have their PI_{max} (maximal inspiratory pressure) evaluated using hand-held pressure manometer equipment. After two weeks, patients will be reviewed again using the same outcome measures.

Keywords: Muscle tiredness, Pulmonary complications, Respiratory devices, Surgery care

INTRODUCTION

Surgery care is important in the treatment of a variety of disorders as well as the alleviation of human suffering. Surgery is essential for meeting basic healthcare needs all across the world, although to varying degrees depending on disease subtypes and epidemiological regions. Surgical demands differ by location and country, based on illness prevalence and nations, and do not meet the people's necessities. According to the World Health Organisation (WHO), treating the disease burden for a global population of 6.9 billion people would necessitate atleast 321.5 million surgical operations [1]. Laparoscopic surgery is now widely established. Benefits of laparoscopic surgery include improved cosmetic results, reduced postoperative pain, and reduced length of hospital stay with patient satisfaction [2]. Tissue trauma causes significant physiological changes immobility, systemic consequences of psychological distress, and a worse quality of life with greater stressor to patients [3].

Upper abdominal surgery includes pancreatectomy, gastrectomy, splenectomy and hepatic resection. Upper abdominal surgery initiates a series of physiological events that result in postoperative pulmonary complications such as increased morbidity, mortality, and hospitalisation. Surgery and general anaesthesia have a direct impact on the respiratory system. There is impairment in postoperative lung volume as closer the incision is to the diaphragm, as compared to other surgical procedures abdominal surgery may results in higher incidence of post pulmonary complications following major abdominal surgery [4]. Respiratory muscles are motor arm of respiratory system as they perform most important function breathing [5]. The primary inspiratory muscle, the diaphragm, works as a barrier between the thoracic and abdominal cavities by retracting it and expanding it to the thorax, leading to negative pressure that raises the thoracic volume [6]. Due to its continuation function, diaphragm is strongly resistant to fatigue [7].

Muscle tiredness affects exercise tolerance in healthy people in a big way. As a result, when it comes to measuring the maximum strength of respiratory muscles, muscle training equipment plays a crucial role. Maximum inspiratory and expiratory pressures are global measures [8]. In patients with diminished respiratory muscle strength, PI_{max} is used as a diagnostic measure to assess inspiratory muscle strength. With a well-established reference volume in diverse populations, it is low-cost portable equipment that is quick to perform (60 cm H_2O female/80 cm H_2O male low limit of normal). An inhalation muscle training device is used in pulmonary rehabilitation to increase breathing muscle strength and their

endurance [9]. Preoperatively in abdominal surgeries, inspiratory muscle training devices have been used to reduce postoperative pulmonary problems as well as improve the quality of life of the patients [10,11]. There have been several studies that support the use of a threshold inspiratory muscle training device, notably in the context of preoperative abdominal operations [12-14]. Hence, the research protocol has been planned with objective to determine and compare how the Power Breathe device and threshold IMT affect the strength of the inspiratory muscles in patients who had upper abdominal surgery.

MATERIALS AND METHODS

This is a comparative research protocol planned to be conducted at Surgical ward of Acharya Vinoba Bhave rural hospital, Sawangi (Meghe), Wardha, India on total 60 patients undergoing upper abdominal surgery after obtaining approval from the Institutional Ethics Committee (Approval no.-:DMIMS(DU)/IEC/2022/899). After completion of study and publication of results, data will be stored in the DMIMSU data repository. The principal investigators will get the participant's written informed permission on a printed form (local language) with signatures and provide verification of confidentiality. Sample size will be calculated on the basis of reference of parent article by the statistician [15].

Inclusion criteria: Patients of both the genders,age between 35-60 years, undergoing upper abdominal surgeries and with ability to understand and follow instructions will be included after taking informed consent.

Exclusion criteria: Haemodynamically unstable participants, those with rib fractures, thoracic vertebra fractures and acute pleuritic chest discomfort and those who will not consent for the study will be excluded from the study.

Study Procedure

Treatment plan will be conducted for two weeks. The screening will be done on the first day and then at the end of 2nd week. The expected study duration is of one year from 2022 to 2023. Research Coordinator and Principle Investigator will supervise randomisation of included study participants into two groups. All patients (Both Group-A and Group-B) participating in the study will sign the consent form and attend preoperative physiotherapy training. Inspiratory muscular strength (PI_{max}) will be used to generate baseline outcome measurements for both groups during which they will be receiving a counselling session about the importance of respiratory training devices along with breathing exercise training sessions to reduce the risk of pulmonary problems after upper abdominal surgery.

On the first day after surgery, both groups will be assessed and educated about postoperative pulmonary issues as well as how to avoid them by self-directed breathing exercises and early ambulation. For two weeks, the intervention will be given for five days a week. Each session will last 15-30 minutes. Following are the two groups:

For group A participants, as per strength of inspiratory muscles assessed by pressure manometer device, Power breathe device will be given. In addition to conventional physiotherapy, breathing exercises consisting of 10 slow deep breaths followed by three coughs will be performed hourly following surgery. Both groups will undertake a standardised aided early ambulation program on the first postoperative day. Patients will be given walking assistance if necessary during the initial ambulation session, and an abdominal support pillow will be used while coughing.

For group B participants, on the basis of the strength of inspiratory muscles, as measured by pressure manometer equipment, a threshold inspiratory muscle training device will be given. Before initiating the intervention, patients will have their PI_{max} (maximal inspiratory pressure) evaluated using hand-held pressure manometer equipment. For two weeks, the intervention will be given twice a day. After two weeks, patients will be reviewed again using the same outcome measures.

Primary outcomes will be measured as PI_{max} and secondary outcome will be measured as length of hospital stay and through SF-36 questionnaire which will measure health-related quality of life [15]. The complete data collection will be done in safe and secured form.

STATISTICAL ANALYSIS

The Statistical Package for Social Sciences (SPSS) 27-OV, Graph pad prism 7.0 V latest version will be used to perform statistical analysis. To compare changes within the group, student t-tests will be utilised. Chi-square test will be used at baseline and for comparing the primary and secondary outcomes between the groups at two weeks of duration.

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