Incentive Spirometers in Hospitalized Patients with Pneumonia

Kinjal Patel, PGY1
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A. Study Purpose and Rationale

Incentive spirometers are often used as part of pulmonary supportive care in hospitalized patients. The use of the device encourages deep inspiration, which is to aid in use of maximal lung volume in setting of pain and immobility. This is desired to prevent as well as hasten reversal of atelectasis.

The data on incentive spirometry's efficacy is limited to post operative patients. The two surgical groups studied the most have been patients undergoing upper abdominal surgery and CABG. Cochrane review of the upper abdominal surgery studies show that there is no demonstrable benefit of incentive spirometry. This meta analysis reviewed 11 studies that were all prospective, but over half did not have clear methods of randomization, and masking was also not clearly part of study design. In general, the studies included were designed to evaluate the efficacy of incentive spirometry or deep breathing exercises in preventing post operative pulmonary complications and restoring/preserving lung function.

The second group of patients in which incentive spirometry has been studied is patients who have had CABG. In this population, there is also a Cochrane review, and the meta analysis included four RCTs, which showed again, a lack of demonstrable benefit with use of the incentive spirometer. However, in this meta analysis, the authors comment that there is need for a better designed study with more statistical power and thus at least in post-CABG patients, one cannot decisively conclude that incentive spirometry is of no benefit. The outcomes were similar to those in the upper abdominal surgery patients, e.g. assessing atelectasis (either by chest radiograph or CT scan), post operative pulmonary complications (like pneumonia), pulmonary function, and duration of hospitalization.

I was unable to locate any meaningful studies for incentive spirometry in non surgical patients. However, in my clinical training, I have noticed sporadic use of the device in hospitalized patients who have pulmonary symptoms. It thus seems worthwhile to attempt to study the efficacy of this intervention in medicine patients whose primary treatment is focused on pulmonary ailment. A common cause of hospitalization is pneumonia. I propose below a study designed to study the efficacy of incentive spirometry in the treatment of patients hospitalized with pneumonia.

B. Study Design and Statistical Analysis

Study Arms:
The treatment arm patients will use an incentive spirometer TID while hospitalized, and the control arm patients will use a sham incentive spirometer TID while hospitalized.

The sham spirometer would have an air leak, so that sustained inspiration is not enforced when taking a breath with the device. I was unable to modify the device myself but would have to contact the manufacturer to ask to see if this is possible. If a sham device cannot be obtained, then the study will be masked to the investigators but not the primary medical team nor the subjects.

Method of randomization will be via a computerized algorithm. Ideally the patient, hospital clinical team and investigators will be masked.

Statistical analysis:
Estimating the change in pulmonary function is difficult, but will set a least difference that still qualifies as clinically relevant at a 10% difference in FVC between the 2 arms. Given there is likely variance in PFTs for the same subject at baseline, we will assume a standard deviation of 5%. Sample size analysis was done using this assumption of 10% proportional change, and for a =< 0.05 and b = 0.2. Using chi square testing with these parameters, it is necessary to have 88 subjects in each arm.

C. Study Procedure.
Incentive spirometer use is not the standard of care, but is used inconsistently for pulmonary supportive care. Use is not with any known risks, and there are no risks associated with not including it in care. This understanding is as per the limited data discussed in (A) and intuitive clinical reasoning.

Patients in both arms will have usual care, e.g. antibiotics and other supportive care, as per the discretion of their primary medical team. In addition, both arms will receive either the incentive spirometer or a sham incentive spirometer, and will be taught how to use it with the aid of an information handout, which will be modeled after the attached one which is from Cleveland Clinic.

The schedule for use of the device will be prior to each meal time, thus TID, and the patient will be asked to take 10 breaths with their assigned device. The schedule should be followed for the duration of the hospitalization.

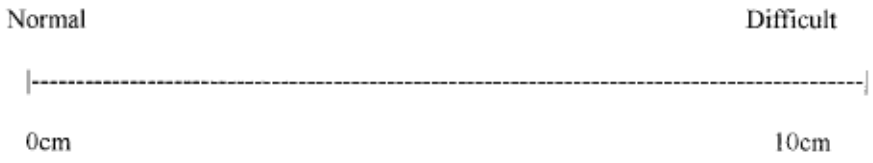
Outcomes of interest are as follows:
Primary outcome: Pulmonary function as measured by spirometry 2 weeks after discharge from the hospital

Secondary outcomes:
-Respiratory comfort assessment by visual analog score
-Duration of hospitalization

D. Study Drugs
Not applicable

E. Medical Device
Incentive spirometer, which is commercially available and NYP supply rooms are stocked with them. There are no safety concerns with this device.

F. Study Questionnaires
Visual analog score for comfort (as used previously to assess respiratory comfort): patient marks off on the line where they think their breathing ease is best reflected



G. Study Subjects
Inclusion criteria:
-age 18 or older
-admitted with clinical diagnosis of pneumonia

Exclusion criteria:
-Intubation during this hospitalization or in the past 1 month
-Acute congestive heart failure
-Pulmonary Embolism
-Diagnosis of COPD
-Cognitive impairment
-anything that precludes use of the incentive spirometer or sham device, e.g. recent surgery in the nasopharynx or oropharynx

H. Recruitment of Subjects
The patients eligible for the trial will be those that are hospitalized on the housestaff and hospitalist medicine services. We will communicate with the physicians who will admit and follow potential subjects via email and ask for their help in recruitment. They will have the study team's cellular numbers and emails so that we can be accessed at any time with questions.

I. Confidentiality of Study Data
The patients enrolled in the study will have their identification info coded into new study IDs, which will de-identify the patient but keep the subjects separated by their study arm.

All de-identified data will be stored in a secure computer spreadsheet file, accessible only to the investigators via password.

J. Potential Conflict of Interest
No conflicts of interest to disclose.

K. Location of the Study
Milstein and Allen Hospital inpatient medicine units.

L. Potential Risks
As there is no standard treatment that is being withheld from any of the patients, there is no obvious medical risk that we can anticipate from participation in the study. Incentive spirometers are innocuous devices and do not have a side effect profile.

M. Potential Benefits
Incentive spirometers may be a useful tool to aid patients with pulmonary symptoms to have a more rapid or efficacious recovery. It is a safe and relatively inexpensive intervention, but there is no compelling clinical data to support use. They have not been formally studied in a non surgical population. This study will help gather evidence in medicine patients. If the study is with positive outcome, then we can choose to validate the findings in more subsets of medical patients with pulmonary symptoms, and then perhaps implement standardized use of incentive spirometry. If the study is negative, it will help support an initiative to rid medical care of an intervention that is ineffective.

N. Alternative Therapies
Not applicable.

O. Compensation to Subjects
Patients will not be offered any compensation.

P. Costs to Subjects
No cost to the patients.

Q. Minors as Research Subjects
Not applicable

R. Radiation or Radioactive Substances
Not applicable

References:

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