ORIGINAL ARTICLE

A Pilot Randomized Control Cross over Study Evaluating the Effectiveness and Safety of Mechanical Percussor Compared with Conventional Chest Physiotherapy in Adults with Productive Cough

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SUMMARY

Introduction: Conventional Chest Physiotherapy (CCPT) remains the mainstay of treatment for sputum mobilization in patients with productive cough such as bronchiectasis and "Chronic Obstructive Airway Disease" (COPD). However CCPT is time consuming requires the assistance of a physiotherapist and limits the independence of the patient. Mechanical percussors which are electrical devices used to provide percussion to the external chest wall might provide autonomy and greater compliance. We compared safety and efficacy of a mechanical chest percusser devised by Formedic Technology with conventional chest percussion.

Methods: Twenty patients (mean age 64years) were randomly assigned to receive either CCPT or mechanical percussor on the first day and crossed over by "Latin square randomisation" to alternative treatment for 6 consecutive days and the amount of sputum expectorated was compared by dry and wet weight. Adverse events and willingness to use was assessed by a home diary and a questionnaire.

Results: There were 13 males and 7 females, eight diagnosed as bronchiectasis and 12 COPD. The mean dry weight of sputum induced by CCPT (0.54g ± 0.32) was significantly more compared with MP (0.40g + 0.11); p-value = 0.002. The mean wet weight of sputum with CCPT (10.71g ± 8.70) was also significantly more compared with MP (5.99g ± 4.5); p-value < 0.001. There were no significant difference in adverse events and majority of patients were willing to use the device by themselves.

Conclusion: The mechanical percussor although produces less sputum is well tolerated and can be a useful adjunct to CCPT

KEY WORDS:
Chronic bronchiectasis, Chronic Obstructive Pulmonary Disease, Manual percussion, Mechanical percussion, Sputum weight

INTRODUCTION

Airway clearance is impaired in a variety of lung diseases such as cystic fibrosis, bronchiectasis and Chronic Obstructive Air way Disease (COPD). Secretions that block the airway can lead to atelectasis and poor oxygenation[1,2]. Improved mobilization of bronchial secretions contributes to improved ventilation-perfusion matching and the normalization of the functional residual capacity.

A variety of physical therapy techniques such as turning, postural drainage, chest percussion and vibration have been employed alone and in combination to facilitate airways clearance. Percussion has long been held as the best method for loosening trapped mucus within the lungs. Conventional Chest Physiotherapy (CCPT) is the current standard treatment for sputum mobilization in patients with productive cough. It is widely advocated as a mainstay of management for this chronic disease [3]. However, chest physiotherapy is time consuming, may require the assistance of a therapist or other caregiver and may be uncomfortable or unpleasant. Alternatively mechanical percussors could be used to provide clapping or percussion to the external chest wall to mimic manual hand percussion. The device could allow more autonomy for patients, better compliance and less fatigue for the operator. Percussors are classified as Class II 510 (k) medical devices by the U.S. Food and Drug Administration (FDA). The devices deliver consistent, programmable (i.e., speed is adjustable) deep pulses. The machine is moved over the patient's chest while the patient assumes a variety of drainage positions.

The Device: A hand held battery operated percussor (LEGA) has been designed by a Malaysian company called Formedic Technology. The illustration of the percussor is given in Figure I. A DC motor is used to create rotational movement (with predetermined speed) that generates force and frequency which eventually creates vibration when the device touches human body. The generated sound wave / resonance wave travels thru human chest wall that helps to loosen phlegm. It has 2 cups which taps alternatively initially at a frequency of 15Hz and increases stepwise to 30Hz within few seconds. The device is applied to the external chest wall that needs to be percussed. It induces cough followed by expectoration of sputum. The treatment is repeated at all conventional chest physiotherapy areas for almost the same duration as CCPT.

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MATERIALS AND METHODS

We designed a short term randomised controlled cross over study to compare the safety and efficacy of the new mechanical percussor (LEGA) with conventional chest physiotherapy.

The study was approved by an independent ethics committee and was conducted in compliance with Good Clinical Practice principles. Informed consent was obtained from all patients.

This trial was performed at the Respiratory Medicine department from December 2011 to June 2012. The study participants consisted of clinically stable "High-resolution Computed Tomography" (HRCT) confirmed adult chronic bronchiectasis patients and clinically confirmed Chronic Obstructive Pulmonary Disease (COPD) patients with chronic sputum expectoration-(producing ≥30ml/day of sputum at baseline) and not carrying out regular chest physiotherapy defined as less than two occasions per week were enrolled into this study. COPD patients had (Forced Expiratory Volume in one second) FEV1 of > 35% of the predicted value.

Patients with primary diagnosis of asthma, active sarcoidosis or pulmonary tuberculosis, history of brittle bones, broken ribs in the past one year or severe osteoporosis, haemoptysis, open wounds or burns or intense pain in the thoracic region, pulmonary embolism, lung abscess, collapsed lungs or a damaged chest wall, recent myocardial infarction, unstable angina or stroke or recent surgery (Within 6 months prior to enrollment) or on any anticoagulants were excluded from the study.

Since this was a Phase I –II study just checking the viability of the investigational product and short term efficacy and safety parameters it was proposed to enrol only a small number of patients. A pilot randomised control cross-over trial of daily chest percussion for 6 days was designed to get three sets of sputum for comparison. Patient to patient variability is controlled by cross over design. However the patient's response to one intervention is usually correlated with the response to another intervention. To minimise the 'carry over effect' of the cross over design patients were randomised according to 'Latin square design' described by Williams[4].

Interactive Voice Randomisation (IVR) was carried out through central telephone. Patients stratified by diagnosis were randomised by permuted block randomisation (with varying block size) to one of the following four sequences:

Day	1	2	3	4	5	6
#1	CCPT	MP	MP	CCPT	MP	CCPT
#2	CCPT	MP	MP	CCPT	CCPT	MP
#3	MP	CCPT	CCPT	MP	MP	CCPT
#4	MP	CCPT	CCPT	MP	CCPT	MP

Each patient thus received 3 sessions of CCPT and 3 sessions of MP over 6 consecutive days.

This type of sequencing minimises the "Carry over effect" of cross over study design as this prevents any patient getting the same modality as the first day's treatment for all three sets. Of the three sets of sputum collected at least in one of the sets the alternate modality becomes the first day's treatment for that set. Since sputum production might vary during different time of the day only once a day treatment in the morning was chosen to get better comparability. CCPT sessions were performed by two qualified study specific physiotherapists and MP Sessions were performed by two trained study specific nurses. In order to ensure uniformity the physiotherapists trained the nurses on the areas of chest where the percussion has to be carried out. Both procedures were conducted over 15 minutes and standardised to ensure uniformity. All sputum produced during 15 minutes of treatment and 5 minutes after treatment were collected, weighed (wet weight), dried at 60^{0}C in a laboratory oven for 48 hours and weighed again (dry weight). Change in lung functions – FEV1 (%predicted) and (Forced Vital Capacity) FVC (%predicted) after each treatment were recorded. The respiratory medicine technicians who carried out the lung functions tests and the laboratory staff who helped to do the weighing of the sputum were blinded to the trial treatments of patients.

Safety parameters such as Chest discomfort, pain, rib fracture, haemoptysis, nausea or vomiting, changes in respiratory rate, heart rate, dyspnoea, and oxygen saturation were monitored during treatment. Since the study was carried out as outpatient procedure patients were provided with a diary to record the adverse events at home and at the end of the study the diary was collected and they were requested to answer a simple questionnaire to assess their preference to either method.

RESULTS

The flow diagram illustrating the disposition of patients is shown in Figure 2. Twenty patients who fulfilled the inclusion/exclusion criteria were enrolled and randomised. All twenty of them completed the six consecutive day treatment and returned the patient preference questionnaire.

The baseline characteristics are as shown in Table I. There were thirteen males and seven females with the mean age of 64 years. Eight of them had been diagnosed as bronchiectasis and 12 as COPD.

Table I: Baseline Characteristics of study population

Age in years, Mean (SD)	64.0 (9.2)
Gender: Male, Female; N (%)	13 (65%), 7 (35%)
Race: Malay, Chinese, Indian; N (%)	7 (35%), 3 (15%), 10 (50%)
Diagnosis: Bronchiectasis, COPD; N (%)	8 (40%), 12 (60%)
Height in metre, Mean (SD)	1.60 (0.06)
Weight in kilograms, Mean (SD)	61.3 (19.0)
Body mass index in kg/m2, Mean (SD)	23.8 (6.9)
Systolic Blood Pressure in mmHg, Mean (SD)	129 (15.8)
Diastolic Blood Pressure in mmHg, Mean (SD)	79.8(10.3)
Respiratory Rate in breaths/min, Mean (SD)	18.5(3.9)

The average dry weight of the sputum produced by each patient during CCPT and mechanical percussor are shown in table II.

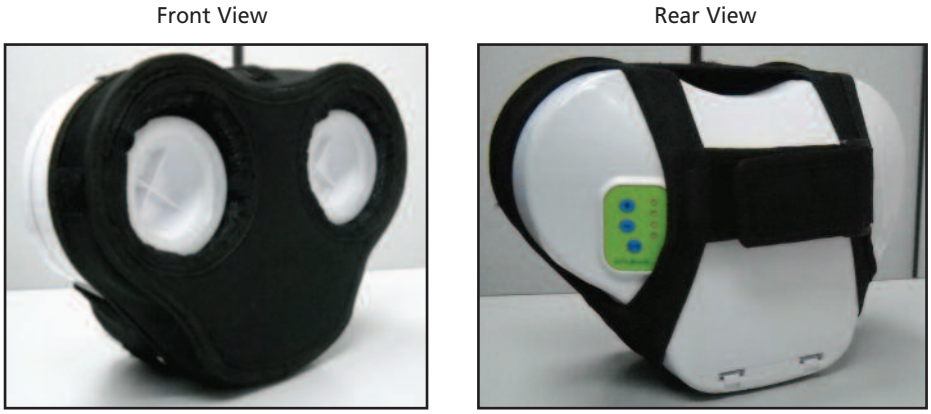

Fig. 1 : Illustration of the Percussor:
It has a DC motor, Rechargeable battery pack, the cups have silicone pad with protein free (Neoprene) material cover. PCB (controls speed / Auto cut off)

CCPT induced more sputum compared with MP (mean dry weight 0.54g versus 0.4g. and wet weight was 10.71g versus 5.99g).

Table II: Average dry sputum weight - manual and mechanical percussion

Average dry sputum weight in Grams		
Patient No	**CCPT**	**Mechanical Percussor**
1	0.49	0.48
2	0.83	0.31
3	1.73	0.57
4	0.48	0.44
5	0.81	0.64
6	0.36	0.23
7	0.26	0.54
8	0.66	0.37
9	0.42	0.35
10	0.52	0.5
11	0.40	0.33
12	0.34	0.29
13	0.22	0.24
14	0.52	0.39
15	0.42	0.36
16	0.37	0.38
17	0.41	0.29
18	0.52	0.42
19	0.48	0.46
20	0.57	0.48
Mean	0.541	0.404
p-value = 0.002		

Mean dry and wet weight of sputum by session is given in Figure 3 and 4.

Figure three shows the mean dry sputum weight and figure four shows the wet sputum weight between treatment groups. The mean dry weight of sputum induced by CCPT (0.54g + 0.32) was significantly more compared with MP (0.40g + 0.11); p-value = 0.002 (Friedman test). The mean wet weight of sputum with CCPT (10.71g + 8.70) was also significantly more compared with MP (5.99g + 4.5); p-value < 0.001 (Friedman test).

There were no significant differences in FEV1, FEV1/FVC ratio, respiratory rate, oxygen saturation, blood pressure or pulse rate between groups.

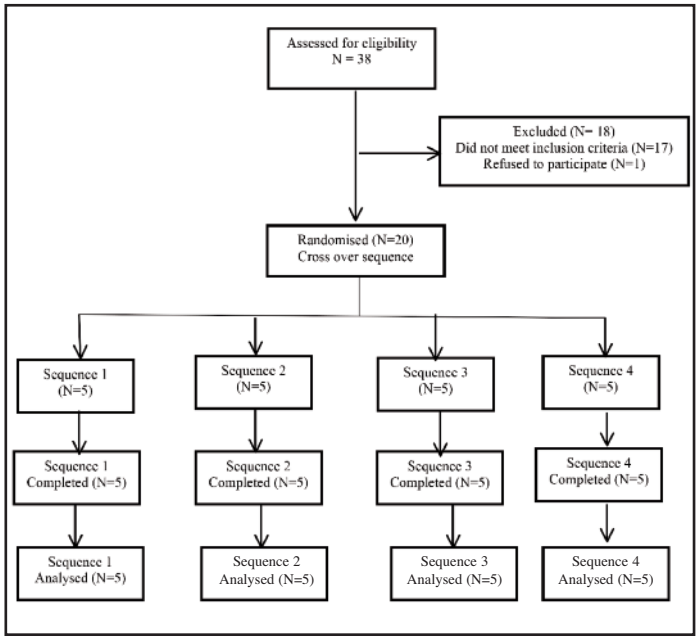

Fig. 2 : Flow diagram showing the disposition of patients.

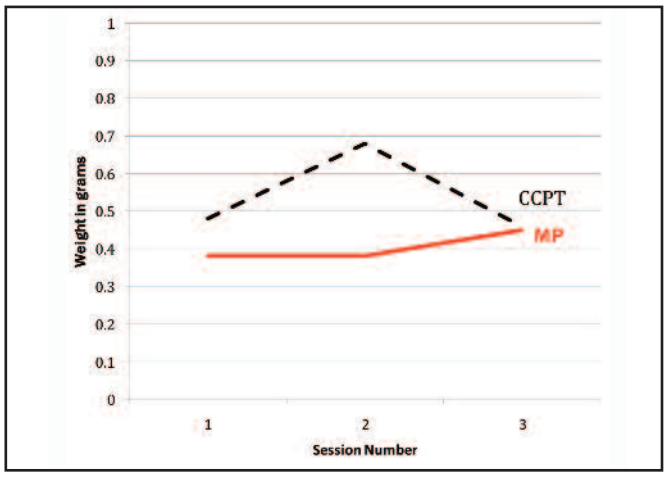

Fig. 3 : Mean dry weight of sputum.

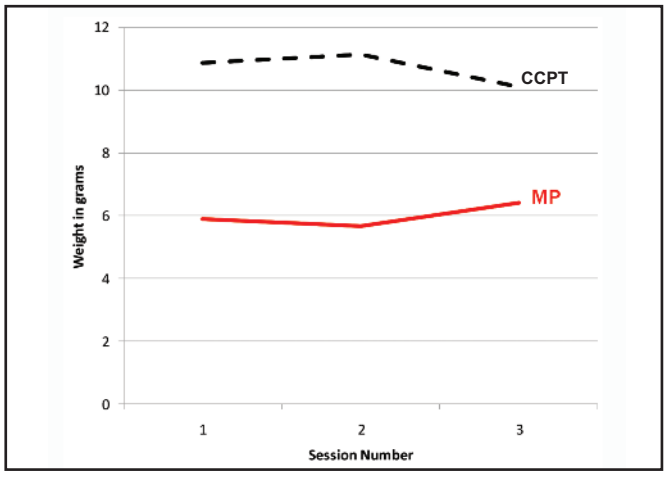

Fig. 4 : Mean wet weight of sputum.

Few adverse events were reported in both groups. Mild pain was reported by three patients (16.7%) in CCPT arm and one patient (5.6%) in MP arm. Mild exhaustion was also reported more frequently with CCPT (5patients- 27.8%) than MP (two patients- 11.1%). The difference was not statistically significant. No serious adverse events were reported in either group. Five patients in CCPT and two in percussor arm complained mild exhaustion. Nine patients in both arms felt that the treatment was very effective.

Patients' preference to either treatment and the reasons for their preference is given in Table III. Twelve out of the twenty patients preferred the use of mechanical percussor.

Table III: Patients' Preference and Reasons

Preference to CCPT (7) 37%	Preference to Mechanical Percussor (12) 63%
More phlegm comes out (3)	Easy to use (6)
Physiotherapists know where to tap (2)	Can use at home and can bring to anywhere(3)
More comfortable (2)	Less painful (2)

Seventeen patients felt that they will be happy to use the device by themselves with the help of a care provider and two patients were not so confident

DISCUSSION

Physiotherapy is vital part of management though mainly in bronchiectasis due to cystic fibrosis it is also a valuable treatment modality in bronchiectasis of other etiology. Our study population had a clinically significant bronchial pathology with chronic sputum production of 30ml or more for 24 hours at entry. This is a randomized cross over trial. The carry forward effect of the cross over design was minimized by 'Latin square sequence randomisation' The primary outcome parameter was sputum weight since sputum weight has been considered to be an appropriate physiotherapy outcome measure in patients with copious sputum production [5].

Our study showed that the mechanical percussor (MP) was well received and tolerated by patients although the amount of sputum produced was less compared with conventional manual chest percussion (CCPT). An earlier study comparing a different physiotherapy device, frequencer to CCPT reports same amount of sputum produced during the two methods[6]. The reason for the lower sputum production in this study is unclear. Possible reasons include greater force exerted with CCPT, lack of familiarity of the device (learning curve of operators) and lack of experience of the nurses with chest percussion. It is also possible that there may be a longer delay in production of sputum with mechanical percussion beyond 5 minutes after treatment.

But pain and exhaustion is reported less frequently with this percussor device. Majority of patients were willing to use the device themselves with the help of a care provider suggesting that this device would be useful for home therapy or when physiotherapists are not available.

This was a short term study trying to concentrate only on the amount of sputum expectoration. Whether the ease of use of the mechanical percussor and the fact that it obviates the necessity for the presence of the physiotherapist will improve compliance among patients to have more regular physiotherapy and if it will result in clinical improvement or airway reversibility have to be ascertained by a long term study.

The small sample size is one of the limitations of the study. But each patient was tested on six occasions and thus the total number of sputum sample collected was 120. However device trials enroll smaller number of subjects compared with pharmaceutical research and this study is to check the viability of the device rather than the clinical improvement.

CONCLUSION

Although MP induced less sputum compared with CCPT, since the respiratory function tests were similar and there were no safety concerns, the mechanical percussor can be a useful adjunct to conventional chest physiotherapy. Achieving an improvement in health related quality of life and autonomy is highly relevant in the management of long term illnesses. However a larger follow up study will be required to confirm the findings and to assess clinical improvement.

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The study was registered in ClinicalTrials.gov and the registration number is NCT01480882

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