Safety and Efficacy of Short-Term Intrapulmonary Percussive Ventilation in Patients With Bronchiectasis

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BACKGROUND: Treatment of bronchiectasis includes drugs, oxygen therapy, and bronchial-clearance maneuvers. OBJECTIVE: To assess the safety and efficacy of intrapulmonary percussive ventilation (IPV) compared to traditional standard chest physical therapy in patients with bronchiectasis and productive cough. METHODS: In a randomized crossover study, 22 patients underwent, on consecutive days, IPV and chest physical therapy. Before each treatment session, immediately after the session, 30 min after the session, and 4 hours after the session we measured SpO₂, heart rate, respiratory rate, and (with a visual analog scale) the patient’s subjective sensation of phlegm encumbrance and dyspnea. Immediately after each treatment session we also measured (via visual analog scale) the patient’s discomfort. We also measured the volume and wet and dry weight of collected sputum. RESULTS: No adverse effects were so severe as to require discontinuation of treatment, and the incidence of adverse effects was similar in the groups (27%). Heart rate (P<0.002) and respiratory rate (P<0.047) decreased during treatment, and sensation of phlegm encumbrance improved (P<0.03) with both treatments. Only IPV improved (P<0.004) the sensation of dyspnea. The patients found IPV more comfortable than our traditional standard chest physical therapy (P<0.03). Both treatments caused important phlegm production, but there were no differences in sputum volume, wet weight, or dry weight. CONCLUSIONS: In patients with bronchiectasis and productive cough, short-term IPV was as safe and effective as traditional chest physical therapy, with less discomfort.

Key words: bronchiectasis; intrapulmonary percussive ventilation; chest physical therapy; rehabilitation; hypersecretion; airway and pulmonary infections. [Respir Care 2011;56(7):984–988. © 2011 Daedalus Enterprises]

Introduction

Proper functioning of bronchial clearance relies on balance between mucus production, transport, and clearance.1 Impairment of this balance can result in phlegm encumbrance, together with changes in physiological clearance mechanisms.1 This can favor recurrent infections, affect ventilatory function, and create a vicious circle of infections and inflammation that can ultimately lead to airway and lung parenchyma destruction.1

Bronchiectasis, a disease that is being diagnosed with increasing frequency,2 consists of segmental dilatation of medium-size bronchi, due to loss of the muscle and elastic components of the bronchial wall in patients without cystic fibrosis (CF). Bronchiectasis is usually associated with chronic cough, increasing secretions, and recurrent airway and pulmonary infections that might result in loss of lung function and lead to early death.2 The goals of bronchiec-
tasis treatment are to reduce the number of exacerbations and infections and to improve patient quality of life by reducing airway inflammation and mobilizing secretions.3,4

Depending on the degree of lung function impairment, accepted standard treatment includes drugs, oxygen therapy, and daily bronchial-clearance maneuvers.3 Proposed secretion management techniques include standard5 and modified1–5 postural drainage, assisted cough,5 active cycle of breathing techniques,5,6 autogenic drainage,5 inspiratory muscle endurance training,5,6 oscillatory positive-expiratory-pressure devices (eg, Flutter5 and Acapella6), and intrapulmonary percussive ventilation (IPV). Although the treatment of mucus hypersecretion is recommended in chronic respiratory diseases,1 there have been no definitive studies or guidelines on preference of one clearance technique versus the others.7

IPV is powered with a pressure of about 50 cm H2O and delivers small bursts of high-flow gas at 100–300 cycles/min,8 which causes airway pressure changes of 5–35 cm H2O, and vibrates the airway walls. IPV improves airway secretion clearance in CF patients,9,10 Duchenne muscular dystrophy,11 pediatric patients with atelectasis,12 COPD exacerbation,13,14 obesity,15 tracheostomized patients16 and patients with acute respiratory failure.13 To our knowledge there have been no trials of IPV in patients with bronchiectasis. We compared the safety, comfort, and efficacy of IPV and our standard traditional chest physical therapy (CPT) method in airway secretion clearance in adult patients with bronchiectasis.

**Methods**

This study was approved by the ethic committees of both Fondazione Maugeri Istituto di Ricovero e Cura a Carattere Scientifico, Lumezzane, Italy, and Ospedale Privato Accreditato Villa Pineta, Gaiato, Italy. All patients gave written informed consent.

**Patients**

We screened all consecutive patients admitted to the respiratory departments of our 2 institutions, from September 2005 to March 2008. The inclusion criteria were:

- Diagnosis of bronchiectasis based on computed tomo-gram
- Daily sputum volume > 20 mL for at least 2 consecutive days
- Clinical stability: no need for medication changes 4 days prior to enrollment
- Normal gas exchange: pH > 7.35 during spontaneous breathing, with or without supplemental oxygen
- No use of sedatives or vasopressors
- No major cardiac arrhythmias or hemodynamic instability (eg, severe hypotension, sepsis, or low cardiac output)

The exclusion criteria were tracheostomy, long-term non-invasive ventilation (NIV), severe and/or irreversible sensory abnormalities, and chest radiograph changes.

The drop-out criteria were withdrawal of patient consent, severe clinical worsening, and occurrence of any of the exclusion criteria.

**Protocol**

We used a randomized crossover design. On 2 consecutive days, each patient performed one of the secretion clearance techniques on the first day and the other technique on the second day, per a computerized randomization list. Both secretion clearance sessions were 30 minutes long. If the patient was on supplemental oxygen, the oxygen flow was maintained constant during both treatments.

**Intrapulmonary Percussive Ventilation**

IPV was provided with the IMP2 (Breas Medical, Mölnlycke, Sweden). Each IPV session included 3 active cycles, including 2 phases at low pressure and high frequency, and another phase at high pressure and low frequency. The patient was in a sitting position. At the end of each cycle the respiratory therapist required the patient to cough. The session was performed without delivery aerosol therapy.

**Chest Physical Therapy**

CPT consisted of a combination of forced expiration, postural drainage, percussion, and vibration.17,18 Each of 3 positions (prone, right-lateral decubitus, and left-lateral decubitus) was maintained for 10 min, and after each position the patient sat upright for 3 min of coughing.

**Measurements**

At baseline we recorded demographics, anthropometry, respiratory function, PaO2, PaCO2, and pH. Before each treatment session (time zero [T0]), immediately after the session (T1), 30 min after the session (T2), and 4 hours after the session (T3) we measured S\textsubscript{pO2}, heart rate, respiratory rate, and (with a visual analog scale19) the patient’s subjective sensation of phlegm encumbrance and dyspnea. At T1 we also measured the patient’s subjective discomfort.
with a 0–100% discomfort visual analog scale.20 We also measured the volume and wet and dry weight of collected sputum. We asked the patients about adverse effects throughout the 30-min treatment session and at T3.

Statistical Analysis

Statistical assumption for paired \( t \) test power calculation was made on the efficacy. On the grounds of our previous experience we estimated an 80% power to detect a reduction of 6 points in the average value of the efficacy proportion between the 2 treatments. Differences were considered significant when \( P < .05 \). The estimated number of patients to be enrolled was 22. Data analysis was with statistics software (SPSS 12.0, SPSS, Chicago, Illinois).

Though we randomized the order of treatments, we could not rule out the possibility that the order of treatment or a learning effect might affect our results, so we divided the patients into 2 groups according to random order: IPV first, and CPT first. We tested for a “period effect” for each variable with a 2-sample \( t \) test (or Mann-Whitney U test for nonparametric variables) to compare the differences between the treatment periods in the latter 2 groups. We tested for a “treatment-period interaction” with a 2-sample \( t \) test that compared the average of response to treatment in each group. If a period effect or treatment-period effect for each variable was found to be statistically non-significant, then we calculated the differences between the 2 treatments with the Student \( t \) test (paired data) or the Wilcoxon test (nonparametric data).

Results

Patients

There were 1,920 patients admitted during the study period. We screened 32 patients and enrolled 12 men and 10 women (Table 1). Reasons for exclusion were: unstable disease (4 patients), tracheotomy (1 patient), NIV (2 patients), and refusal (3 patients). All the patients completed both airway clearance sessions. All the patients were clinically stable, and had moderate hypoxemia, mild hypercapnia, obstructive pattern, and reduced respiratory muscle function, but were able to cough spontaneously.

Response to Treatment

Table 2 shows the mean differences between IPV and standard CPT in collected sputum and change in respiratory rate, heart rate (beats/min), and \( S_{\text{PO}_2} \). IPV or CPT were similarly safe in all the patients, as demonstrated by stability or mild improvement in physiological response during their application. In detail:

- \( S_{\text{PO}_2} \) showed no significant variation with IPV or CPT from T0 to T3: from 92 ± 2% to 93 ± 2% (\( P = .051 \)) with IPV, and from 93 ± 2% to 93 ± 3% (\( P = .56 \)) with CPT. There was no significant difference between the treatments (\( P = .34 \)).

- With both IPV and CPT, heart rate significantly decreased from T0 to T3: from 86 ± 11 beats/min to 82 ± 11 beats/min with IPV (\( P = .002 \)), and from 87 ± 10 beats/min to 83 ± 11 beats/min (\( P = .038 \)) with CPT. There was no significant difference between the treatments (\( P = .82 \)).

- Respiratory rate significantly decreased with IPV, from 21 ± 4 breaths/min at T0 to 19 ± 4 breaths/min at T3 (\( P = .02 \)), whereas it did not significantly change with CPT (21 ± 4 breaths/min at T0 versus 21 ± 5 breaths/min at T3, \( P = .58 \)). There was a significant difference between the treatments (\( P = .047 \)).

Adverse effects (dry throat, nausea, and/or fatigue) occurred in 27% of the patients with both IPV and CPT, but the adverse effects were not serious enough to require discontinuation of treatment.
Collected Sputum

With IPV and CPT, 29% of patients produced < 20 mL, 41% produced 20 – 40 mL, 16% produced 40 – 60 mL, and only 14% produced > 60 mL of sputum at T3. At T3 there were no significant differences between the groups in sputum volume, wet weight, or dry weight (see Table 2).

Dyspnea

Dyspnea did not worsen with either treatment. IPV significantly improved dyspnea, from 35 ± 29% at T0 to 23 ± 20% at T3 (P = .004), but CPT did not (33 ± 27% vs 27 ± 26%, P = .09). However, there was no significant difference between the groups (P = .35).

Sensation of Phlegm Encumbrance

Sensation of phlegm encumbrance significantly improved from T0 to T3 in both groups: from 47 ± 35% to 27 ± 32% with IPV (P = .001), and from 48 ± 1% to 37 ± 35% with CPT (P = .03). There was no significant difference between the groups (P = .48).

Discomfort

Post-treatment mean IPV-induced discomfort was lower: 23 ± 17% with IPV, versus 40 ± 27% with CPT (P = .03), though there was high variability in these measurements (Fig. 1).

Discussion

In stable adults with bronchiectasis, IPV and CPT had a similar safety profile and physiological and efficacy response, but IPV had less discomfort. Previous studies have found IPV safe, well tolerated, and effective in various hypersecretive diseases, but to our knowledge this is the first study of IPV in patients with bronchiectasis.

Tsurata et al. and Van Ginderdeuren et al. found no significant changes of heart rate after IPV in 2 different trials with obese and CF patients. Our study confirms IPV’s cardiovascular safety in patients with bronchiectasis. Similar to the study by Van Ginderdeuren et al., we observed no change in $S_{\text{O}_2}$.

In 2 physiological studies with animals, Banzett et al. and Bohn et al. investigated the effects of IPV on respiratory control. Their data suggest that the rhythmic variations of pressure in the airways produced by high-frequency percussions can induce a bradypnea reflex that originates from mechanoreceptors and from rhythmic vibrations of the rib cage and intercostal muscles, and acts on the respiratory centers. In patients with COPD exacerbation treated with IPV, Vargas et al. observed respiratory-rate reduction similar to what we found in our patients.

As in other studies, short-term IPV caused no major adverse effects: we observed dry throat, nausea, and fatigue, which are probably related to the pressurization of air into the mouth and airways. We did not use humidification during IPV, and it is reasonable to suppose that humidification could reduce the incidence of these adverse effects.

Van Ginderdeuren et al. measured dyspnea with IPV combined with autogenic drainage in 20 stable CF patients and found no significant changes after 15 min of IPV. We found significant dyspnea improvement after IPV, and we speculate that this could be from a decrease in airways resistance following expectoration. That we found reduced perception of phlegm encumbrance with both IPV and CPT supports that hypothesis.

We found less discomfort with IPV than with CPT. This effect was similar to the one reported by Marks et al. in CF patients. Conversely, Varekojis et al. found no significant difference in comfort between IPV, high-frequency chest-wall compression, and CPT in pediatric CF patients. Our finding might be explained by the discomfort caused by frequent position changes, or by the fact that the patient was in the lateral or prone position during CPT.

IPV was as effective as CPT in terms of sputum volume and weight, which agrees with the findings of Natale et al. in CF patients treated with IPV, aerosol therapy, and CPT. Furthermore, in 24 CF patients Varekojis et al. found wet sputum weight significantly higher with IPV than with either high-frequency chest-wall compression or CPT.

Limitations

Our test of IPV’s effectiveness was short-term, so we cannot conclude that longer or repeated application of IPV...
would further improve outcomes. Also, we chose sputum volume as a primary outcome, but we know that several factors influence sputum volume, including rheological characteristic of the sputum, and swallowing. We are also aware that there is some difficulty in finding proper outcome measures in studies of bronchial hygiene techniques.

Conclusions

Short-term IPV and CPT are similarly safe and effective in patients with bronchiectasis and productive cough, and IPV was associated with less discomfort. We recommend studies on IPV's cost-effectiveness before general clinical application of IPV. However, as a practical clinical implication, our study suggests that, in a hospital setting, IPV is safe in patients with bronchiectasis, and may be especially useful with patients intolerant of CPT because they are unable to maintain lateral or prone position or develop bronchospassm or discomfort during manually assisted maneuvers.4

ACKNOWLEDGMENT

We thank Alessandro Bettini for editing assistance.

REFERENCES