ARTICLE

Intrapulmonary Percussive Ventilation vs Incentive Spirometry for Children With Neuromuscular Disease

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Background: Pulmonary infections can be life threatening for children with neuromuscular diseases who have impaired ability to clear secretions. Intrapulmonary percussive ventilation (IPV) is a pneumatic device that delivers air and aerosol to the lungs at frequencies of 200 to 300 cycles per minute at peak pressures from 20 to 40 cm H_2O. Anecdotal reports and pilot studies show its safety and effectiveness in mobilizing secretions in patients with cystic fibrosis.

Objective: To test the hypothesis that IPV used in a pulmonary program for adolescents with neuromuscular disease would reduce the number of days of antibiotic use for pulmonary infection.

Methods: A randomized, controlled study was conducted to compare efficacy of IPV with incentive spirometry (IS) in reducing number of days of antibiotic use in adolescents with neuromuscular disease. The secondary endpoints were the number of respiratory infections, hospitalizations, and school days missed.

Results: A total of 18 patients were enrolled (9 IPV, 9 IS). Antibiotic use was significantly higher with IS (24/1000 patient-days) compared with IPV (0/1000 patient-days), (incidence rate ratio, 43; 95% confidence interval, 6-333). The IS group spent more days hospitalized (4.4/1000 patient-days vs 0/1000 patient-days) than the IPV group (incidence rate ratio, 8.5; 95% confidence interval, 1.1-67). The IPV group had 0 episodes of pneumonia or bacterial bronchitis compared with 3 events in the IS group, although this did not meet statistical significance.

Conclusion: Intrapulmonary percussive ventilation as part of a preventive pulmonary regimen reduced days of antibiotic use and hospitalization for respiratory illness in adolescents with neuromuscular disease.

Arch Pediatr Adolesc Med. 2005;159:526-531

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PULMONARY COMPLICATIONS are common and can be life threatening in patients with neuromuscular diseases (NMD).[1] Patients with NMD have ineffective muscle function, which results in small tidal volumes and reduced cough effectiveness.[2,3] They are predisposed to atelectasis, retention of airway secretions, and respiratory infection. Respiratory infections prevent patients from attending school, rehabilitative or recreational programs. Additional consequences of pulmonary infections include exposure to multiple courses of antibiotics with associated risks of acquisition of antibiotic-resistant microorganisms, antibiotic-associated colitis, and medical complications associated with hospitalization in an intensive care setting.

Treatment options for mobilizing and clearing secretions and preventing atelectasis include incentive spirometry (IS), traditional chest physiotherapy with postural drainage, manual cough assist, percussion therapy with handheld percussors or vest, mechanical insufflation/exsufflation, intermittent positive pressure breathing, and intrapulmonary percussive ventilation (IPV).[4,5]

An intrapulmonary percussive ventilator (Impulsator F00012; Percussionaire Corp, Sandpoint, Idaho) is a pneumatic device that delivers high-flow-rate bursts of air and aerosol to the lungs at a frequency of 200 to 300 cycles per minute. Pulsatile breaths are delivered at a peak pressure of 20 to 40 cm H_2O, titrated by visualizing percussive movement of the intercostal spaces. Breaths are delivered using a mouthpiece, and the lungs percussed for 5- to 15-second intervals over a 15- to 30-minute period.[6] Proposed mechanisms of action include enhanced alveolar recruitment and mucociliary clearance through bronchodilation from a combination of bronchodilatory medication, and improved lung inflation.[7]

Prior reports have shown the safety and effectiveness of IPV in mobilizing airway

secretions.[8-13] A preliminary report examining the efficacy and safety of IPV in patients with NMD included 4 patients (3 with NMD) treated with IPV for pulmonary infiltrates and/or atelectasis.[13] Two patients with NMD had significant improvement in blood oxygenation and chest radiographic findings; the third had a slower response and developed transient third degree heart block and hypoxemia from mucous plugging following IPV.

We became interested in the role of IPV in preventing respiratory illness in patients with NMD after 2 winters with high rates of respiratory illness. Between 1998 and 1999, 24 patients with NMD at a residential rehabilitation facility were prescribed 18 courses of antibiotics for 168 days of antibacterial therapy; 3 were hospitalized at acute care facilities for pulmonary infections. During 1997 through 1998, there were 18 patients with NMD, 32 courses of antibiotics, 272 days on antibiotics, and 10 hospitalizations. Based on published pilot data and our institution's experience with IPV during acute illness, we hypothesized that use of IPV in a preventive regimen would reduce number of days on antibiotics for respiratory infection in patients with pulmonary dysfunction caused by NMD, and would be well-tolerated by patients and acceptable to caregivers.[14] The rationale for using IPV in a preventive program for patients with NMD was to prevent atelectasis and mobilize secretions in patients unable to benefit from traditional techniques such as IS because of muscle weakness. It was also important to determine if IPV could be performed safely in a population at risk for mucous plugging.

We performed a randomized, controlled trial to study the efficacy of IPV in reducing days of antibiotic use and, secondarily, preventing respiratory infection, days missed from school, and hospitalizations in children and young adults with pulmonary compromise caused by NMD.

METHODS

PATIENT POPULATION

The study site is a 120-bed residential facility providing medical, rehabilitative, educational and recreational services to children with physical disabilities. Patients with impaired pulmonary function (defined by restrictive physiology with vital capacity <60% predicted, maximum inspiratory pressure <90 cm H_2O and maximum expiratory pressure less than 100 cm H_2O) caused by NMD were eligible. Of the 23 eligible patients, 18 were enrolled, 2 patients with tracheostomy tubes were excluded because IPV was part of their standard pulmonary regimen, and 3 declined to participate (**Table 1**). Consent to participate was obtained from the parent, patient, or legal guardian.

STUDY DESIGN

The study was a prospective, randomized trial of IPV or IS (standard of care) used daily from October 1, 1999, through April 30, 2000. After consent was obtained, patients were assessed by investigators for ability to perform IS and IPV. All subjects were able to perform both, and all were able to maintain a mouth seal and adequate facial muscle tone required for proper IPV technique.

Patients were randomized to IPV or IS using computer-generated randomization schedules (Metstat version 2.01, Cleveland, Ohio), which were prepared in blocks of 4. Both groups received instruction and practice with their respective treatment techniques. Patients assigned to IS performed IS (Voldyne 2500; Hudson RCI, Temecula, Calif) twice daily for 5 to 10 minutes. Patients randomized to IPV received treatments twice daily, using 6 mL of normal saline and a percussion frequency of 120 cycles per minute. Driving pressure (set at the minimum pressure that induced visible chest oscillations) was determined individually for each subject and was maintained consistently during the study. The range of driving pressures used was 20 to 40 cm H_2O.

Treatments took 10 to 15 minutes for complete aerosolization of saline. Though the manufacturer recommends using albuterol sulfate during IPV treatments, this was not part of this trial because of concern for exacerbating tachycardia, already present in some subjects with muscular dystrophy and dilated cardiomyopathy. Treatments were supervised by a respiratory therapist or nurse trained in manual cough assist in case mucous plugging occurred.

Subjects were evaluated at the beginning and end of the study to assess adequacy of randomization in terms of severity of illness and decline of pulmonary function during the study, and antibiotic use in the year before the study. Spirometry and lung volumes were determined and muscle strength assessed by measuring maximum voluntary ventilation, maximum inspiratory pressure, and maximum expiratory pressure.[15] The same respiratory therapist conducted pulmonary function testing during the study. Current institutional protocols were used to determine whether patients required intensification of their pulmonary regimen or initiation of antibiotics. Intensification of regimen occurred when subjects developed increased airway secretions, fever, lower than baseline oxygen saturation level, or wheezing. Options included initiating or increasing number of IPV treatments per day, administering albuterol sulfate with the IPV treatment if bronchospastic, initiating antibiotics when indicated, or manual cough assist.

Practice guidelines for treatment of bronchitis and pneumonia were in place during the study and they outlined specific criteria for the initiation of antibiotics for bronchitis and pneumonia. A 7- to 10-day course of antibiotics was initiated for acute bacterial bronchitis if the subject had cough, purulent sputum, temperature greater than or equal to 38°C, oxygen saturation within 2% to 3% of the patient's baseline, and no infiltrate on chest radiograph. Treatment for pneumonia

Table 1. Clinical Characteristics of Study Subjects*

	IS (n = 9)	IPV (n = 9)
Median age (range), y	17 (14-19)	17 (11-19)
Male	8 (89)	6 (67)
Diagnosis		
DMD	5 (56)	5 (56)
SMA	1 (11)	1 (11)
SCI	1 (11)	1 (11)
Mitochondrial	1 (11)	1 (11)
OI	1 (11)	1 (11)
Days of antibiotic use for prior year†	40 (2)	37 (2)

Abbreviations: DMD, Duchenne muscular dystrophy; IPV, intrapulmonary percussive ventilation; IS, incentive spirometry; OI, osteogenesis imperfecta; SMA, spinal muscular dystrophy; SCI, spinal cord injury.

*Unless otherwise indicated, values are presented as number (percentage).

†For the 1998-1999 school year, the year prior to the study, there were 1890 possible total days for antibiotic prescription.

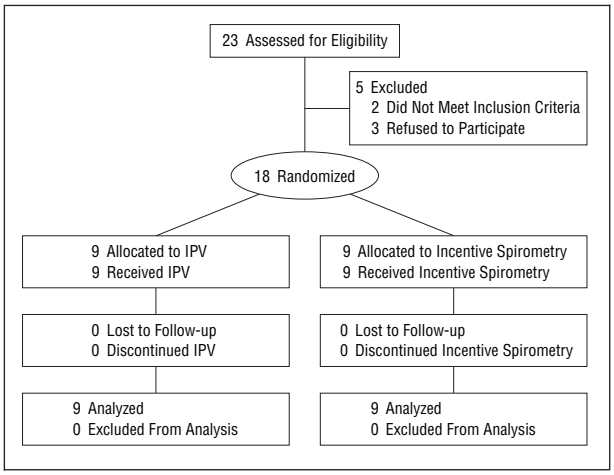

Figure. Flow diagram of subject progress through randomized trial. IPV indicates intrapulmonary percussive ventilation.

(10-14 days) was initiated if the subject demonstrated cough, purulent sputum, temperature greater than or equal to 38°C, decline in oxygen saturation greater than 3% from the baseline, consolidation on chest examination, and infiltrate on chest x-ray film. Primary practitioners at this facility initiated antibiotic therapy for respiratory illnesses based on these criteria, but were not blinded to the treatment group of their patients. Length of therapy was based on treatment guidelines and response to treatment. Patients were also cared for by community-based physicians (who were unaware of this study and did not necessarily use the practice guidelines) when home during school vacations. Antibiotics prescribed by community physicians were also recorded.

A nursing and patient satisfaction survey was conducted on completion of the study. The study was approved by the Institutional Review Board at Boston Medical Center and the Ethics Committee of the residential facility.

DATA ANALYSIS

The primary outcome was number of days on antibiotics for respiratory illness. Secondary outcomes were days of school missed owing to respiratory illness and days of hospitalization for respiratory illness. Sample size calculations indicated that with 9 patients in each group, the study would have 85% power to detect a 33% reduction in mean days on antibiotics, with a significance level of 0.05. Data analysis was performed by assessing comparability of groups by analysis of baseline characteristic variables using χ^2 tests or 2-tailed Fisher exact tests for categorical variables, and *t* tests for continuous variables. Pulmonary function tests were analyzed using nonparametric techniques. We used Poisson distribution to analyze outcome measures that were expressed as incident rate ratios with 95% confidence intervals.

RESULTS

Eighteen patients were enrolled from October to December 1999, and followed until April 30, 2000 (**Figure**). Nine patients received IPV and 9 received IS. Median age for each group was 17 years, with ranges of 11 to 19 years for IPV and 14 to 19 years for IS. Neither group received physiotherapy or postural drainage as part of their routine pulmonary hygiene. One subject in each group received nocturnal noninvasive ventilation for chronic respiratory failure related to underlying NMD. Both subjects used bilevel positive airway pressure using a nasal mask before the study, and continued this modality throughout the study. All subjects were nonsmokers, and none had chronic bronchitis. There were no differences between groups in age, race, gender, diagnosis, and antibiotic use from 1998 to 1999 (Table 1).

Twelve subjects (6 IPV, 6 IS) were able to perform spirometry, lung volumes, maximum voluntary ventilation, maximum inspiratory pressure, and maximum expiratory pressure. The 6 subjects (3 IPV, 3 IS) unable to provide a complete set of pulmonary function test data did not have partial results included in the data analysis. Four subjects were unable to maintain an adequate mouth seal for 6 seconds during spirometry. Two subjects had difficulty coordinating inspiratory and expiratory efforts on command. There were no differences between groups in severity of neuromuscular weakness at baseline or completion of the study, or in decline of pulmonary function as indicated by tests (**Table 2**).

Patients in the IPV group did not receive any antibiotics during the study period. Patients in the IS group received 44 days of antibiotics. Rate of antibiotic use, measured as days of antibiotic use, was significantly higher in the IS group (incidence rate ratio [IRR], 43; 95% confidence interval [CI], 6-333). Three courses of antibiotics were prescribed for 3 subjects in the IS group. Patients in the IS group were hospitalized for a respiratory illness for 8 days (1 subject), compared with 0 days for the IPV group (IRR, 8.5; 95% CI, 1.1-67) (**Table 3**).

Three patients in the IS group missed 5 days of school because of respiratory illness, compared with 1 day missed by a patient in the IPV group; this difference was not statistically different (IRR, 4.8, 95% CI, 0.5-37). Patients in the IS group (n=3) had 3 episodes of pneumonia or bacterial bronchitis compared with none for patients in the IPV group (IRR, 3.9; 95% CI, 0.43-35). The apparent discrepancy between school days missed and hospitalization days in the IS group occurred because hospitalization occurred during school vacation, so no school days were missed.

We reviewed number of supplemental respiratory treatments received by all subjects because of the low infection rate during the study year compared with previous years. This analysis was done to detect subtle markers of respiratory worsening indicated by intensification of a pulmonary regimen, but not requiring antibiotics. The IS group required significantly more supplemental respiratory treatments than the IPV group: 166 albuterol sulfate inhalation treatments vs 60 for the IPV group (IRR, 2.75; 95% CI, 2.05-3.76). The IS group received 172 IPV treatments vs 22 extra IPV treatments for the IPV group (IRR, 8.06; 95% CI, 5.16-12.66) (**Table 4**).

COMMENT

Patients with NMD using IPV in a preventive pulmonary regimen had significantly fewer days on antibiotics and days hospitalized for respiratory disease in this study. Fewer school days were missed and fewer pneu-

Table 2. Pulmonary Function Tests Before and After Study*

	Before (n = 9)			After (n = 9)		
	IS	IPV	*P* Value	IS	IPV	*P* Value
Predicted FEV1, %	42	49	NS	42	42	NS
Predicted FVC, %	35	36	NS	39	38	NS
TLC, L	3.2	3.1	NS	2.7	3.1	NS
MVV, L/min	24	36	NS	62	51	NS
MIP, cm H_2O	–12	–36	NS	–46	–47	NS
MEP, cm H_2O	36	32	NS	45	37	NS

Abbreviations: FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; IPV, intrapulmonary percussive ventilation; IS, incentive spirometry; MEP, maximum expiratory pressure; MIP, maximum inspiratory pressure; MVV, maximum voluntary ventilation; NS, not statistically significant, $P>.05$; TLC, total lung capacity.
*Data are expressed as the median.

Table 3. Clinical Outcomes for 18 Patients With NMD Treated With IS or IPV

	IS (n = 9)	IS No./1000 Patient-Days	IPV (n = 9)	IPV No./1000 Patient-Days	IRR (95% CI)
Days on antibiotics*	44	24	0	0	43 (6-333)
No. of pulmonary infections*	3	1.7	0	0	3.9 (.43-35)
School days missed for respiratory illness	5	4.5	1	.95	4.8 (.5-37)
Days hospitalized for pulmonary function*	8	4.4	0	0	8.5 (1.1-67)

Abbreviations: CI, confidence interval; IPV, intrapulmonary percussive ventilation; IRR, incidence rate ratio; IS, incentive spirometry.
*One added to each cell in order to make comparison between control and IPV groups. Analysis completed using total person-time.

Table 4. Supplemental Treatments Required Because of Pulmonary Symptoms in Patients With NMD Using IS or IPV

	IS (n = 9)	IPV (n = 9)	IRR (95% CI)	*P* Value
Additional IPV	172	22	8.06 (5.16-12.66)	<.001
Additional IS	4	0*	4.47 (0.553-40)	NS
Albuterol sulfate inhalation	166	60	2.78 (2.05-3.76)	<.001

Abbreviations: CI, confidence interval; IPV, intrapulmonary percussive ventilation; IRR, incidence rate ratio; IS, incentive spirometry; NMD, neuromuscular disease; NS, not statistically significant, $P>.05$.
*One added to each cell in order to make comparison. Analysis completed to total person-time.

monia and bronchitis episodes occurred in the IPV group. Patients in the IS group required more supplemental respiratory treatments and more frequent intensification of their respiratory therapy with nebulized albuterol sulfate or IPV.

To date, efficacy of IPV in preventing respiratory complications in patients with NMD has not been assessed. A preliminary report published after completion of this study demonstrated safety and effectiveness of airway clearance of IPV in 8 patients with Duchenne muscular dystrophy who had a tracheostomy. Intrapulmonary percussive ventilation improved mucus transport from the peripheral respiratory tract as measured by a higher weight of collected secretions. Intrapulmonary percussive ventilation was well tolerated and no adverse events occurred.[14]

A pilot study of 9 patients with cystic fibrosis comparing IPV with traditional chest percussion and postural drainage showed that IPV was as well tolerated as chest physiotherapy.[7] Intrapulmonary percussive ventilation has been compared with a flutter device to determine the ability to cause bilateral basal chest oscillations. In 10 patients with thick inspissated secretions and/or atelectasis, IPV was more effective in inducing chest oscillations.[16]

Intrapulmonary percussive ventilation is effective for mobilizing secretions in patients with severe burns or smoke inhalation injuries. The United States Army Institute reported results on 1978 IPV treatments on 25 patients who could not receive traditional chest physiotherapy because of burns to the chest and back. Intrapulmonary percussive ventilation treatments mobilized pulmonary secretions effectively in these patients.[8] Intrapulmonary percussive ventilation treatments are now prescribed at a leading burn center for patients requiring chest physiotherapy who are immo-

bilized because of healing skin grafts, burns, or donor sites on their trunk.[17]

Intrapulmonary percussive ventilation should be more effective than IS in preventing and treating atelectasis/microatelectasis in patients with NMD because it provides assistance in mobilizing secretions. Effectiveness of IS depends on inspiratory muscle strength, whereas IPV applies positive pressure and does not require generation of an inspiratory force to prevent atelectasis. Intrapulmonary percussive ventilation is particularly suited to the needs of patients with NMD because patients do not need to return to bed for treatments, leading to fewer interruptions in school, rehabilitative and recreational activities.

A limitation of the study was that the primary providers were not blinded to the treatment that their patient was receiving because it was not possible to create a sham IPV treatment. It is possible that treatment decisions were influenced as a result of knowing the patient's study group. If nursing and respiratory staff perceived additional benefit from IPV treatments, it may have biased the results by favoring more supplemental treatments in the IS group.

The investigators confirmed that primary caregivers at the study site initiated antibiotics with adherence to the practice guidelines of the facility. There are no evidence-based guidelines for antibiotic treatment for bronchitis or pneumonia in the NMD population, and no standard length of therapy. Duration of therapy was based on clinical response assessed by the clinician, rather than adherence to a standardized protocol. This potential confounding factor was an issue for both groups and affected length of treatment more than the number of courses of treatment, and did not favor 1 group more than the other.

Another potential limitation is that a standard IPV regimen specifying the mechanical frequency, pressure, and length of pauses was not used. Subjects had varying levels of neuromuscular weakness, body habitus, and stamina that precluded application of a uniform protocol. The minimum pressure required to create visible chest oscillations was determined for each subject and maintained at that level throughout the study (20-40 cm H_2O). Subject stamina also affected duration of IPV treatments. Intrapulmonary percussive ventilation treatment length was the time required to completely aerosolize 6 mL of saline, and although possible to complete an IPV treatment in 5 minutes, most subjects required 10 to 15 minutes.

Small sample size was another limitation of this study. Recruiting a large number of patients for a prospective, randomized study would require multiple study sites, but it would be a way to confirm these findings. During the study, there were fewer respiratory illnesses than in previous years. Confounding factors that may have contributed to a reduction in respiratory illnesses included the yearly variation in circulating respiratory pathogens and development of institutional programs during the study. Practice guidelines for treatment of patients with respiratory illness were developed and implemented. All patients were offered influenza and pneumococcal vaccines. These programs may have resulted in improved health during the study. It is possible that staff behavior was changed by raising the level of awareness about the importance of pulmonary toilet in patients with NMD.

A previous study in patients with cystic fibrosis comparing IPV with standard aerosol/chest physiotherapy showed no difference in use of antibiotics or hospitalization between the 2 groups.[18] Our results differ from this study because of the difference in patient populations. Patients with cystic fibrosis have chronic production of viscous secretions and are colonized routinely with *Pseudomonas aeruginosa* that may reduce effectiveness of IPV in mobilizing these secretions.

Our results are consistent with those of previous pilot studies demonstrating safety of IPV. No serious adverse effects occurred related to use of IPV; specifically, there were no episodes of mucous plugging. One patient developed minimal swelling of his lip related to the mouthpiece, which was corrected easily by switching the type of mouthpiece. In a pilot study of IPV, 1 patient with muscular dystrophy and cardiomyopathy developed heart block and hypoxemia during IPV treatment. The authors concluded that IPV therapy had mobilized the secretions, but the patient's muscle weakness prevented him from clearing them, causing acute airway obstruction.[13] Based on this report, our subjects were monitored by a nurse or respiratory therapist trained in cough assist techniques during and after IPV treatments. The standard of practice at this facility is that IPV is performed under the supervision of a caregiver experienced in cough assist techniques. A patient with NMD may require manual or mechanical cough assist to clear secretions mobilized by IPV treatments.

Patient satisfaction with IPV treatments was favorable, as assessed by questionnaire, with patients indicating ability to remain sitting in their wheelchairs during IPV as the main advantage of IPV compared with chest physiotherapy and postural drainage. A survey was also conducted to assess nursing satisfaction with use of IPV therapy. Nurses reported that it took 5 to 15 minutes to complete an IPV treatment. Depending on muscle strength, patients were able to assist during IPV therapy, which promotes self-care and independence, according to C. Dewey, RN (written communication, March 2000).

Intrapulmonary percussive ventilation therapy as a part of a preventive pulmonary regimen was successful in reducing number of days of antibiotic use and hospitalization days secondary to respiratory infection in adolescents and young adults with NMD. Use of IPV therapy in other settings, such as home care programs, may also help improve the quality of life for patients with NMD, by minimizing antibiotic use and rates of pneumonia and hospitalization.

Accepted for Publication: January 1, 2005.
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Funding/Support: This study was supported in part by a grant from the Deborah Munroe Noonan Memorial Fund, Boston, Mass; intrapulmonary percussive venti-

lation devices provided by Percussionaire Corp, Sandpoint, Idaho; Parker B. Francis Fellowship Award, Harvard School of Public Health, Boston (Dr Reardon).
Previous Presentations: Presented in part at the American Thoracic Society International Conference; May 19, 2002; Atlanta, Ga.
Acknowledgment: We thank our patients, their families, and the nursing staff for their enthusiastic participation. We thank Mary O'Toole, Maureen Bradley, Bonnie Rowe, and Cathy Dewey for their tireless efforts. We also thank Suzanne Steinbach, MD, for her critical review of the manuscript.

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