1 Web-only supplement

2

- 3 Lessons learned from a randomized trial of airway secretion clearance techniques in cystic
- 4 fibrosis

5

- 6 Marci K. Sontag Ph.D., Alexandra L. Quittner, Ph.D., Avani C. Modi, Ph.D., Don Giles, Joni
- 7 M. Koenig, B.S., Christopher M. Oermann, M.D., Michael W. Konstan, M.D., Robert Castile,
- 8 M.D., Frank J. Accurso, M.D

Methods

1

2 The 17 Treatment Satisfaction Survey (TSS) questions were summarized into 4 domains: 3 effectiveness, convenience, comfort, and overall satisfaction; mean satisfaction scores were derived, as described elsewhere. E1 Results from the 12 domains of the Cystic Fibrosis 4 5 Questionnaire (CFQ) Teen/Adult (48 items for teens 14 years or older) and CFQ-Child (36 items for children 7 to 13 years) measures were pooled for analyses, as previously published. E2;3 6 7 Response choices generally included ratings of frequency and difficulty on a 4-point scale 8 (1=always to 4=never; 1=a lot of difficulty to 4=no difficulty) or true/false responses (1=very 9 true to 4=very false). Scores were standardized on a 0-100-point scale, with higher scores 10 representing better quality of life. 11 The Daily Phone Diary (DPD) was administered every 4 months, and was quantified as 12 the percent of prescribed treatment time reported during each 24 hour period surveyed, limited to 100%. 4;5 The DPD, an evidence-based assessment of adherence 6, uses a cued recall procedure to 13 14 track participants through their activities in a 24 hour period prior to the phone call. The calls 15 were made by independent interviewers in a centralized office. Data were collected on the DPD 16 for the first 5 assessments, spaced approximately 4 months apart. Collection of data from the DPD was sparse after the 5th assessment as the study was discontinued before many subjects 17 reached the 6th assessment. 18

1 Training instructions provided to sites for each airway clearance technique

2

3

PD&P

- 4 Each of the six positions are to be clapped or vibrated for 4 minutes. After each position the
- 5 patient is to do three forced expiratory techniques (FET) and cough, continue with FET and
- 6 coughing until all mobilized mucus has been cleared. All nebulizer treatments will be done as
- 7 directed by the investigator.

8

- 9 1. Posterior apical segments of right and left upper lobes: Patient sitting up leaning forward on a pillow.
- 11 2. Superior and inferior segments of lingula: Patient one quarter turn from supine with left
- side up lying on wedge.
- 13 3. Medial and lateral segments of right middle lobe: Patient one quarter turn from supine
- with right side up lying on wedge.
- 15 4. Lateral segment of right lower lobe: Patient directly on left side with right side up lying
- on wedge.
- 17 5. Lateral segment of left lower lobe and medial (cardiac) segment of right lower lobe:
- Patient directly on right side, with left side up lying on wedge.
- 19 6. Posterior basal segments of right and left lower lobes: Patient prone lying on wedge

OPEP Treatment

20

- Patient is to sit in a chair with their back straight and chin slightly elevated. Proper angle
- of the device is important. The patient should start out with the stem parallel to the floor,
- 23 experiment with the angle of the device, for best results use the angle that provides the strongest

- 1 fluttering sensation in the chest. Patients are to keep the cheeks stiff, (they may need to hold
- 2 their cheeks with their hands). Flutter treatments should be done for 20 minutes. All nebulizer
- 3 treatments will be done as directed by the investigator.

Stage 1 loosening and mobilization breaths:

- 5 Inhale slowly, to about 3/4 total lung capacity (TLC), hold the breath for 2-3 seconds,
- 6 exhale at a reasonably fast but not to forced rate (exhalation should be balanced to provide the
- 7 most amount of fluttering felt within the chest).
- 8 Repeat step one 6-12 times (depends on patient and how quickly mucus is mobilized).
- Patients should be encouraged to suppress their need to cough until all loosening breaths
- 10 have been completed.

4

11

17

18

Stage 2 mucus mobilization and expectoration:

- Inhale slowly to TLC, hold the breath for 2-3 seconds, and then forcefully exhale as
- completely as is comfortable, repeat 1-2 times. If mucus is not coughed out following 2 breaths,
- have the patient do 2-3 FET followed by coughing.
- 15 Continue with the above two steps until all loosened mucus had been cleared. Stage one
- and two are repeated for 20 minutes.

HFCWO

- Each frequency will be done for five minutes with deep breathing to total lung capacity
- 20 (TLC) every two minutes, pressure will remain constant at 6. After each cycle three FET will be
- done followed by a cough, continue with FET and coughing until all mobilized mucus has been
- cleared. The patient may be in semi-fowlers, sitting, or standing throughout the entire vest
- treatment. Bronchodilator treatments may be started with the first cycle and continued (turning

- off nebulizer while coughing) until finished, all other nebulizer treatments will be done as
- 2 directed by the investigator.
- 3 1. Frequency 10 for 5 minutes with TLC breaths every 2 minutes, followed by 3 FET and
- 4 coughing, continue with FET and coughing until clear.
- 5 2. Frequency 12 for 5 minutes with TLC breaths every 2 minutes. followed by 3 FET and
- 6 coughing, continue with FET and coughing until clear.
- 7 3. Frequency 13 for 5 minutes with TLC breaths every 2 minutes. followed by 3 FET and
- 8 coughing, continue with FET and coughing until clear.
- 9 4. Frequency 14 for 5 minutes with TLC breaths every 2 minutes. followed by 3 FET and
- 10 coughing, continue with FET and coughing until clear.
- Alternative settings to be used if patients report that no mucus is expectorated at the end
- of the 5 minute settings.

17

18

- Frequency 12 for 10 minutes with TLC breathing every 2 minutes, followed by 3 FETs
- and coughing, continue with FETs and coughing until clear.
- 15 Frequency 14 for 10 minutes with TLC breathing every 2 minutes, followed by 3 FETs
- and coughing, continue with FETs and coughing until clear.

Forced Expiratory Technique (FET)

- The subject may be in the semi-Fowlers, sitting, or standing position while performing
- 20 forced expiratory technique (FET). FET is to be performed after each position during chest
- 21 physical therapy and after each cycle during Flutter and HFWCO therapy.
- 22 1. Inhale to total lung capacity, followed by a 2-3 second breath hold.

- 1 2. Keeping the glottis open, perform a forced exhalation maneuver to functional
- 2 residual capacity. Repeat step 1 and 2 three times.

5

- 3 3. Inhale to total lung capacity then cough to clear loosened secretions.
- 4 4. If secretions are mobilized, continue with step 1, 2, and 3 until clear.

1 2 3		References
3	(1)	Oermann CM, Swank PR, Sockrider MM. Validation of an instrument measuring patient
4		satisfaction with chest physiotherapy techniques in cystic fibrosis. Chest 2000; 118(1):92-97.
5	(2)	Quittner AL, Buu A, Messer MA, Modi AC, Watrous M. Development and validation of The
6		Cystic Fibrosis Questionnaire in the United States: a health-related quality-of-life measure for
7		cystic fibrosis. Chest 2005; 128(4):2347-2354.
8	(3)	Modi AC, Quittner AL. Validation of a disease-specific measure of health-related quality of life for
9		children with cystic fibrosis. J Pediatr Psychol 2003; 28(8):535-545.
10	(4)	Modi AC, Quittner AL. Utilizing computerized phone diary procedures to assess health behaviors
11		in family and social contexts. Child Health Care 2006; 35(1):29-45.
12	(5)	Modi AC, Lim CS, Yu N, Geller D, Wagner MH, Quittner AL. A multi-method assessment of
13		treatment adherence for children with cystic fibrosis. J Cyst Fibros 2006; 5(3):177-185.
14	(6)	Quittner AL, Modi AC, Lemanek KL, Ievers-Landis CE, Rapoff MA. Evidence-based assessment
15		of adherence to medical treatments in pediatric psychology. J Pediatr Psychol 2008; 33(9):916-936.
16		
17		