

Objective Versus Self-Reported Adherence to Airway Clearance Therapy in Cystic Fibrosis

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BACKGROUND: Historically, studies of adherence to airway clearance therapy in cystic fibrosis (CF) have relied on self-reporting. We compared self-reported airway clearance therapy adherence to actual usage data from home high-frequency chest wall compressions (HFCWC) vests and identified factors associated with overestimation of adherence in self-reports. **METHODS:** Pediatric patients who perform airway clearance therapy with a HFCWC vest were eligible to participate. Objective adherence data were obtained from the HFCWC device, which records cumulative utilization time. Two readings at least 5 weeks apart were collected. Objective adherence was recorded as a ratio of mean-to-prescribed daily use (%). Self-reported adherence data were collected with a caregiver survey at enrollment. Adherence rates were categorized as low (< 35% of prescribed), moderate (36–79% of prescribed), and high (\geq 80% of prescribed). An overestimation was present when self-reported adherence was at least one category higher than objective adherence. **RESULTS:** In the final sample ($N = 110$), mean adherence by usage data was 61%. Only 35% of subjects ($n = 38$) were highly adherent, and 28% ($n = 31$) were low adherent. In contrast, 65% of subjects ($n = 72$) reported high adherence and only 8% ($n = 9$) reported low adherence ($P < .001$). Nearly half of self-reports (46%) overestimated adherence. In a multiple regression analysis, overestimation was associated with multiple airway clearance therapy locations (odds ratio 7.13, 95% CI 1.16–43.72, $P = .034$) and prescribed daily use \geq 60 min (odds ratio 3.85, 95% CI 1.08–13.76, $P < .038$). Among subjects with prescribed daily airway clearance therapy \geq 60 min, the odds of overestimating adherence increased 3-fold (odds ratio 3.04, 95% CI 1.17–7.87, $P = .02$) in a lower-income (< \$50,000/y) environment. **CONCLUSIONS:** Self-reports overestimated actual adherence to airway clearance therapy, and the overestimation increased with treatment occurring in multiple households and prescribed therapy duration. Among participants with prescribed airway clearance therapy \geq 60 min, overestimation increased with lower income. Objective measures of adherence are needed, particularly for lower-income children and those receiving treatments in multiple locations. *Key words:* adherence; airway clearance; chest physical therapy; high-frequency chest wall compressions; cystic fibrosis. [Respir Care 2019;64(2):176–181. © 2019 Daedalus Enterprises]

Introduction

Adherence, defined as the extent to which a person's behavior (in terms of taking medications, following diets,

or executing lifestyle changes) coincides with medical or health advice,¹ involves actions and intentions that are difficult to quantify.² In the absence of established standards for assessment, adherence has been measured in a variety of ways, each with its own strengths and limita-

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tions.³ Overall, the available measures are either subjective, such as self-reports by patients or caregivers, or objective, such as missed appointments, pill counts, electronic monitoring, chart reviews, and serum assays of drug levels. In subjective measures, data are easily collected, but there is the potential for information bias or recall bias, resulting in inadequate reliability and overestimation of adherence.⁴⁻⁷

Airway clearance therapy is a standard component of the daily therapeutic regimen^{8,9} for patients with cystic fibrosis (CF), the second most common life-shortening genetic disorder in the United States.¹⁰ Adherence to airway clearance therapy in CF has been estimated at 40–60% by subjective, self-reported measures.¹¹⁻¹³ Although disagreement between self-reported and actual adherence has been reported for other components of the CF regimen (eg, nebulizer treatments),¹⁴ assessments of airway clearance therapy have relied historically on self-reports. This study investigated the discrepancy between self-reported and objectively measured adherence to airway clearance therapy in pediatric patients with CF. We compared the 2 adherence measures using data from the patients' home airway clearance therapy equipment, a high-frequency chest wall compression (HFCWC) vest, and we identified factors associated with overestimation of self-reported adherence.

Objectively measured adherence to airway clearance therapy in pediatric patients with CF has been associated with patient age and prescribed therapy duration,¹⁵ as well as maternal education, household income, and the number of adults in the household.¹⁶ We expected that these factors will also be impactful when comparing self-reported and objective adherence measures in this population. We proposed 2 study hypotheses: self-reports will overestimate actual adherence to airway clearance therapy, and overestimation will be positively associated with prescribed treatment duration, patient age, lower parental education, lower household income, and fewer adults in the household.

Methods

Study Population

Pediatric patients at the University of Alabama at Birmingham CF Center who perform airway clearance therapy with the HFCWC vest ($n = 161$) were eligible to participate. Vest compressors feature a built-in chronom-

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QUICK LOOK

Current knowledge

Studies of adherence to airway clearance therapy in CF have relied on self-reporting, which may overestimate actual adherence rates. Factors associated with overestimation of self-reported adherence to airway clearance in this population have not been identified.

What this paper contributes to our knowledge

We compared self-reported adherence to actual usage data from home high-frequency chest wall compression vests and found that nearly half of self-reports overestimated actual adherence. The overestimation increased with treatment in multiple households and prescribed treatment duration. Among subjects with prescribed treatment of at least 60 min, overestimation increased with lower income. Objective measures of adherence are needed, particularly in lower-income patients and those receiving treatments in multiple locations.

eter that records cumulative device utilization time, offering an accurate, objective adherence measure. HFCWC is the most common method for airway clearance therapy in the United States, used by 86% of patients with CF, age 6–18 y.¹⁰

Of all eligible patients, 126 (78%) were invited to participate in the study. Of those who enrolled ($n = 120$), 116 (97%) completed the study. Missing data resulted in the exclusion of 5% of observations ($n = 6$). The final analyses included 110 subjects. The study was approved by the University of Alabama at Birmingham Institutional Review Board for Human Use (Protocol X140124004).

Data Collection

Objective adherence data were obtained from the subject's home HFCWC device. Two readings were recorded: the first within 2 d of study enrollment, and the second approximately 5 weeks after baseline. The difference between the 2 readings, divided by the number of days between them, provided an average daily use of the HFCWC vest. In-patient days were subtracted from the number of days between readings, if applicable. Self-reported adherence data were collected with a paper questionnaire at study enrollment. The survey also collected data on the family's demographics, socioeconomic characteristics, and health behaviors. Clinical data were abstracted from the CF Patient Registry.

Adherence Measures

Objective adherence rate was represented as a ratio of mean-to-prescribed daily use (%). Prescribed daily use was provided by the respiratory therapist. The self-reported adherence measure was adopted from the validated Treatment Adherence Questionnaire–CF.¹⁷ This well-established tool has strong psychometrics, including high test–retest reliability and parent–adolescent agreement. Only questions pertaining to airway clearance were used: “In a typical week, how often does your child do airway clearance?” (Not at all; 1–2 times per week; 3 times per week; 4 or more times per week; Once a day; Twice a day; Three or more times per day); and “In a typical week, how many minutes does your child spend doing each airway clearance treatment?” (0 min; 5 min; 10 min; 15 min; 20 min; 25 or more min). Self-reported adherence rates were calculated based on responses about frequency and duration of treatments. Both objective and self-reported adherence were coded in 3 categories: low (< 35% of prescribed), moderate (36–79% of prescribed), and high (\geq 80% of prescribed) in accordance with previously used cut-offs.^{16,18} The discrepancy between self-reported and objective adherence was coded as “1 = Yes” when the difference between the 2 measures was at least 1 category (eg, high vs moderate or moderate vs low).

Control Variables

Data on caregiver age, race, gender, educational attainment, annual household income, health insurance (private/public), marital status, number of adults in the household, and location of airway clearance therapy treatments were collected with a paper survey at study intake. Clinical data were abstracted from the CF Patient Registry. Lung function was reported as FEV₁ % predicted, with values estimated based on Wang equations.¹⁹

Statistical Analysis

Univariate statistics, including means, standard deviations, frequencies, and proportions, were obtained for all non-missing cases. Bivariate relationships were estimated with analysis of variance, simple logistic regression, or cross-tabulation using the Pearson chi square test for cells with > 5 observations and Fisher exact statistics for cells with \leq 5 observations. Adherence overestimation was further examined with multivariable logistic regression. Factors in the model included variables with a significance level $P < .10$ in the bivariate analyses. Statistical tests were 2-tailed and were conducted using a 5% significance level ($\alpha = .05$). Analyses were performed with Stata software, version 14 (StataCorp, College Station, Texas).

Table 1. Characteristics of Study Participants (N = 110)

Variable	% or Mean (SD)
Caregiver characteristics	
Age, y	41.1 (8.0)
White	91.8
Female	84.6
Married/cohabiting	85.5
Paternal education \leq high school	34.6
Maternal education \leq high school	20.9
Household income < \$50,000	40.9
Public health insurance	35.5
One-adult households	10.9
Patient characteristics	
Age, y	11.2 (4.7)
F508del homozygous genotype	52.7
<i>P. aeruginosa</i> ever	36.4
CF-related diabetes	14.6
Depressive symptoms	12.7
Other comorbidities	70.0
Lung function, FEV ₁ % predicted	
< 85	21.8
85–99	34.6
\geq 100	27.3
N/A (age < 6 y)*	16.4
Airway clearance therapy characteristics	
Prescribed daily duration \geq 60 min	83.6
Multiple locations	9.1
HFCWC vest type	
Hill-Rom, TheVest	86.4
Respirtech, InCourage System	11.8
Electromed, SmartVest	1.8
Adherence	
Objective (mean-to-prescribed daily use, %)	60.6 (31.0)
\leq 35%	28.2
36%–79%	37.3
\geq 80%	34.6
Self-reported	
\leq 35%	8.2
36%–79%	26.4
\geq 80%	65.5
Overestimation (self-reported > objective)	46.5

N = 110 subjects

* Subject was age-ineligible for pulmonary function test.

Results

Characteristics of the Sample

The characteristics of the sample are presented in Table 1. Mean caregiver age was 41 y, and mean subject age was 11 y. The majority of caregivers were non-Hispanic white (92%), female (85%), and married/cohabiting (86%). Thirty-five percent of fathers and 21% of mothers had a high-school education or less; 41% of households had income

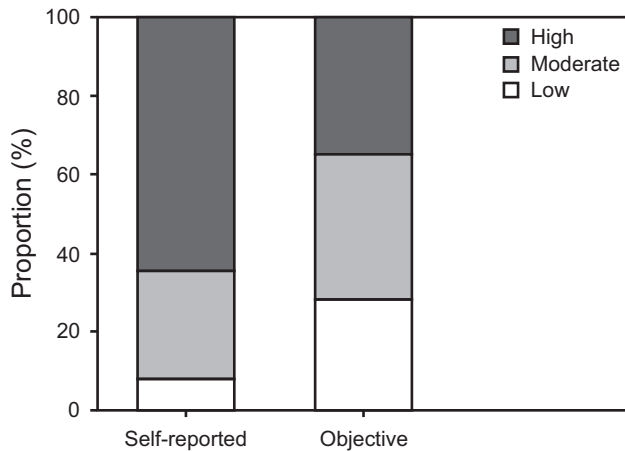


Fig. 1. Self-reported vs objective adherence (% of prescribed daily therapy) to airway clearance therapy. $P < .001$ between self-reported and objective data for each category of adherence. High adherence: $> 80\%$ of prescribed daily therapy, Moderate adherence: $36\text{--}79\%$ of prescribed daily therapy, and Low adherence: $\leq 35\%$ of prescribed daily therapy.

$< \$50,000/y$, 36% had public health insurance, and 11% were single-adult households. In 9% of cases, airway clearance therapy took place in multiple locations (ie, in more than one household, as with divorced parents or with care split between parents and grandparents). The majority of subjects (84%) had prescribed daily airway clearance therapy of 60 min or more, and the majority of vests (86%) were The Vest (Hill-Rom, Batesville, Indiana).

Adherence Rates

Mean time between HFCWC vest utilization readings was 37 d . On the basis of utilization data, the mean adherence rate was 61% of prescribed. Only 35% of all subjects ($n = 38$) were highly adherent ($\geq 80\%$ of prescribed), and 28% ($n = 31$) were low-adherent ($\leq 35\%$ of prescribed). On the basis of caregiver self-report, 66% of subjects ($n = 72$) were highly adherent, and 8% ($n = 9$) were low adherent. Nearly half of caregivers (47%) assessed their adherence inaccurately ($P < .001$) (Fig. 1). These results support our hypothesis that self-reports overestimate actual adherence to airway clearance therapy.

Overestimation of Self-Reported Adherence

Table 2 shows results of bivariate analysis of adherence overestimation by caregiver, patient and airway clearance therapy characteristics included in Table 1. Only variables with $P < .10$ are presented. Among caregiver characteristics, overestimation of adherence was associated with income $< \$50,000/y$ (odds ratio [OR] 2.56 , 95% CI $1.17\text{--}5.59$, $P = .02$). Clinical phenotype was not significantly

Table 2. Factors Associated with Overestimation of Self-Reported Adherence

	Odds Ratio (95% CI)	P
Caregiver characteristics		
Age	0.95 (0.90–1.00)	.050
Income $< \$50,000$	2.56 (1.17–5.59)	.02
Patient characteristics		
<i>P. aeruginosa</i> ever	0.48 (0.22–1.07)	.07
FEV ₁ % pred. $> 100\%$	0.48 (0.20–1.14)	.10
Airway clearance therapy characteristics		
Multiple airway clearance therapy locations	5.30 (1.07–26.24)	.041
Prescribed duration $\geq 60\text{ min}$	1.03 (0.99–1.07)	.09

$N = 110$ subjects. Only variables with $P < .10$ are presented.

Table 3. Multiple Logistic Regression of Adherence Overestimation

Variables	Odds Ratio (95% CI)	P
Multiple airway clearance therapy locations	7.13 (1.16–43.72)	.034
Prescribed duration $\geq 60\text{ min}$	3.85 (1.08–13.76)	.038
Caregiver age	0.97 (0.91–1.02)	.23
Income $< \$50,000$	1.85 (0.78–4.35)	.16
<i>P. aeruginosa</i> ever	0.64 (0.26–1.62)	.35
FEV ₁ % pred $> 100\%$	0.50 (0.19–1.35)	.17

$N = 110$ subjects. Likelihood ratio chi square (6) = 21.09 , $P < .01$.

associated with increased odds of inaccurate self-reported adherence. Nonsignificant trends toward agreement between objective and subjective adherence were observed in subjects with a history of *P. aeruginosa* (OR 0.48 , $P = .07$) and those with a FEV₁ $> 100\%$ predicted (OR 0.48 , $P = .10$). Having multiple locations for airway clearance therapy delivery was significantly associated with adherence overestimation (OR 5.30 , 95% CI $1.07\text{--}26.24$, $P = .041$).

Table 3 presents results from multiple logistic regression of adherence overestimation. In the model, which included all variables with $P < .10$ in the bivariate analyses, multiple airway clearance therapy locations (OR 7.13 , 95% CI $1.16\text{--}43.72$, $P = .034$) and prescribed airway clearance therapy duration of $\geq 60\text{ min}$ (OR 3.85 , 95% CI $1.08\text{--}13.76$, $P = .038$) were statistically significant predictors of overestimation, increasing the risk of inaccurate self-reports approximately 7-fold and 4-fold, respectively.

Among the subgroup of subjects with prescribed daily airway clearance therapy of $\geq 60\text{ min}$, household income $< \$50,000/y$ was associated with a 3-fold increase in the odds of adherence overestimation (OR 3.04 , 95% CI 1.17--

Table 4. Adherence Overestimation When Prescribed Daily Treatment Is ≥ 60 min

Variables	Odds Ratio (95% CI)	P
Multiple airway clearance therapy locations	6.88 (0.75–63.34)	.09
Caregiver age	0.95 (0.90–1.01)	.13
Income < \$50,000	3.04 (1.17–7.87)	.02
<i>P. aeruginosa</i> ever	0.73 (0.26–2.01)	.54
FEV ₁ % pred. > 100%	0.76 (0.26–2.20)	.61

N = 110 subjects.
Likelihood ratio chi square (5) = 17.37, *P* < .01.

7.87, *P* = .02) after controlling for the same covariates (Table 4).

The results from multiple regression analysis (Tables 3 and 4) support our hypothesis that overestimation of airway clearance therapy adherence is positively associated with prescribed treatment duration and lower household income. The association of overestimation with older patient age, lower parental education, and fewer adults in the household is not supported; instead, location of airway clearance therapy treatments in > 1 household is a significant predictor of overestimated adherence.

Discussion

We compared objective and subjective reports of airway clearance therapy adherence to quantify the disagreement between these measures and to underscore the necessity of objective measures in CF adherence studies. According to caregiver self-reports, only 8% of subjects had low adherence, while objective data revealed 28% were low adherent. Conversely, 66% of caregiver self-reports claimed high adherence, whereas the objective data showed only 35% to be highly adherent. Nearly half (47%) of self-reports overestimated airway clearance therapy adherence. These results indicate a large magnitude of overestimation and posit that self-reports are not a reliable assessment of airway clearance therapy adherence. Subjective reports of airway clearance therapy adherence in the home environment are problematic without adequate confirmatory technology. Although HFCWC utilization data offer a compelling measure of adherence, absence of automated, direct data transmission leads to their limited incorporation into clinical care. Equipping HFCWC vests with electronic monitoring technology is a feasible advancement that allows real-time assessment of adherence for clinical or research purposes. HFCWC vest manufacturers have begun incorporating wireless connectivity into vests (eg, Hill-Rom's VisiVest, Electromed's SmartVest Connect, and RespirTech's In-Courage). This effort will be most successful if manufacturers, insurance companies, health care providers, and CF

stakeholders work to make the new, connected devices available to all patients quickly, without extensive wait periods for those who already own a non-connected vest. Programs to ensure that vest data are shared with and effectively used by patients and clinicians will also be necessary.

As with clinical practice, most research of airway clearance therapy adherence has also relied on self-reports. We are aware of only one published study that similarly reported a gap between subjective and objective measures.¹⁵ No prior research has identified sources of this disagreement. Our study extends the CF adherence literature by investigating predictors of adherence overestimation. We show that multiple locations of airway clearance therapy and prescribed daily airway clearance therapy duration ≥ 60 min are associated with increased odds of overestimation. Among those with prescribed daily airway clearance therapy of ≥ 60 min, lower income (< \$50,000/y) is a risk factor for overestimation. These findings point to the importance of the caregiver environment for adherence to airway clearance therapy. Our prior research similarly identified that family structure and access to financial resources play an important role in airway clearance therapy adherence.¹⁶ Because low-income children and those who receive care in multiple households are at increased risk of overestimating adherence, they should be prioritized recipients of interventions to collect objective airway clearance therapy adherence data.

Objective and self-reported adherence tap different behavioral constructs and measure different phenomena.²⁰ Self-reported adherence essentially is a measure of one's *perception* of adherence. Self-reports reflect one's perceived sense of control,²¹ self-esteem,²² and self-efficacy,²³ as well as one's knowledge about the prescribed treatment regimen.²⁴ One of the difficulties in airway clearance therapy adherence research is determining what has been prescribed, and this is further complicated by occasional changes in prescribed regimen due to pulmonary exacerbation or bacterial acquisition. If a written plan is not provided at each out-patient or in-patient visit, it is difficult to assess if the patient and family understand correctly what has been prescribed. As reported previously, written treatment plans are not always offered to families of patients with CF.²⁴ Unfortunately, the Treatment Adherence Questionnaire–CF does not include a question to determine what the respondent believes the prescribed regimen to be. To detect discrepancies between perceived prescribed regimen and what was actually prescribed, a written airway clearance therapy plan should be provided.

Our study has several limitations. This is a single-center sample, which limits the generalizability of findings. The relatively high objective adherence rate (61%) compared to adherence rates estimated in the literature (40–47% for children with CF)¹³ may reflect changed adherence behav-

ior due to the awareness of being observed. Nevertheless, the rate is consistent with adherence rates published in 2 other airway clearance therapy studies (69% and 58%, respectively).^{12,15} Another limitation is that utilization data from the HFCWC vests were collected by study staff over the telephone because the vests in the study were not equipped for direct data transmission. Caregivers were not notified when study staff would call to record a reading, either at baseline or follow-up, and on many occasions the follow-up reading was provided by a different caregiver than the baseline reading. Despite these measures to rule out information bias, the potential for inaccurate utilization data exists. Direct data transmission from HFCWC devices is preferred when possible. In addition, the study staff did not verify whether HFCWC pressure and frequency settings matched prescribed settings. It is also possible for patients to let the equipment run without doing the treatment. Even wireless-connected vests leave room for errors or intentional misuse, such as turning the device on without wearing it. Integration of sensors for pressure and human capacitance will be necessary to guarantee proper wear and to safeguard against misuse.

Conclusions

Caregiver self-reports overestimated actual adherence to airway clearance therapy in pediatric patients with CF. As the magnitude of overestimation is large and is present in nearly half of caregivers, self-reports are not an accurate measure of adherence. Multiple treatment locations and higher prescribed treatment duration increase the odds of adherence overestimation. Among subjects with prescribed treatments of at least 60 min daily, overestimation increased with lower income. Objective data from HFCWC equipment should be used in CF care, particularly with patients who receive care in multiple low-income households.

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