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Original Research

ASTHMA

FEV_1 Performance Among Patients With Acute Asthma*

Results From a Multicenter Clinical Trial

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Objective: **To determine the ability of patients seen for acute asthma exacerbations in the emergency department (ED) to perform good-quality FEV_1 measurements.**
Methods: **Investigators from 20 EDs were trained to perform spirometry testing as part of a clinical trial that included standardized equipment with special software-directed prompts. Spirometry was done on ED arrival and 30 min, 1 h, 2 h, and 4 h later, and during follow-up outpatient visits.**
Measurements: **Study performance criteria differed from American Thoracic Society (ATS) guidelines because of the population acuity and severity of illness as follows: ability to obtain acceptable FEV_1 measures (defined as two or more efforts with forced expiratory times ≥ 2 s and time to peak flow < 120 ms or back-extrapolated volume < 5% of the FVC) and reproducibility criteria (two highest acceptable FEV_1 values within 10% of each other).**
Results: **Of the 620 patients (age range, 12 to 65 years), > 90% met study acceptability criteria on ED arrival and 74% met study reproducibility criteria. Mean initial FEV_1 was 38% of predicted. Spirometry quality improved over time; by 1 h, 90% of patients met study acceptability and reproducibility criteria. Patients with severe airway obstruction (FEV_1 < 25% of predicted) were initially less likely to meet quality goals, but this improved with time. The site was also an independent predictor of quality.**
Conclusion: **When staff are well trained and prompt feedback regarding adequacy of efforts is given, modified ATS performance goals for FEV_1 tests can be met from most acutely ill adolescent and adult asthmatics, even within the first hour of evaluation and treatment for an asthma exacerbation.**
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Key words: acute disease; asthma; spirometry; task performance

Abbreviations: ATS = American Thoracic Society; BEV = back-extrapolated volume; BMI = body mass index; ED = emergency department; ERS = European Respiratory Society; FET = forced expiratory time; PEF = peak expiratory flow; PEFT = time to peak flow

Current practice guidelines for the treatment of an acute asthma exacerbation, such as in the emergency department (ED) setting, recommend that objective measures of pulmonary function such as peak expiratory flow (PEF) and FEV_1 be used.[1] Mechanical peak flow meters are most commonly used in the ED setting since they are inexpensive

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None of the investigators have any financial interest in the company that manufactures the spirometer used in the study. Dr. Silverman has consulted for AstraZeneca, and Dr. Simonson is an employee of AstraZeneca. Ms. Flaster and Dr. Enright have no conflicts of interest to report.
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and easy to use. However, FEV_1 as a measure of asthma severity has advantages compared to PEF. These include greater accuracy, less effort dependence, better repeatability, and for some spirometers the availability of real-time graphics and quality assurance checks to confirm reliability of the results.[2,3]

Performance of spirometry in the ED presents challenges not faced in office practice or a pulmonary function laboratory. ED patients are often acutely short of breath, fatigued, uncomfortable, and anxious. Coughing during forced exhalation maneuvers is more common in acutely ill patients. In addition, the ED environment itself can be chaotic, and the patient may have never performed spirometry before.

Recommended standard procedures and goals for performance of diagnostic-quality and research-quality spirometry have been published,[4–6] and studies have shown that these goals can be met by approximately 90% of patients tested in a pulmonary function laboratory,[7] as well as approximately 90% of children and adults in research studies.[8,9] However, the ability to perform spirometry in asthmatics during an acute exacerbation has not been reported. A multicenter clinical trial[10] evaluating the efficacy of a leukotriene-modifying agent to treat acute asthma in adults used subsequent change in FEV_1 as an important outcome measure, providing the data for this analysis. The goal of this study was to describe the performance of spirometry for purposes of obtaining an FEV_1 among acutely ill asthmatics in an ED setting.

Materials and Methods

Inclusion and exclusion criteria for the trial have been described.[10] Briefly, patients were 12 to 65 years old and presented with an acute episode of asthma, with FEV_1 <70% of predicted at ED entry and after a single aerosol treatment with albuterol. Spirometry was performed on ED arrival (baseline, time 0) and after 30, 60, 120, and 240 min. Albuterol treatments were administered after each spirometry test. For patients not hospitalized, follow-up spirometry was scheduled at day 10 and day 28 after ED discharge. Patients who relapsed prior to the scheduled visit were not required to maintain the follow-up appointment. For this analysis, we included all patients who had one or more spirometry tests done during the study.

All centers used the same model spirometer (KoKo Spirometer; Pulmonary Data Services; Lewisville, CO) for the ED visit and outpatient follow-up. Percentage of predicted FEV_1 was calculated according to Crapo et al,[11] with predicted values for African-American patients calculated as 88% of the predicted value for whites.[12] Hispanics, Asians, and others used the predicted value for whites. Spirometer calibration was checked using a 3-L syringe each day of testing.

Training

Investigators were first trained as a group during a half-day session. Most of the investigators performing spirometry were ED study personnel (registered nurse, physician assistant, or research assistant) who had no prior training in spirometry. The investigators were taught to use the equipment, transmit the data electronically, understand study-specific criteria, and perform spirometry under a number of difficult practice scenarios (*eg*, uncooperative patient, coughing, tongue-obstructing mouthpiece, poor efforts). This was followed by a second, half-day review session conducted at each individual site. After completion of the training sessions, investigators were required to independently obtain and transmit three sets of spirometry tests on nonstudy individuals for central review of quality.

Spirometry Technique

All patients were asked to sit straight, either in a chair or on a stretcher with their legs over the side. They were instructed to inhale completely and then exhale with maximal force, for at least 2 s. A tight seal was ensured around the mouthpiece. To reduce discomfort, nose clips were not used. Patients were told to "take as deep a breath as possible" and "blast as fast and hard as you can" and "keep blowing until I ask you to stop." Coaching was active and vigorous, instructions repeated as necessary, and patients given immediate feedback regarding their technique.

Quality Goals

American Thoracic Society (ATS) recommendations for within- and between-maneuver acceptability criteria were modified for the acutely ill population.[5] Maneuver acceptability was defined for this study as a back-extrapolated volume (BEV) $< 5\%$ of the FVC or 0.15 L, whichever is greater, or a time to peak flow (PEFT) < 120 ms. To further ensure a strong start to the effort, investigators were encouraged to obtain a PEFT < 85 ms (although a PEFT < 120 ms was considered acceptable). Since the majority of study patients would have severe airway obstruction and be unable to obtain a volume-time plateau (even after exhalation for 20 s),[13] and since the important spirometry value was FEV_1 and not FVC, the acceptable duration of maneuvers (forced expiratory time [FET]) was only 2 s (and not ≥ 6 s). However, many staff coached the patients to exhale for > 6 s. Performance of three or more acceptable efforts was requested, but two acceptable efforts were considered adequate. FEV_1 values were considered adequately reproducible if the two best acceptable efforts matched within 10%, instead of the 1987 ATS recommendation of 5% or 0.10 L[4] or the 1994 ATS recommendation of 0.20 L.[5] FVC reproducibility was not considered because we did not attempt to obtain the FVC.

At the end of each maneuver, the computer displayed whether the most recent maneuver and test session met study acceptability and reproducibility goals, and corrective measures were suggested on the screen as needed. Graphs of the inspiratory and expiratory efforts were displayed in real time, and the flow-volume loop and volume-time spirogram were displayed immediately after each maneuver. All raw maneuver data were stored in the computer and sent for independent central review. Feedback was given through a structured document when compliance to criteria was good, and telephone follow-up (and in one instance a site visit) was made when criteria were not generally met.

Statistical Methods

Factors associated with test session acceptability and reproducibility were determined using univariate and then multivariate