

SAFETY AND TOLERABILITY OF HYPERTONIC SALINE IN PATIENTS WITH CYSTIC FIBROSIS AND FEV1 LESS THAN 40% PREDICTED

Marsoni, N.¹; Miranda, JA¹; Bandara, M²; Zuckerman, JB²; Parker, HW¹

¹Pulmonary Section, Dartmouth-Hitchcock Medical Center, Lebanon, NH, USA

²Division of Pulmonary and Critical Care Medicine, Maine Medical Center, Portland, ME, USA



Background

Inhaled hypertonic saline (HTS) has been shown to be an inexpensive, safe, and efficacious treatment for reducing the frequency of exacerbations and improving quality of life in CF patients with moderately reduced lung function (FEV1 >40% predicted) [1].

However, HTS may precipitate bronchospasm and promote swelling of intraluminal mucus plugs that can be difficult for patients with severe lung disease to mobilize.

The purpose of this pilot study was to evaluate the safety and tolerability of HTS in adult CF patients with severe lung disease.

Methods

During a 5 month period, adult CF patients with baseline FEV1 <40% predicted were identified at 2 CF Centers.

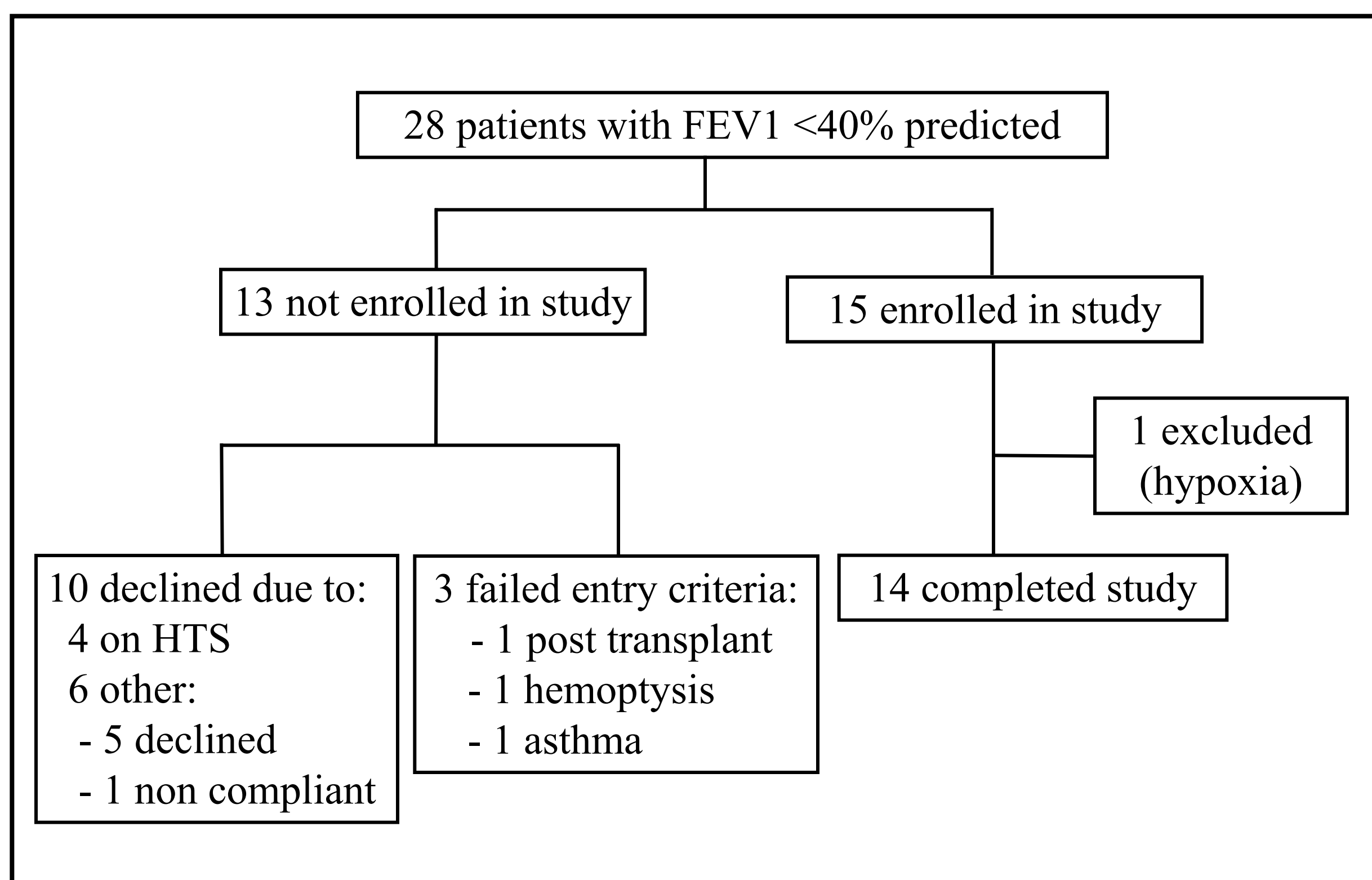
After meeting study criteria, participants were consented and enrolled for testing.

Baseline spirometry was obtained after pre treatment with albuterol via metered dose inhaler. If the FEV1 was <40% predicted, 5 ml 7% HTS was administered by nebulizer, and spirometry was repeated 15 minutes later.

During and after HTS treatment, study subjects were closely monitored, and each was given a questionnaire to identify subjective findings related to treatment.

Spirometric values pre- and post-HTS were compared using the two tailed t-test.

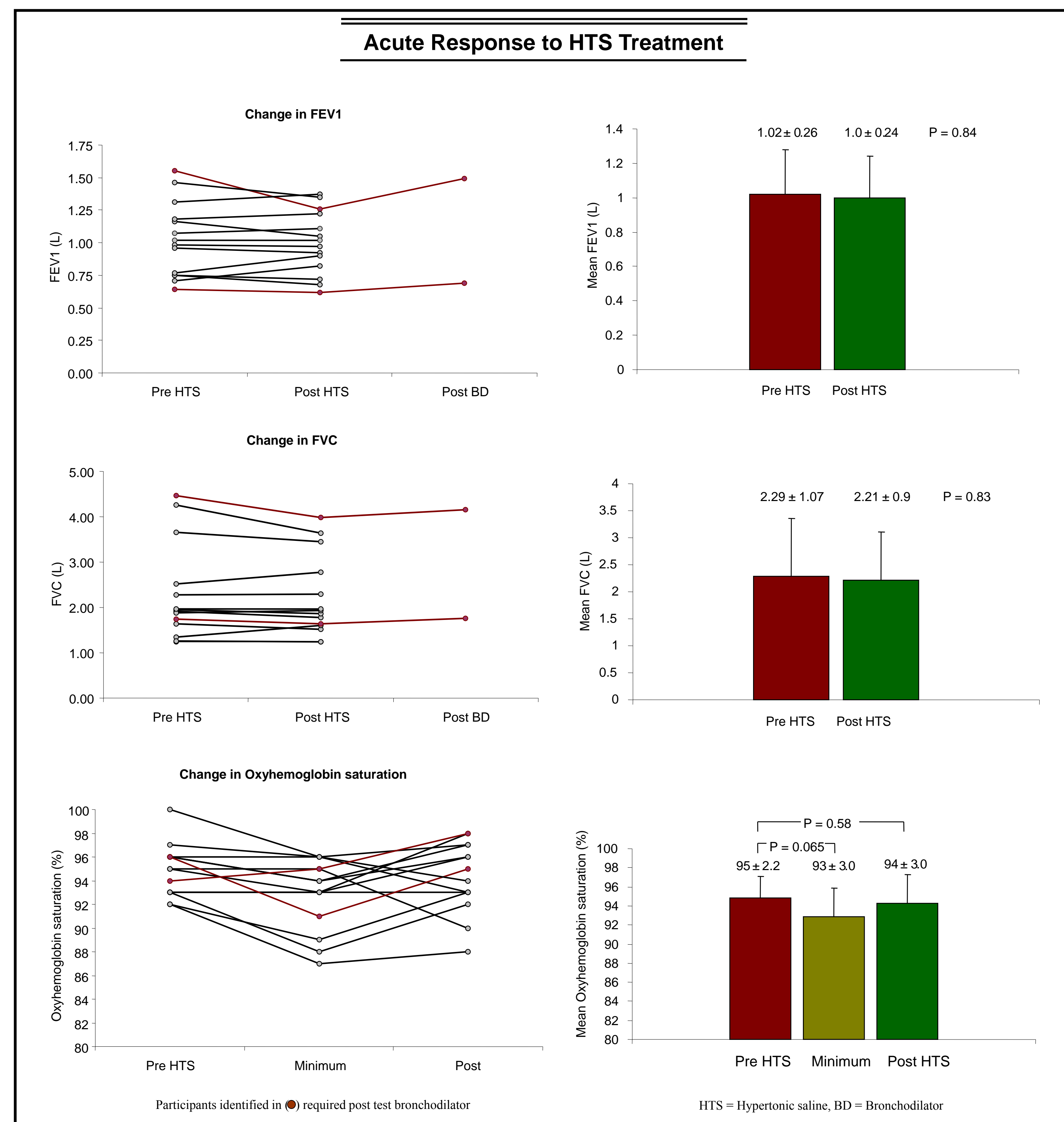
Patient inclusion



Results

Participant Characteristics (n = 14)	Value
Age/yr	33 ± 7
Male	6 (43)
BMI	19 ± 3
FEV1 (% of predicted value)	
Mean	30 ± 6
Range	22 - 39
FVC (% of predicted value)	
Mean	54 ± 16
Range	31 - 85
Regular use of bronchodilator	14 (100)
Regular use of rDNase	14 (100)
Regular use of steroid inhaler	5 (36)
Regular use of azithromycin	11 (79)
Prior use of HTS	3 (24)
Microbiology	
<i>Pseudomonas</i>	13 (93)
<i>Staph aureus</i>	7 (50)

Values are given as mean ± SD, No. (%)

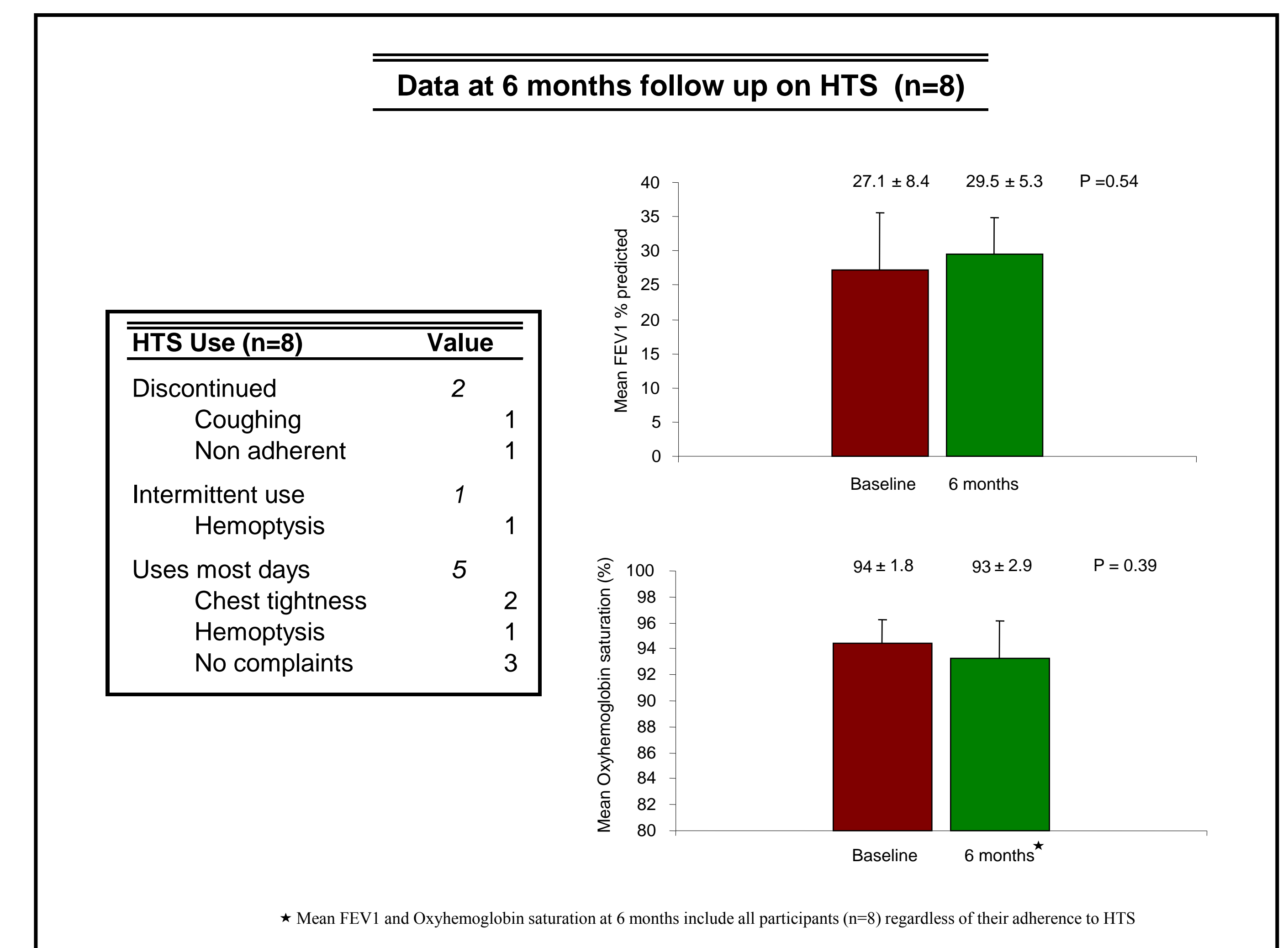


Results

Adverse Reactions (n=14)	Value
Cough	12 (86)
Wheezing	4 (29)
Hemoptysis	4 (29)
Chest tightness	3 (21)

Values are given as No. (%)

At one center patients were given the option to continue use of HTS after successfully completing the testing visit (n = 8).



Conclusions

- Initiation of hypertonic saline under close observation in CF patients with severe airflow obstruction seems to be generally safe and well tolerated, though considerable individual variation was observed.
- A larger, prospective, controlled study would be useful to assess the long-term safety and efficacy of HTS treatment in this patient population.

References

1. Elkins MR, Robinson M, Rose BR et al. A controlled trial of long term inhaled hypertonic saline in patients with cystic fibrosis. N Engl J Med 2006;354:229-240