Highly Portable Noninvasive Ventilator Increases Exercise Endurance in Patients with Chronic Lung Disease

Lana Hilling, RCP, MAACVPR[1], Cindy Cayou, RCP[1], Richard S. Kops, MD[1], Richard J. Morishige, MS, RRT, RAC[2], Nicholas S. Hill, MD[3]

[1]John Muir Health Pulmonary Rehabilitation Program, Concord, CA, USA [2]Clinical Research Consulting, Castro Valley, CA, USA [3]Tufts Medical Center, Pulmonary, Critical Care and Sleep Division, Boston, MA, USA

BACKGROUND

A new portable noninvasive ventilator was evaluated in patients with GOLD 2-4 COPD or interstitial lung disease for its impact on exercise endurance.

For individuals with respiratory insufficiency or failure, standard oxygen therapy is insufficient for relieving dyspnea and fatigue experienced during physical exertion.

New ambulatory therapies are needed to improve endurance and oxygenation while decreasing dyspnea and fatigue during physical activity. We evaluated the impact of a novel ventilator that delivers TAV™ therapy for these key measures.

TAV therapy was delivered using New Aera's SideKick™ TAV™ system (Tidal Assist™ Ventilation)*, consisting of a 4 oz., pocket-sized ventilator paired with a small nasal pillow interface (Figure 1) and a pressurized gas source.. The system is designed to be compatible with oxygen concentrators, cylinders, wall sources and compressed air. It can provide up to 100 LPM and 18 centimeters of synchronized positive inspiratory pressure.

METHODS

TAV and oxygen therapies were compared in a randomized, controlled, crossover study for their impact on exercise endurance, oxygen saturation and dyspnea.

The study was conducted at the John Muir Health Pulmonary Rehabilitation Facility (Concord, CA). Study subjects were participants in John Muir's or Stanford Health Care – ValleyCare's (Livermore, CA) pulmonary rehabilitation program. Following IRB approval, subjects with moderate to very severe oxygen-dependent chronic lung disease were enrolled.

At Visit 1, baseline physiologic measures were obtained and subjects received training on the TAV system and the cycle ergometer. Peak work rate (PWR) exercise levels, flow rates for the oxygen cannula, and TAV settings were established. During Visit 2, subjects exercised to maximum endurance at a constant work rate (CWR) of 80% of PWR while using, in random order, the TAV system or supplemental oxygen via standard cannula. Exercise tests were separated by a 1.5 hour rest period. A concentrator or E-tank was used as the oxygen source for both oxygen and TAV therapies. Except for endurance time, endpoint comparisons were taken at the point of exercise termination for the shorter CWR test in each subject (referred to as "isotime").

*U.S. 510(k) cleared for adult hospital and homecare use.

RESULTS

Patients exercised longer, with markedly better oxygenation and less dyspnea and leg fatigue, on TAV therapy than on oxygen therapy alone.

Eighteen subjects (9F/9M) with COPD (n=15, GOLD 2-4) or ILD (n=3) completed the study. Mean ± SD age was 68 ± 9 years. Mean ± SD CWR was 28.7 ± 14.1 watts. A significant increase in mean CWR exercise time was observed using the TAV system compared with standard cannula oxygen (↑7.4 min). In addition, significant improvements in isotime SpO_2 (↑6.0 %), Borg dyspnea score (↓3.0), and leg fatigue score (↓2.5) occurred when using the TAV system. Isotime heart rate was not significantly different between study treatments. Subjects found the TAV system to be easy to use and comfortable to wear. No serious adverse events were observed during the study.

CONCLUSIONS

TAV therapy demonstrated significant potential value for patients with moderate to severe lung disease not adequately supported by supplemental oxygen alone.

The TAV system is non-invasive, highly portable, and easy to operate. It was well received by the patients in the study. When compared to standard oxygen therapy alone, TAV therapy provided significant statistical and clinical improvements in mean exercise endurance, SpO_2, dyspnea, and leg fatigue.

Patients with chronic lung disease struggle with worsening dyspnea and fatigue with exertion; this progressive condition limits their ability to participate in normal activities of daily life.

TAV therapy has promise to improve patient outcomes, including quality of life, for this large patient population with limited treatment options.

JOHN MUIR HEALTH   Tufts Medical Center

CHEST Annual Meeting 2015   Montréal CANADA

Table 1. Subject Characteristics: Demographic and baseline pulmonary function (n=18)

Dx	Age (yrs)	Gender	BMI (kg/m^2)	FEV1 (% pred)	FVC (% pred)	FEV_1/FVC (%)	GOLD Class (2/3/4)
COPD (15)	68 ± 9	8F / 7M	26.8 ± 5.4	32 ± 11	53 ± 16	48 ± 10	1/7/7
ILD (3)	72 ± 12	1F / 2M	37.5 ± 17.4	61 ± 12	55 ± 4	85 ± 6	NA

Data presented as mean ± SD. BMI: body mass index; FEV1: forced expiratory volume in one second; FVC: forced vital capacity; COPD: Chronic obstructive pulmonary disease; GOLD: Global Initiative for Chronic Obstructive Lung Disease; ILD: Interstitial lung disease

Figure 1: The SideKick™ TAV™ device and nasal pillow interface

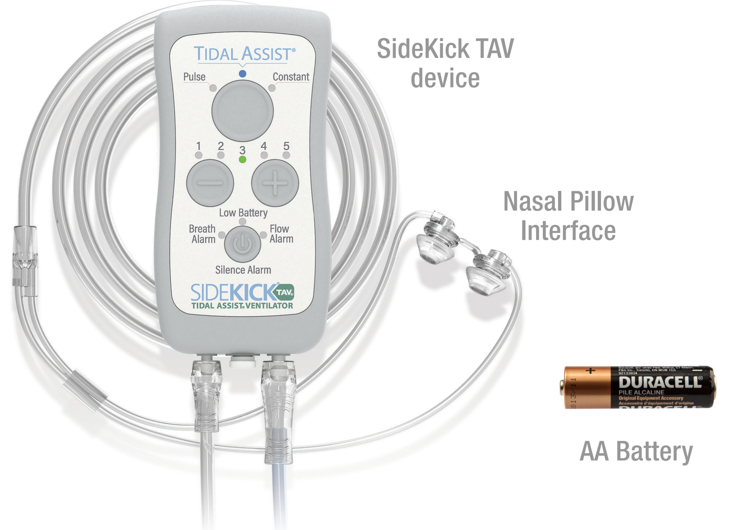


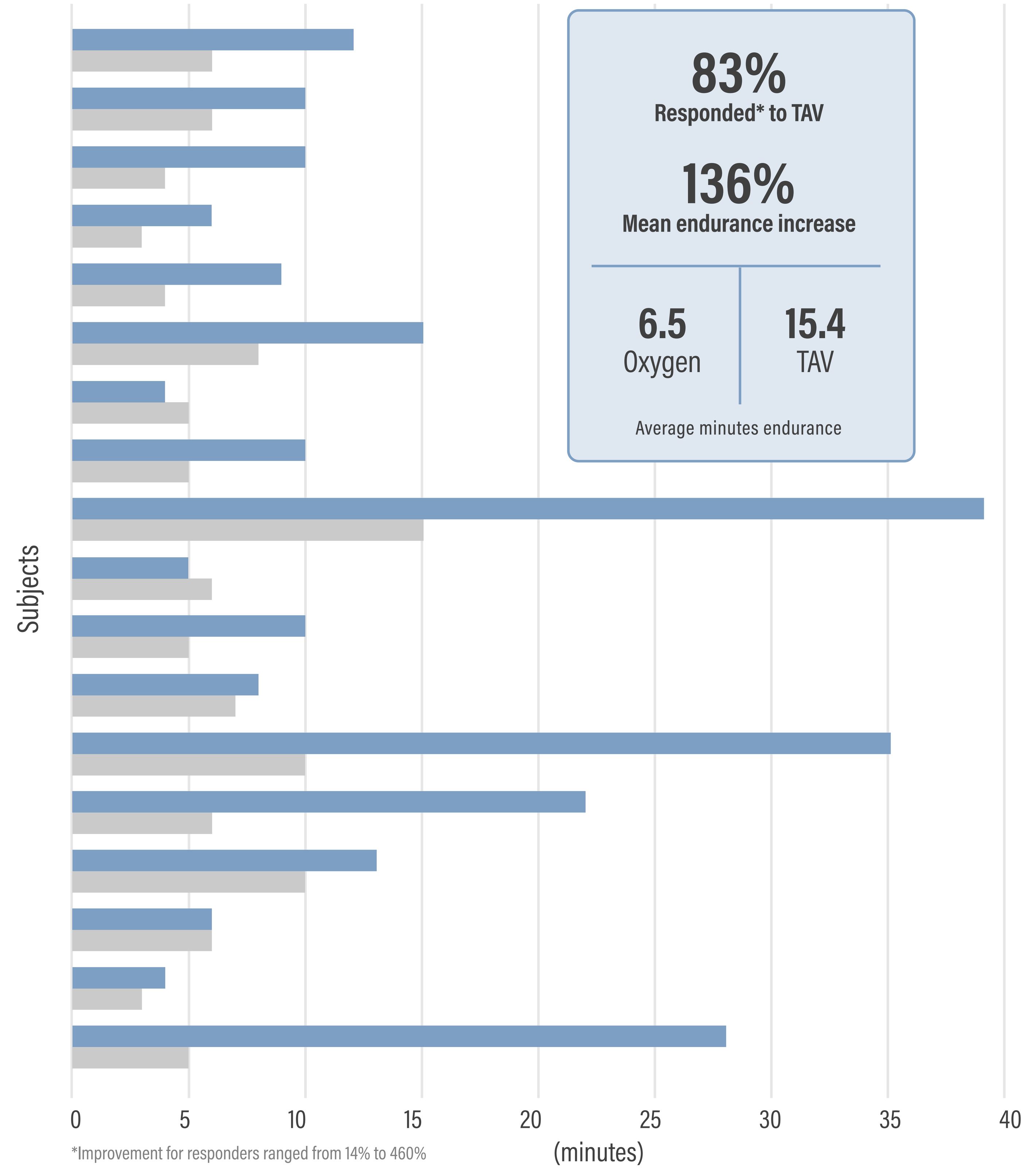
Figure 2: Subject using the SideKick TAV system during exercise testing

Table 2. Results of CWR Exercise Testing (n=18)

Isotime	TAV	O_2	95% CI Difference	Significance level†
Exercise time*	13.7	6.3	3.1 to 11.6	p < .001
SpO_2†	96.8%	90.8%	4.4 to 7.5	p < .0001
10 point Borg††	3.0	6.0	-3.2 to -1.4	p < .001
Leg fatigue††	3.0	5.5	-2.9 to -0.9	p < .01
Heart rate	111	113	-4.6 to 2.3	NS

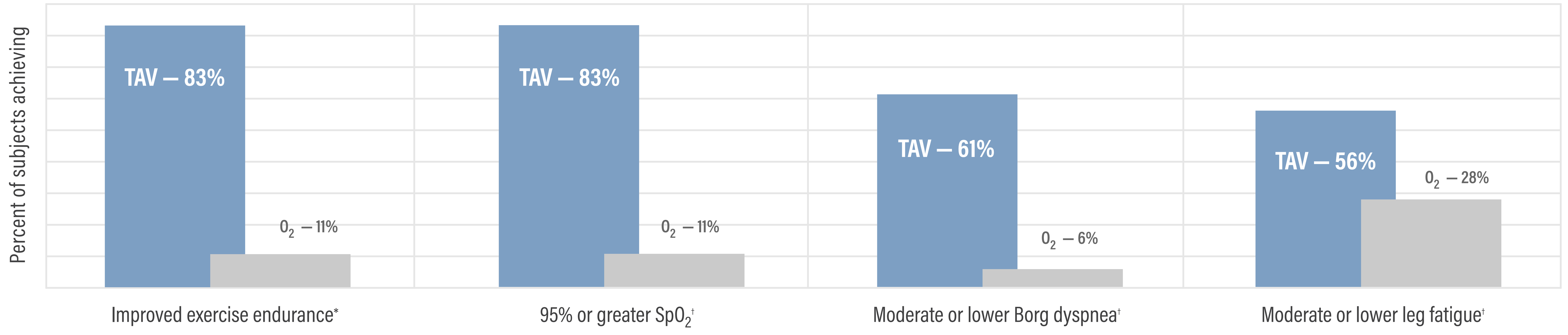
* Taken at end of test †Two tailed ††Median

Exercise Endurance: TAV vs. Standard Oxygen



*Improvement for responders ranged from 14% to 460%

TAV's Impact on Exercise Endurance, SpO_2, Dyspnea, and Leg Fatigue



*14% or greater increase over other therapy †at isotime