Final Report for HSR&D Project NRI 07-033

Project Title: **Using a Functional Assessment to Optimize Oxygen Therapy in Chronic Lung Disease**

Principal Investigator: **Miriam Cohen MSN**

Project Funding Dates: **January 1, 2008 - April 30, 2009**

Final Report Date: **July 21, 2009**

This final report presents the findings and conclusions of the author(s); it does not necessarily represent the Department of Veterans Affairs (VA) or HSR&D. This research was supported by the Department of Veterans Affairs, Veterans Health Administration, Health Services Research and Development Service.

Final Report Abstract

Background

Chronic obstructive lung disease (COPD) is characterized by airflow obstruction that is progressive over many years. Advanced COPD is associated with oxygen desaturation leading to a series of complications including decreased survival. Standard methods to evaluate the oxygen status of these patients underestimate their oxygen needs when measured by ambulatory techniques while patients are in the home environment. Our prior work has extended ambulatory monitoring by simultaneously measuring physical activity with accelerometers to link oxygen desaturation to specific categories of daily activity. This pilot project studied whether the Continuous-Scale Physical Function Performance (CS-PFP) test, an assessment utilizing a range of domestic tasks, could more accurately predict oxygen desaturation in the home environment than the standard assessments.

Objectives

Objective #1: Estimate the sensitivity, specificity, positive predictive value, negative predictive value, total prediction error and Akaike information criterion (AIC) of each of the standard tests and the 10 tasks of the CS-PFP to predict oxygen saturation during four categories of daily living defined by accelerometers: Walking, Slow/Intermittent Walking (SIW), Active-not-Walking (ANW) and Rest.

Objective #2: Determine the optimal combination of tests to achieve the best prediction of oxygen desaturation in each daily activity category.

Methods

Veterans at VA, NYHHCS Brooklyn campus with severe and very severe COPD were recruited to undergo standard assessment for oxygen desaturation, CS-PFP testing and a 2-day ambulatory study wherein continuous measurements of oxygen saturation and daily activity were monitored. For standard testing and the tasks of the CS-PFP, oxygen desaturation was defined as oxygen saturation nadir by pulse oximetry <90%. Oxygen desaturation during the ambulatory study was defined as the percent time oxygen saturation was <90% during the accelerometer-define activity categories. Logistic regression analysis using stepwise selection technique with the total prediction error and AIC was used to determine the best combination of tasks to predict oxygen desaturation during daily living.

Findings

54 subjects completed testing. For the Walk category, the standard hallway walk test (HWT). For SIW, the two tests that best predicted desaturation were the HWT and the laundry task. By combining the tasks, the AIC score improved. The combined model was >100 times more likely to be correct than the other standard tests and were not statistically significantly different from the observed distribution of desaturators. For ANW, tasks with the lowest prediction error were the laundry and reach tasks. The combined model was >2500 times more likely to be correct than the standard tests alone and were not statistically significantly different from the observed distribution of desaturators. The best predictors of desaturation during Rest were the pot carry and the scarves tasks. The probability of these tasks to correctly classify desaturators during Rest was >15 times more likely than the standard tests, but did not achieve a statistically significantly difference from the standard test of oxygen saturation <90% at rest.

Status

Completed

Impact

We have assessed the value of the CS-PFP to predict oxygen desaturation during categories of daily living defined by activity monitors. We have constructed a 5-task test that is comprised of the best combination of tasks and standard tests that accurately predicted desaturation during daily living. We propose that this new test can define the profile of diurnal oxygen desaturation, offer a new method to categorize COPD disease severity, determine short- and long-term outcomes of mild, moderate and severe hypoxemia and provide a feasible new type of assessment on which to base an oxygen prescription.

Final Report Narrative

Background

Chronic obstructive lung disease (COPD) is characterized by airflow obstruction that is progressive over many years and is largely irreversible. Advanced COPD is associated with arterial oxygen desaturation leading to a series of complications and, ultimately, decreased survival. Long-term oxygen therapy (LTOT) can improve survival and clinical outcomes in these patients, but the optimal target of oxygen saturation that translates into improvements is not known.

The standard method to evaluate patients with chronic lung disease for oxygen desaturation is to measure oxygen tension or pulse oximetry during rest and "exertion". Exertion is commonly assessed by either a formal six-minute walk test (6MWT) or a shortened hallway walk test (HWT), wherein a patient walks in a corridor until the onset of dyspnea or fatigue. These standard assessments that are performed in the clinical setting frequently underestimate the oxygen needs of patients when measured by ambulatory techniques while patients are engaged in their usual daily activities. Our prior work has extended ambulatory oximetry monitoring by simultaneously measuring activity with accelerometers and in this way link oxygen desaturation to four distinct categories of daily activity: walking, slow/intermittent walking, active-not-walking and resting. Our preliminary work has demonstrated that these standard tests poorly predict desaturation in these activity categories. This pilot study focused on the utility and efficacy of a new approach to evaluate patients at risk for oxygen desaturation. We studied whether the Continuous-Scale Physical Function Performance (CS-PFP) test, an assessment that utilizes a range of domestic tasks, could more accurately predict oxygen desaturation in the home environment than the standard assessments. We hypothesized that using the CS-PFP to assess oxygen desaturation would lead to the development of a clinical assessment tool that accurately predicted the individual profile of oxygen desaturation as patients live freely in their home environment.

Objectives

Objective #1: Estimate the sensitivity, specificity, positive predictive value, negative predictive value, total prediction error and the Akaike Information Criterion (AIC) of each of the 10 tasks of the functional assessment to predict oxygen saturation during four categories of daily living.
-Functional Assessment: Continuous Physical Functional Performance 10 Test
-Desaturation: oxygen saturation <90% measured by pulse oximetry
-Categories of Daily Living defined by accelerometers: Walking, Short/Intermittent Walking, Active-Not-Walking and Rest

Objective #2: Determine the optimal combination test to achieve the best prediction of oxygen desaturation in each daily activity category. Estimate the sensitivity, specificity, positive predictive value, negative predictive value, total prediction error and the AIC score of the optimal combination test in predicting oxygen desaturation.

Methods

a. Study Design: This cross-sectional descriptive study was conducted over 10 months (June 2008 - April 2009). Patients with severe COPD underwent functional assessment using the testing protocol of the CS-PFP followed by a 2-day ambulatory study of continuous ambulatory oximetry and daily activity. Measurements of oxygen desaturation during each task of the functional assessment were compared to oxygen desaturation during daily activity categories defined by accelerometers.

b. Setting: The study was conducted at the Brooklyn campus of VA New York Harbor Health Care Services. Subjects were recruited from the primary care and pulmonary clinics.

c. Participants/Patients: Veteran patients with severe and very severe COPD were studied. Patients

were included if they qualified for home oxygen by standard criteria; had pulmonary function testing confirming obstructive disease (FEV1/FVC <70%) and FEV1 < 50% or DLCO < 50%; or had a resting oxygen saturation < 94%. All participants were ambulatory and able to perform functional testing. All subjects provided written informed consent.

d. Interventions or exposures (if any): this was a non-interventional pilot study

e. Measurements/Outcome Measures:

Materials:
Standard assessment for oxygen desaturation included measurements of oxygen saturation while subjects are at rest and during a HWT. The HWT consisted of five 50 foot walks at different speeds down a corridor. For one walk, subjects were asked to walk at their fastest comfortable speed. For another walk, subjects were coached to walk very slowly. For the remaining walks, subjects were asked to walk at their "normal" walking speed; at a speed between "normal" and their fastest speed; and finally at a speed between "normal" and their slowest speed.

The CS-PFP is an assessment of physical function. This test requires a fixed laboratory space and is administered under standard conditions with trained personnel. The test consists of common household tasks that test upper and lower body strength, flexibility, coordination and endurance. Tasks of the CS-PFP range in difficulty from low to high assuring that a wide range of functional tasks are assessed. The CS-PFP includes carrying a pot of weight, donning and doffing a jacket, picking scarves up from the floor, reaching to a high shelf, sweeping, transferring laundry from a washer to a dryer, transferring laundry from the dryer to a basket, stair climbing, getting down and up from the floor, carrying groceries and a standard 6MWT. Testing followed the published protocol and scripted dialog.

The WristOx pulse oximeter (Nonin Medical, Inc.) was used to measure oxygen saturation. This oximeter has the capacity to collect oxygen saturation in 4-second sampling epochs over 30 - 34 hours.

To measure daily activity, we used two pizo-electric activity monitors. These activity monitors generate an electrical output that is proportional to acceleration that is applied to it, that is then processed to obtain an "activity count". For this study, the RT3 Research Tracker accelerometer (www.StayHealthy.com, Monrovia, California) was worn at the waist. This is a triaxial accelerometer that can accurately detect acceleration even at very slow speeds typical of the COPD population. The second activity monitor, the Mini MotionLogger actigraph (Ambulatory Monitoring, Inc, Ardsley, New York), was worn at the wrist. This device measures generalized motion and is most commonly used to detect sleep patterns.

Procedure:
Oxygen saturation was taken during a period when the subject was sitting quietly. They then performed a hallway walk test. Each subject then underwent functional testing following the protocol of the CS-PFP. Oxygen saturation was monitored throughout testing.

Following functional testing, subjects were fitted with the accelerometer, actigraph and the pulse oximeter. In order to account for the known variability in activity counts between RT3 devices and among different subjects, an individual calibration procedure was performed, as previously described (COHEN, in press). This calibration translates RT3 output into standard measurements of miles-per-hour. Subjects were instructed to wear the three monitors until the battery of the pulse oximeter ran out, which resulted in 30 - 34 hours of continuous data collection for each subject.

Data Analysis:
For each subject, oximetry was measured during the standard assessments and during CS-PFP testing. Oxygen saturation nadir was recorded for each task. Desaturation was defined as nadir of <90%.

For each subject, the activity and oximetry data recorded during the ambulatory study were downloaded from the devices into a personal computer for analysis. Activity counts were classified into four categories using thresholds established in prior studies: Walking is defined as recorded intervals with estimated speed > 0.70 mph; non-acceleration is defined as intervals with estimated speed < 0.25 mph; slow/intermittent walking (SIW) is defined as intervals with estimated speed < 0.70 mph and >0.25 mph. We further differentiated the non-acceleration intervals into two separate activity categories by scoring the wrist actigraphy data for "sleep". Rest is defined as intervals with estimated speeds < 0.25 mph with actigraphy counts scored as "sleep". Active-not-walking (ANW) is defined as intervals with speeds < 0.25 mph with actigraphy counts not scored as "sleep".

Once accelerometry data were scored into categories of activity, their association with oxygen desaturation was determined. From the synchronized oximetry and activity channels of the recording, all intervals with oxygen saturation <90% were identified. Intervals of desaturation were then linked to the activity category during which they occurred. Walking-related desaturation was defined as oxygen desaturation that occurred during or two minutes after walking activity. The two-minute "phase lag" period was required to appropriately link any extended period of re-saturation to the walking activity. Short/Intermittent-walking-related desaturation was calculated in a similar manner. Desaturation related to Rest and ANW was calculated without a consideration of a phase-lag effect. Activity-related desaturation was expressed as an index, or the percent time oxygen saturation was <90% during each of the activity categories (minutes of desaturation linked to activity category *100/ number of minutes the subject engaged in that category). A desaturation index (DSI) was calculated for each activity category.

Desaturation during daily activities was defined by the DSI thresholds that have been established for each accelerometer-defined activity category. Briefly, using a regression tree grown by binary recursive partitioning, a prediction model was structured to define the hierarchical relationship between activity and oxygen desaturation. This was accomplished by formulating the tree to determine the DSI cut point that predicted a decline in activity performance. The DSI cut points for each activity category obtained from the analyses are as follows: DSI walking = 10%, DSI SIW = 10%, DSI ANW = 4%. The DSI for the category Rest was adapted from the nocturnal oxygen desaturation literature that defines important nocturnal desaturation as desaturation for 30% of sleep time. Thus, DSI above these cut points were considered significant.

Statistical Analysis:
Descriptive statistics (means, standard deviations, and frequency distributions) were generated for demographic information and clinical presentation to characterize study participants. The time spent in each activity category and DSI were calculated for the study cohort.
Pilot work demonstrated that oxygen saturation measured during the 6MWT, HWT and at rest, (the standard tests used in the clinical setting to assess oxygen desaturation), poorly predicted desaturation during free-living. Since the activity categories of SIW and ANW cover the most time in daily activities, improvement in the prediction error was focused on these two categories. Based on the preliminary data, the total prediction error was estimated to be between 30 - 40% in these two categories. We expected that the new best (combination) test would reduce the total prediction error to about 10%. The preliminary data show that the correlation between the 6MWT and the HWT was 0.68 with 99% CI of (0.48, 0.95). Because both the standard tests and new tests use measurements from physical activities, we anticipated that they would be correlated and their correlation was conservatively assumed to be at least 0.4 (0.1 below the lower bound of the correlation between the two standard tests). A sample of 40 subjects would provide 80% power to detect the difference of 20% and 10% in prediction error at the 5% level.

For objective #1, the prevalence of oxygen desaturation in all categories daily activities and the 95 CI% were calculated. In each category of daily activity, sensitivity, specificity, positive predictive value, negative predictive value and total prediction error and their 95% CI were calculated for each of 10 tasks of the functional assessment for overall study participants.

For objective #2, logistic regression analysis using stepwise selection technique with Akaike information criterion (AIC) was used to determine the best combination of tasks to predict oxygen desaturation during daily living. The absolute value of the AIC score has little meaning; rather the focus is on the relative size. This measure indicates a better fit when it is smaller. The measure is not standardized and is not interpreted for a given model. For two models estimated from the same data set, the model with the smaller AIC is preferred and a probability of superiority can be estimated. The tasks with the lowest total prediction errors and the lowest AIC scores were combined to determine the best combination tests to predict desaturation. Either the Chi-square analysis or the Fisher exact analysis was performed to confirm that the models were a good fit for the data and Sign tests were performed to compare the predictive value of the new tests to the predictive value of the standard tests. Statistical analyses, including the formulation of the decision tree, were performed with the open source statistics program 'R'.

Findings

Sixty-seven subjects with COPD were recruited for testing. Nine subjects were eliminated from final analysis due to excessive artifact in oximetry data from poor contact of probe. An additional four subjects were eliminated from the final analysis: three subjects wore the devices for less than 24 hours and one subject failed to return one of the devices. The 54 remaining subjects had severe COPD (mean FEV1 47.35 + 17.58; mean DLCO 48.6 + 17.9); eighteen subjects were on LTOT.

Subjects spent 12.4 + 7 % of their time engaged in Walking, 19.6 + 6 % of their time in SIW, 57.0 + 11 % of their time in ANW and 11.1 + 9 % of their time in Rest. Walking contributed 45.4 + 28% of overall desaturation; SIW contributed 16.0 + 16 %; ANW contributed 15.6 + 15%; and Rest contributed 14.6 + 23%.

The results of the standard clinical assessment for oxygen desaturation are as follows: 7 subjects had oxygen saturation <90% at rest and 22 subjects had oxygen saturation nadir <90% during the HWT.

During the CS-PFP testing, more subjects desaturated during the high effort tasks and fewer desaturated during the low effort tasks. For example, 17 subjects desaturated (achieved nadir <90%) during the 6MWT and an equal number desaturated during the HWT; 14 subjects desaturated during the grocery walk and the second laundry task; 12 subjects desaturated during floor sweep and reach tasks. In contrast, fewer subjects desaturated during the remaining tasks, counts are as follows: donning and doffing a jacket: 10 subjects, climbing a flight of stairs: 9 subjects, carrying a pot: 8 subjects, picking up scarves from the floor: 7 subjects and sitting and rising from the floor: 6 subjects. Using the DSI cut points for each activity category noted in the Methods/Data Analysis section, a total of 32 subjects desaturated during daily living: 14 subjects desaturated during Walk alone; 5 subjects desaturated during Walk and SIW; 5 subjects desaturated during Walk, SIW and ANW; 6 subjects desaturated during all activity categories; and one subject desaturated only during Walk and Rest.

Positive and negative predictive values, the total prediction error and the AIC score for oxygen desaturation during each task of the CS-PFP and the standard tests were calculated to predict desaturation during the four categories of daily activity.

For the Walk category, the 6MWT and the HWT best predicted desaturation (total prediction errors of 0.21 and 0.13; AIC scores of 53.32 and 50.33, respectively). None of the tasks of the CS-PFP alone or in combination were found to improve this prediction error. The 6MWT was 4.46 times more likely than the HWT to correctly classify desaturators during Walking. The HWT and the 6MWT classifications were not statistically significantly different from the observed distribution of desaturators (chi-square, $p > 0.05$ for both tests). The Sign Test was not done, as no new tasks were found to be superior to the standard tests.

For the activity category SIW, desaturation during the 6MWT and at rest poorly predicted oxygen desaturation during SIW (total prediction errors 0.19 and 0.33; AIC scores 47.54 and 60.89,

respectively). The two tests that best predicted desaturation were the HWT and the laundry task (total prediction error of 0.15 and 0.13; AIC scores of 46.48 and 45.33, respectively). By combining both the HWT and the laundry task, the AIC score decreased to 38.38. The combined model was 58 times more likely to be correct than was the HWT alone, 98 times more likely to be correct than the 6MWT and >10,000 times more likely to be correct than was oxygen saturation <90% at rest. The predictions from the new combined test were not statistically significantly different from the observed distribution of desaturators (chi-square, $p = 0.30$). The new tests were significantly different from the standard tests (Sign test, $p<0.5$).

For the activity category ANW, the prediction errors of the standard tests ranged from 0.17 for the HWT (AIC = 43.40) to 0.32 (AIC = 51.94) for oxygen desaturation at rest. The tasks with the lowest error in predicting desaturation were the laundry and reach (total prediction errors of 0.07 and 0.08 respectively). The AIC scores for these two tasks were the lowest of all tasks tested (30.90 and 30.80). By combining laundry and reach, the AIC decreased to 27.68. The combined new model was >2500 times more likely to be correct than the HWT and >10,000 times more likely to be correct than desaturation during either the 6MWT or desaturation at rest. The predictions from the new combined test were not statistically significantly different from the observed distribution (Fisher exact, $p = 0.15$) and significantly different from the standard tests (Sign test, $p <0.5$).

For the Rest category the HWT and 6MWT were poor predictors of oxygen desaturation (prediction errors >0.30, AIC scores > 38). The best predictors of desaturation during Rest were the pot carry task and the scarves task. The total prediction error and AIC scores were identical for both tasks (0.10 and 33.25, respectively). Desaturation during either of these tasks best predicted desaturation during the accelerometer-defined activity category of Rest. As the AIC scores for these tasks were identical, desaturation during either of these would equally predict desaturation during Rest. The probability of these tests to correctly classify desaturators during Rest was 26 times more likely than the HWT and 32 times more likely than the 6MWT. In fact, we found that these CS-PFP tasks were 15 times more likely to predict desaturation during Rest than the standard assessment of measuring desaturation "at rest". The predictions from the new tests were not statistically significantly different from the observed distribution (Fisher exact, $p = 0.24$), but the Sign test was not statistically significant (sign test, $p >0.5$), suggesting that the new tests are no different from the old tests in identifying desaturators.

Discussion

The results of this pilot study confirm that patients with severe COPD can have prolonged periods of oxygen desaturation during daily living which is not accurately predicted by the standard assessments performed in the clinical setting. This pilot study has expanded the clinical assessment of patients at risk for desaturation by evaluating the prognostic value of oxygen saturation during ten household tasks to predict desaturation while subjects were engaged in their usual daily activities at home. Prediction models were derived from the best test or task or combination of tests or tasks that predicted oxygen desaturation during categories of daily activity defined by accelerometers.

Standard clinical practice assesses oxygen saturation during rest and during a walk test that reproduces "exertion". Because the 6MWT is cumbersome to perform in the clinical setting, exertion is frequently extrapolated from a "hallway walk test", wherein the patient walks in a corridor until the onset of dyspnea or fatigue. While this modified walk test is practical, the lack of standardization complicates its usefulness. We chose to standardize this test by asking patients to walk in a corridor a set distance of 50 feet at five different speeds. Thus, this test consisted of a series of short walks with a range of self-selected walking speeds. The 6MWT proved to be only a marginally better test than our HWT to classify patients as desaturators during Walking in daily life. No new task demonstrated an improvement in the ability to predict desaturation during this activity. Thus, we conclude that not only does this standardized HWT predict oxygen desaturation during walking in real life with acceptable accuracy, but is a reasonable alternative to the 6MWT.

The HWT also performed well in conjunction with the laundry task in predicting desaturation during SIW.

SIW is defined as continuous acceleration less than the speed of walking or sporadic periods of acceleration at the speed of walking that occur for less than one minute. Patients with COPD engage in this type of activity at approximately the same frequency as they do continuous walking. This activity category contributed approximately 16% to overall diurnal desaturation. The laundry task required subjects to remove clothes from a top-loading washer and place them in a front-loading dryer and, thus, required subjects to sustain a stooped posture while lifting clothes and weights that simulated wet laundry. While it is known that patients with COPD frequently report increased dyspnea with this type of activity, this is the first evidence that bending and lifting has high oxygen cost. Thus, these results suggest that as the standard tests for "exertion" cannot accurately predict desaturation during periods of activity other than walking, inclusion of other tests, such as the laundry task, may be required to improve accuracy.

This paradigm shift to expand assessments for oxygen desaturation other than walking becomes more apparent when considering the activity category ANW. This activity category is defined by upper extremity activity in the absence of detectable acceleration. While our data show that 15% of diurnal desaturation occurs during this activity category, the standard assessments performed poorly in predicting which patients were likely to desaturate. We have demonstrated that desaturation during the laundry task and the reach task predicted desaturation during ANW. These tasks assess upper body strength and flexibility. These findings highlight the impact of upper extremity activity on oxygen saturation and suggest that an assessment that includes upper extremity activity would improve prediction of oxygen status in the large, non-walking portion of daily living.

The activity category Rest is defined by the wrist actigraph. Inactivity can be isolated by this activity monitor and can detect periods of sustained quiescence. We found that the best predictors for oxygen desaturation during Rest were the pot carry and the scarves tasks. Pot carry requires subjects to carry a pan of weight from one counter to another and the scarves task requires subjects to pick up four scarves from the floor. The pot carry and the scarves tasks are ranked as either light or moderate effort in the CS-PFP and are performed early in the testing sequence. These subjects desaturated while performing activities that required very modest effort and thus have a low threshold for desaturation. While the two tasks accurately predicted desaturation during Rest, this model did not perform statistically better than did oxygen saturation <90% at rest, possibly due to the small number of subjects that desaturated during Rest. These results suggest that a test of light effort may identify a subset of patients at risk for extended periods of desaturation, but more study is needed to clarify this issue.

a. Limitations

This study included only patients with severe COPD that were at high risk for oxygen desaturation with exertion. It is not known whether these prediction models will perform in a similar manner in patients with COPD of a lesser severity. Addition of the CS-PFP tasks did not improve the prediction of desaturation during Walking. This was anticipated as the tasks of the functional testing require less metabolic cost than does continuous walking. As desaturation during walking in some individuals with less severe disease may require sustained exertion, it is not known whether these results will also be accurate in populations with less severe disease.

Conclusions and Impacts

The findings of this pilot study demonstrate that a large portion of oxygen desaturation that occurs during daily living is routinely overlooked when using the standard assessments alone. By testing the value of a range of household tasks to predict desaturation during daily living, we have developed models that offer improved accuracy. Desaturation during low effort tasks predicted desaturation during the non-ambulatory activity categories of daily living. Desaturation during a combination of moderate effort tasks predicted desaturation during the intermediate activity category of SIW. Desaturation during a walk test predicted desaturation when walking in daily life. The prediction errors of the new models were superior to the standard tests for all daily activities with the exception of predicting desaturation during continuous walking.

Our results show that some subjects desaturated only during Walk. Those patients who desaturated during SIW also desaturated during Walk. Similarly, those patients who desaturated during ANW also desaturated during all categories of walking activity in daily life. And finally, with the exception of one individual, those patients who desaturated during Rest also desaturated during the Walk, SIW and ANW activity categories. Thus, a rank order of the best combination of tasks can be constructed.

From the results of this study, we propose to expand the assessment for oxygen desaturation during daily living with the following serial set of tests. First, we recommend an assessment of oxygen saturation at rest. If oxygen saturation at rest is < 90%, it is likely that desaturation will occur during all activities of daily living. If oxygen saturation at rest is > 90% and < 94%, we recommend performing a standardized HWT to determine the likelihood of desaturation during walking in daily life. If oxygen saturation remains >90% during the HWT, desaturation during daily activity is not likely. If oxygen saturation during HWT is <90%, the likelihood of desaturation during walking is high and additional testing is necessary to determine whether desaturation will occur during other daily activities. If oxygen saturation during the HWT is <90%, we recommend having patients pick up four scarves from the floor or carry a pot of weights a distance of 2 meters to predict whether desaturation may occur while resting. If oxygen saturation is <90% during either of these tasks, the probability of desaturating during all daily activities is high. If the scarves or pot carry tasks are negative (oxygen saturation remains >90%), we recommend performing the laundry task. If oxygen saturation remains >90% during the laundry task, it is likely that desaturation will occur only during continuous walking in daily life. If oxygen saturation drops <90% during bending and lifting (simulating the laundry task), it is likely that desaturation will occur during continuous walking and slow/intermittent walking in daily life. Further assessment is necessary to determine whether desaturation will occur during activities performed while stationary. We recommend that those patients who desaturate during the laundry task also perform the reach task. If patients desaturate while reaching to a high shelf, it is likely that desaturation will occur during all activities of daily living with the exception of desaturating while they are at rest.

Thus, we have presented a serial test containing a combination of two standard test and three common household tasks to predict oxygen desaturation during daily living. The final test is simple and easily reproducible in the clinical setting. The required testing equipment is easily acquired and familiar to patients. In addition, the test does not require excessive burden for either patients or clinic staff and can be performed in less than fifteen minutes in the frailest patient group.

We have demonstrated that this new test offers a substantial improvement in predicting oxygen desaturation in daily life over the standard tests currently used in practice. While the clinical impact of desaturation during daily activities is not known, this new test provides a model by which the severity of oxygen saturation can be defined. As such, it offers the possibility of a new classification for disease severity. As there is a hierarchy of activity-induced desaturation, patients can be classified as desaturators during continuous walking alone, during all walking activity (Walk + SIW), during walking and during activities performed while stationary (Walk + SIW + ANW) and, finally, those that desaturate during all activities of daily living (Walk, SIW, ANW and Rest). This classification begins to address the issues regarding important clinical outcomes from varying severity in oxygen desaturation which, prior to these findings, have been difficult to define.

In addition to providing a classification for disease severity, this test may offer a new assessment on which to base the oxygen prescription. Oxygen therapy offers significant benefits in those COPD patients with chronic hypoxemia at rest. Immediate benefits include improvement in exercise capacity, reduction of dyspnea and possibly sleep consolidation. Long-term benefits include improved survival. Patients without chronic hypoxemia, who have exercise-induced desaturation alone, have poorer exercise performance, more dyspnea and worse survival than normoxic patients with the same degree of airways obstruction. Although a survival benefit has never been established for these patients, oxygen therapy can improve mood, neurocognitive function and quality of life. Thus, the benefits from oxygen therapy are significant in terms of both health outcomes and quality of life. Because of this, there is an interest in identifying which patients would gain the most benefit from oxygen therapy and in tailoring

therapy to maximize benefit.

Current practices titrate oxygen prescriptions for rest and "exertion". Most often, patients are prescribed a liter flow at rest and are instructed to adjust their liter flow on ambulatory tanks during continuous walking, such as excursions outdoors. Our data suggest that in order to correct exertional desaturation, liter flow adjustments may be required for a broader range of activities. Whether prescriptions titrated to maintain adequate oxygen saturation during the new test can ameliorate desaturation during daily living is a compelling new area of study.

In summary, standard tests to assess oxygen desaturation performed in the clinical setting under-estimate the oxygen desaturation profile at home when patients with severe COPD are engaged in their usual daily activities. We have assessed the value of the CS-PFP, a standardized test of functional performance that consists of 10 household tasks, to predict oxygen desaturation during categories of daily living defined by activity monitors. From the results, we have constructed a 5-task test that is comprised of the best combination of tasks and standard tests that accurately predicted desaturation during daily living. We propose that this new test can define the profile of diurnal oxygen desaturation. In this way, this new tool may offer a new method to categorize COPD disease severity, determine short- and long-term outcomes of mild, moderate and severe hypoxemia and provide a feasible new type of assessment on which to base an oxygen prescription.

Alerts and Recommendations to HSR&D

None

Appendix 1: Product List

Not Applicable

Appendix 2: Discussion of Project Changes

Not Applicable

Publications/Citations

There are currently no citations for this project.