Balance Assessment and Treatment in Individuals with Chronic Obstructive Pulmonary Disease

by

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A thesis submitted in conformity with the requirements for the degree of Doctor of Philosophy

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Abstract

Preliminary evidence suggests that balance deficits constitute an important secondary impairment in individuals with chronic obstructive pulmonary disease (COPD). The main objective of this thesis was to describe balance impairment and fall risk in individuals with COPD and to examine interventions for improving balance and reducing fall risk in the context of pulmonary rehabilitation. The first study of this thesis showed that falls are common in patients with COPD and that fallers are characterized by impairments in standard clinical balance measures, such as the Berg Balance Scale and Timed Up and Go. In the second study, we found that the exercise component of conventional pulmonary rehabilitation has only modest effects on balance and fall risk in COPD, highlighting the need to examine the role of balance-specific training for these patients. The third study of this thesis identified the postural control subsystems most responsible for the observed balance deficits in COPD. Compared with age-matched controls, individuals with COPD demonstrated reductions in all balance control subsystems and slower reaction times in response to external perturbations. In this study, we also showed that deficits in balance in patients with COPD were associated with peripheral muscle weakness and reduced physical activity levels. These results informed the design of the final study of this thesis, a randomized controlled trial evaluating the addition of specific balance training to
pulmonary rehabilitation for improving balance in patients with COPD. Preliminary results from this study suggest that the addition of thrice weekly balance exercises to a conventional pulmonary rehabilitation program is effective for optimizing gains in measures of functional balance and fall risk. The findings from the four studies included in this thesis support the need for incorporating balance assessment and treatment for at-risk patients with COPD, as part of their comprehensive management.
Acknowledgments

I would like to acknowledge several people without whom this thesis would not have been possible. First, I would like to thank all the volunteers who participated as subjects in the included studies; this thesis would not have been possible without them and it was truly a pleasure to meet each and every volunteer.

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Preface

Thesis Format

This thesis is presented in manuscript style format, and includes four published manuscripts, with one manuscript in preparation. Chapter 1 includes a summary of the research problem, research objectives and a review of the literature. Portions of a published review paper are included as part of the literature review. Chapters 2-4 consist of published manuscripts. Chapter 5 is the final study of this thesis, in which data collection is still ongoing, therefore the manuscript is in preparation and the results presented are preliminary. An overall discussion follows in Chapter 6 that integrates the findings and knowledge, and outlines avenues for future research.

Summary of Original Contributions (in order of appearance in thesis)


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Chapter 1

1 Introduction

1.1 Summary of problem

Chronic obstructive pulmonary disease (COPD) is an inflammatory disorder characterized by progressive airflow limitation.\(^1\) It is the fourth leading cause of death in Canada,\(^2,3\) and is projected to rank third in 2020 in global burden of disease.\(^4,5\) It is well-established that, in addition to the pulmonary pathology, individuals with COPD develop systemic manifestations of the disease including peripheral muscle dysfunction,\(^6,7\) weight loss,\(^8\) osteoporosis,\(^9\) and psychological problems such as anxiety and depression.\(^10\) Emerging evidence suggests that individuals with COPD also demonstrate important deficits in balance control.\(^11-15\)

The ability to maintain balance is critical for mobility, avoidance of falls and functional independence in daily living. Balance impairment has been associated with an increased risk of falls and a resulting increase in mortality rate among older adults.\(^16-18\) A large cross-sectional study reported that COPD was second only to osteoarthritis in its association with the number of falls in elderly women.\(^19\) In a recent prospective study, individuals with COPD were found to have a projected annual fall rate of 1.2 falls per person, more than four times the incidence reported in older adults.\(^20,21\) Given the devastating consequences of falls in older adults, an improved understanding of the balance deficits present in individuals with COPD is essential to guide the development of balance training and fall prevention programs for this population.
The general objective of this thesis was to describe balance impairment and fall risk in individuals with COPD and to examine interventions for improving balance and reducing fall risk in the context of pulmonary rehabilitation. The ultimate goal of this research is to inform the development of evidence-based rehabilitation assessment and treatment strategies to prevent/attenuate functional decline in patients with COPD.

1.2 Literature review

As this thesis draws on literature from both respiratory rehabilitation and geriatrics, the following review is divided into three main sections: 1) Overview of COPD; 2) Balance and falls in the elderly; and 3) Balance and falls in COPD.

1.2.1 Overview of COPD

1.2.1.1 COPD: definition, prevalence and clinical presentation

A common and costly respiratory disorder, COPD is characterized by the presence of expiratory airflow reduction due to chronic bronchitis or emphysema.\(^2,22\) It is the fourth leading cause of death in both men and women in Canada,\(^2,3\) and is projected to be the third leading cause of death in the world by 2020.\(^5\) The prevalence of COPD increases with age with the highest prevalence being in individuals aged 65 years and over.\(^23,24\)

COPD is a progressive disease associated with an amplified chronic inflammatory response to noxious particles or gases in the airways and lung. It is caused by a combination of small airways disease (chronic bronchiolitis) and parenchymal destruction (emphysema).\(^4\)

Pathological changes include increased inflammatory cell types in various parts of the lung
and structural changes resulting from repeated injury and repair; these changes lead to air trapping and progressive airflow limitation.\textsuperscript{4} Risk factors for COPD include exposure to cigarette smoke, environmental or occupational pollutants, recurrent pulmonary infections, pre-existing atopy or airway hyper-responsiveness, and alpha-1 anti-trypsin deficiency.\textsuperscript{4,24}

The most common manifestations of COPD include dyspnea, impaired exercise tolerance, chronic cough with or without sputum production, and wheezing.\textsuperscript{1} In the context of the above symptoms, a diagnosis of COPD is confirmed through measurement of airflow limitation by spirometry (generally defined as a postbronchodilator FEV\textsubscript{1}–FVC ratio less than 0.70).\textsuperscript{4} The natural course of COPD is that of progressive worsening of airflow limitation, repeated exacerbations, respiratory failure and premature death.

1.2.1.2 Secondary impairments in COPD

In addition to the pulmonary pathology, COPD is associated with a broad array of systemic manifestations that have a considerable impact on the symptoms, quality of life, and mortality.\textsuperscript{4,25} Peripheral muscle dysfunction,\textsuperscript{6,7} weight loss,\textsuperscript{8} osteoporosis,\textsuperscript{9} cardiovascular problems,\textsuperscript{4} and anxiety and depression are among the most well-established systemic effects of COPD.\textsuperscript{10}

The impact of COPD on a range of functional limitations is increasingly recognized. In a large cohort study, limitations in lower extremity functioning, exercise performance, skeletal muscle strength, standing balance, and performance of basic physical tasks, were noted in patients with varying degrees of COPD severity compared with an age-matched referent group.\textsuperscript{13} Of interest, a subsequent study of secondary disability in COPD demonstrated that such functional limitations had a greater impact on the development of disability than
respiratory impairment. These findings are in line with previous research showing that exercise tolerance, health-related quality of life, and participation in activities of daily living, are commonly impaired out of proportion to lung function impairment in patients with COPD. Consequently, there is a recognized need for a shift from a focus on assessment and management of airway obstruction in COPD, to the comprehensive assessment and rehabilitation of the diverse extra-pulmonary effects of the disease.

1.2.1.3 Management of COPD

Smoking cessation and pharmacologic therapy (inhaled bronchodilators and inhaled corticosteroids) are the first steps to reducing the symptoms of COPD and the frequency and severity of exacerbations. However, existing medications for COPD have not been shown to cure or reverse the long-term decline in lung function. Other treatment options for patients with COPD include pulmonary rehabilitation, oxygen-therapy (for patients with resting hypoxemia), ventilator support (for patients with very severe COPD), and surgical treatments for selected patients (including lung volume reduction surgery, lung transplantation and bullectomy).

1.2.1.4 Pulmonary rehabilitation

International guidelines for management of COPD recognize pulmonary rehabilitation as an integral therapeutic intervention for individuals with COPD. The rehabilitation program is provided by a multi-disciplinary team and typically consists of supervised exercise, disease-specific education and self management, and nutritional, psychological and social support. There is excellent evidence that pulmonary rehabilitation increases exercise
tolerance, reduces dyspnea, and improves health-related quality of life in individuals with COPD. These beneficial effects have been shown to be independent of age and use of supplemental oxygen. Tailoring programs to optimize the magnitude of treatment effects and to ensure the benefits of rehabilitation are long-lasting remain important areas of study.

1.2.2 Balance and falls in the elderly

1.2.2.1 Falls in the elderly

Falls are a leading public health problem in older adults. One in three adults over the age of 65 fall each year and 20-30% will suffer moderate to severe injuries that increase their risk of morbidity and mortality. In addition to injury, loss of mobility and independence, falls have also been shown to have profound negative effects on the psychological well-being of older adults. Fear of falling has been shown to negate gains made through rehabilitation and contribute to further increase in risk of falls.

Risk factors for falls may be categorized as intrinsic or extrinsic. Intrinsic risk factors are patient-related and include advanced age, chronic diseases, muscle weakness, gait deviations, mental status alterations, and medications. Extrinsic factors include environmental hazards or hazardous activities such as walking on slippery surfaces or impulsiveness. The risk of falling increases considerably as the number of risk factors increase; in community-dwelling older adults, the risk of falling is 8% with no risk factors and increases to 78% for those with four or more risk factors. Impairments in balance are widely recognized as one of the most important modifiable intrinsic risk factors for falls among older adults.
Comprehensive fall risk assessment entails evaluation of previous falls, cognition, balance, gait, strength, chronic diseases, mobility, nutrition and medications. Typically, risk assessment of elderly individuals residing in the community is based on instruments that measure functional balance and mobility. Despite the number of fall risk factors that must be considered in relation to fall risk, this thesis will focus exclusively on balance given its importance as a risk factor that is amenable to therapy.

1.2.2.2 Balance control

Successful maintenance of balance, or postural control, requires that the centre of mass (COM) be maintained within the limits of the base of support (BOS). This is neither a simple nor a fixed task. Rather, the ability to stand upright on two legs is an extremely complex skill that requires the integration of multiple somatosensory, neuromuscular, as well as central nervous system (CNS) inputs which must be constantly updated and fine-tuned under an array of situations in everyday life. While the ability to maintain balance during stance is a formidable skill in and of itself, optimal postural control requires centrally initiated dynamic postural adjustments to be made prior to the initiation of voluntary movement (such as taking a step); this must also occur in response to external perturbations which threaten to move the COM outside the BOS and potentially cause a fall. Both static (maintaining equilibrium with minimal movement) and dynamic (maintaining

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1 A version of this section has been published. Reprinted with permission from: Novamedia srl: Beauchamp MK, Brooks D, Goldstein RS. Deficits in postural control in individuals with COPD- emerging evidence for an important secondary impairment. Multidisciplinary Respiratory Medicine 2010;5(6):417-21.
equilibrium with moving BOS) postural control are essential to maintain stability and avoid falls.\textsuperscript{42}

The ability to react to sudden and unpredictable perturbations is critical to dynamic postural control. Of particular importance to preventing falls are change-in-support reactions in which rapid compensatory stepping or reaching responses are used to respond to unexpected disturbances.\textsuperscript{43} These change-in-support reactions are the only recourse against large perturbations\textsuperscript{42} but have also been shown to be frequently used after small perturbations.\textsuperscript{45} Reactive control reactions occur very rapidly; for example, a compensatory step is completed in approximately half the time needed to complete a rapid volitional step.\textsuperscript{46} Video footage from geriatric facilities demonstrated that compensatory stepping reactions are used in 32-45\% of falls or near falls.\textsuperscript{47,48}

Despite the rapid speed of these change-in-support reactions, the control is extremely complex and suggests a level of central organization. While volitional movements can be planned in advance, the direction, magnitude and speed of compensatory reactions must be adapted ‘on-line’ to account for both the unpredictable body motion caused by the perturbation, as well as environmental constraints on movement such as location of railings or obstacles.\textsuperscript{46} Another important distinction between compensatory stepping reactions and volitional stepping pertains to anticipatory postural adjustments (APAs).\textsuperscript{43,46} In volitional stepping, an APA acts as a feedforward strategy that directs the COM toward the stance leg in preparation for the impending instability caused by lifting the swing foot. In contrast, during compensatory stepping reactions in response to perturbations, APAs are usually absent or significantly truncated.\textsuperscript{49,50} The sophisticated nature of these balance recovery
reactions likely involve cortical and higher-level cognitive processing, however the specific mechanisms are not fully understood.

The postural control system is affected by age with many studies showing a decline in postural stability from the age of 50 onwards.52, 53 Age-related changes in balance are well recognized as a result of a combination of a decline in muscle strength, sensory functioning and speed of sensorimotor responses.53 These changes negatively influence both anticipatory and compensatory postural control. Studies investigating change-in-support reactions in the healthy elderly compared to young adults have shown that older adults are more likely to execute these reactions at lower levels of instability and to take multiple steps to recover balance or to reach or grasp objects for support.43, 46 Whether or not the onset timing of these balance recovery reactions are slower in older adults is subject to some debate, however the contradictory results are likely a consequence of differences in perturbation methods used to assess change-in-support reactions.54 Nevertheless, many of the above age-related differences have been shown to predict falls in older adults.46, 55, 56 Consequently, balance assessment and training are one of the key foci of rehabilitation and falls prevention programs for older adults.16

1.2.2.3 Balance assessment

Clinical balance assessment tools serve three main purposes: 1) to predict fall risk by screening for general balance impairments; 2) to monitor responses to interventions; and 3) to determine the underlying cause of the balance impairment. There are many different balance assessment measures; in one systematic review, a total of 68 balance tests were identified.57 The choice of balance test depends on the purpose of the assessment, practice
setting, and familiarity with the measure. A recent survey of Canadian physical therapists practicing in Ontario found that the single-leg stance test, the Berg Balance Scale and Timed Up and Go were the most commonly used balance measures in the orthopedic, neurologic, geriatric and general rehabilitation settings. Measures of balance confidence, such as the Activities-Specific Balance Confidence Scale, are also often considered as part of a complete clinical balance assessment as they have been shown to correlate well with standard balance scales and with risk of falls. These functional balance tests are helpful to identify balance problems, predict fall risk and document changes with interventions, however provide little information as to the underlying systems responsible for the balance deficits. More recently, tools such as the Balance Evaluation Systems Test (BESTest), have been designed to provide a more comprehensive assessment of the specific sub-systems involved in postural control to enable therapists to better focus their treatment on the underlying balance deficits (e.g., postural responses vs. sensory orientation). Of note, the BESTest is one of the few clinical balance tools that incorporates the assessment of change-in-support reactions in response to manually applied perturbations. Please see Table 1-1 for an overview of some of the most commonly used clinical balance tests.

Table 1-1: Overview of commonly used clinical balance tests

<table>
<thead>
<tr>
<th>Balance Measure</th>
<th>Description</th>
<th>Advantages</th>
<th>Limitations</th>
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<tr>
<td>Activities-Specific Balance Confidence (ABC) Scale$^{59, 63, 64}$</td>
<td>16-item questionnaire. Respondents rate their balance confidence for specific daily activities from 0% (no confidence) to 100% (complete confidence) and the total score is averaged.</td>
<td>Includes common daily activities, only 10 min to complete, good test-retest reliability, relates to fall risk, minimal detectable change established</td>
<td>Relies on self-report, does not identify cause of balance deficit</td>
</tr>
<tr>
<td>Test Name</td>
<td>Description</td>
<td>Reliability/Validity</td>
<td>Notes</td>
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<tr>
<td>----------</td>
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<td>----------------------</td>
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</tr>
<tr>
<td>Balance Evaluation Systems Test (BESTest)</td>
<td>36-item test grouped into 6 systems of postural control: biomechanics, stability limits, anticipatory postural adjustments, postural responses, sensory orientation, stability in gait. Each item is scored from 0 (worst performance) to 3 (best performance). Total and section scores are provided as percentages.</td>
<td>Determines the underlying cause of balance problems and allows for focused treatment, good inter-rater reliability, correlated with balance confidence.</td>
<td>30 min to perform, association with fall risk not known, need for equipment, no data on responsiveness.</td>
</tr>
<tr>
<td>Berg Balance Scale (BBS)</td>
<td>14-item performance based test including stability in sitting, standing and during transitions. Items scored from 0 (unable/unsafe) to 4 (independent/efficient/safe). Maximum score is 56.</td>
<td>Relates to fall risk, only 15 min to perform, high inter-rater reliability, minimal detectable change established, normative values.</td>
<td>No identification of type of balance deficit, ceiling effect, does not test dynamic balance during gait.</td>
</tr>
<tr>
<td>Community Balance and Mobility Scale (CB&amp;M)</td>
<td>13-item test of dynamic stability developed for the traumatic brain injury population and scored on a 6-point scale from 0 (worst performance) to 5 (best performance).</td>
<td>Good test-retest reliability, less subject to ceiling effects seen in other scales.</td>
<td>Validation studies limited to neurological populations, 30 min to perform, does not identify cause of balance problem, association with fall risk not known, no data on responsiveness.</td>
</tr>
<tr>
<td>Functional reach</td>
<td>Assesses how far a participant can reach beyond the length of their arm while maintaining a fixed standing position</td>
<td>Simple to perform, predicts falls, good inter-rater and test-retest reliability, minimal detectable change established, normative values.</td>
<td>Only a single task, no identification of cause of balance problem.</td>
</tr>
<tr>
<td>One-leg stance</td>
<td>Records the time a participant is able to stand on one-leg unassisted.</td>
<td>Simple to perform, good inter-rater and inter-subject reliability, relates</td>
<td>Only a single task of static balance, no identification of cause of balance.</td>
</tr>
</tbody>
</table>
Timed Up and Go (TUG)\textsuperscript{61,73} Time to stand up from a chair, walk to a line 3m away, turn around, walk back and sit down is recorded. Subjects walk at usual pace.

Simple to perform, excellent inter- and test-retest reliability, predicts falls, minimal detectable change established, normative values\textsuperscript{68}

Only a single mobility task, no identification of cause of balance problem

While functional balance tests are easy to perform and therefore suitable for daily clinical use, laboratory techniques such as electromyography, kinematics and kinetics, provide a continuous evaluation of postural control with a level of precision not accessible in observationally-based clinical assessments.\textsuperscript{74} The precision of measurement and closer approximation of the physiologic components engaged in the maintenance of stability are important advantages of including such measurements in a comprehensive evaluation of balance.

Three types of analysis are commonly used to evaluate postural control in the laboratory: 1) kinematics is concerned with details of the movement itself rather than forces (e.g., motion analysis) 2) kinetic analysis (e.g., force plate measurements) entails the analysis of forces and the moments of forces that are developed during movements, and 3) electromyography (EMG) can be used to measure bioelectric changes associated with skeletal muscle activity.\textsuperscript{62} These techniques can be utilized to precisely describe a patient’s postural sway, anticipatory postural adjustments and compensatory balance reactions. In addition, these laboratory measures of postural control have been shown to predict risk of falls.\textsuperscript{75}
Given that the majority of falls occur as a result of unpredictable balance disturbances, measurement of compensatory reactions in response to externally applied perturbations is an important component of a complete balance assessment. While applying manual perturbations is the simplest option (as in the BESTest), use of laboratory techniques allows the precise and controlled delivery of the perturbation as well objective measurement of the response. The most common perturbation methods include use of moving platforms, use of cable systems where the subject is suddenly released from a leaning posture, and use of weights and pulleys or an electric motor to pull on a cable attached the subject’s pelvis.\textsuperscript{54, 56} Such perturbation paradigms have been shown to reliably evoke compensatory behavior.\textsuperscript{76, 77} Amplitude and latency of postural muscle responses can be assessed using EMG recordings, as well as the amplitude of centre-of-pressure (COP) movement using a force plate. While stepping patterns, which have been shown to be related to fall risk,\textsuperscript{78} can also be tracked, the inclusion of EMG and COP measures are essential for precise measurement of these extremely fast movements, which cannot be accurately evaluated with visual observation alone. In particular, delays in muscle response latencies, which can only be assessed with EMG, have been shown to be related to falls\textsuperscript{78} and offer causative insight into decreased stability and increased fall risk.

1.2.2.4 Balance training

By convention, balance training programs for older adults typically include a combination of lower extremity strength training with static and dynamic exercises designed to progressively challenge the patient’s ability to maintain the COM within their BOS under different sensory conditions (unstable surfaces, eyes closed, etc.).\textsuperscript{79} Although perturbation-based training and
dual-task training are common practice in physiotherapy, these strategies have only recently gained attention in the literature for promoting effective balance recovery reactions and reducing fall risk.\textsuperscript{80, 81}

Not all types of exercise have been shown to improve balance and fall risk to the same degree. A recently updated systematic review and meta-analysis by Howe et al. found that certain types of exercise (gait, balance, coordination and functional tasks, 3D exercise and multiple exercise types) are effective in improving clinical balance performance in older adults.\textsuperscript{82} In this review, positive effects of exercise were found for the TUG, BBS and one-legged stance. In general, the effective interventions involved dynamic exercises in standing performed three times a week for three months. While muscle strength has been shown to contribute to balance performance among older adults,\textsuperscript{83} results from a recent systematic review indicate there is limited evidence to support progressive resistance training as a single intervention for improving balance.\textsuperscript{57}

In two recent systematic reviews, exercise was shown to be effective for reducing falls in older people.\textsuperscript{84, 85} Gillespie et al. found results in favour of multiple-component group exercise, Tai Chi, and individually prescribed home-based exercise for reducing the rate and risk of falling in community dwelling older adults.\textsuperscript{85} In fact, in this Cochrane review, exercise was found to be the only effective intervention among those examined which included multifactorial fall risk assessment and intervention, home safety modification and vitamin D supplementation. In a systematic review of exercise interventions for the prevention of falls, Sherrington et al. noted greater relative effects on falls from training programs that included exercises that challenged balance, used a higher dose of exercise, and did not include a walking program.\textsuperscript{84} The finding that exercise programs that did not include
walking reduced fall rates more than those that involved walking may be explained by the possibility that time spent walking in these programs took the place of time spent undergoing specific balance training. Of note, it is likely that the inclusion of balance training accounts for the fact that several interventions that appear to differ were found to be similarly effective in reducing fall rates. For example, Tai Chi and the home-based exercise programs included in these reviews primarily involved balance training.\(^8^6\) Overall, the evidence in support of exercise with targeted balance training for fall prevention is sufficiently compelling that the American Geriatrics Society recommends exercise with balance training either as a single intervention or as an essential component of a falls intervention strategy for community-dwelling older adults at risk of falling.\(^1^6\)

There is limited information as to the mechanism for improved balance following exercise interventions. It is thought that supra-spinal mechanisms might be responsible for training-induced improvements in postural control.\(^8^7\) That is, after training, less neural effort may be required to maintain postural stability due to increased task automatization.\(^7^9\) However, further study is required to confirm this theory.

1.2.3 Balance and falls in COPD

1.2.3.1 Balance in COPD\(^1\)

There is limited research examining deficits in postural control among individuals with COPD; Table 1-2 provides an overview of these studies. The first investigation in this area, a study by Butcher and colleagues of 30 patients with severe COPD (FEV\(_1\) 38% predicted), identified impairments in functional balance as measured by the Community Balance and
Mobility Scale and the Timed Up and Go test, as well as increased postural sway, compared with age-matched healthy controls. In this study, it was suggested that balance and coordination deficits correlated with measures of severity of airflow obstruction (FEV$_1$) and consequent reduced physical activity levels in patients with COPD. In a large prospective cohort study, Eisner and colleagues observed that individuals with moderate COPD (FEV$_1$ 62% predicted; n = 1202) performed significantly worse on two tests of functional balance (Functional Reach Test and a tandem stance task) as compared with 302 healthy age-, sex- and race-matched controls.

Two studies have considered the influence of fatigue on laboratory measures of static balance in patients with moderate to severe COPD. Chang and colleagues investigated static postural control following sub-maximal exercise in 19 COPD (FEV$_1$ 46% predicted) subjects. The authors reported that in the absence of visual input patients with COPD demonstrated impaired static postural control (i.e., increased sway) following a six-minute walk test. It was hypothesized that the increased postural sway following exercise was related to decreased peripheral muscle strength and endurance as well as to the increase in ventilation following exertion. Smith et al. compared postural sway as well as lumbar spine and hip movement in 12 people with severe COPD (FEV$_1$ 33% predicted) with 12 healthy controls, before and after participation in upper limb exercise. Subjects with COPD demonstrated increased mediolateral sway and angular motion of the hip compared to healthy controls. This finding has important implications, as mediolateral displacement has been shown to be closely related to falls in older adults. This mediolateral displacement was reported to further increase after upper limb exercise, a finding attributed to the impact of trunk muscles on balance and respiration.
In a more recent study, Roig et al. compared measures of postural control in 20 elderly COPD patients (FEV\textsubscript{1} 47% predicted) with 20 healthy, age-matched controls.\textsuperscript{15} Participants stood on a force plate in a visual surround system and were challenged to stay upright under increasingly challenging conditions; both the force plate and the visual background were manipulated in order to assess the contribution of the vestibular, somatosensory and visual sensory systems to postural stability (Sensory Organization Test). Individuals with COPD experienced more frequent “falls” (defined as when a subject needed to take a step or touch the background to regain balance) and exhibited marked deficits in postural control, compared to controls. Of interest, the authors did not observe an association between muscle weakness or the level of physical activity and deficits in postural control.

Table 1-2: Overview of studies evaluating deficits in postural control in COPD\textsuperscript{2}

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample</th>
<th>Key outcomes</th>
<th>Key findings</th>
</tr>
</thead>
<tbody>
<tr>
<td>Butcher et al. 2004\textsuperscript{11}</td>
<td>30 COPD (FEV\textsubscript{1} 38% predicted), age 71 yrs; 21 controls, age 68 yrs</td>
<td>Finger-to-nose test, Toe Tap, Timed Up and Go Posturography, Community Balance and Mobility Scale</td>
<td>Deficits in functional balance and coordination in COPD compared to controls. Increased sway for eyes open, moving platform test</td>
</tr>
<tr>
<td>Eisner et al. 2008\textsuperscript{13}</td>
<td>1,202 COPD (FEV\textsubscript{1} 62% predicted), age 58 yrs; 302 age, sex and race matched controls</td>
<td>Standing balance task from Short Physical Performance Battery, Functional Reach Test</td>
<td>Poorer performance on standing balance task and functional reach in COPD vs. controls</td>
</tr>
<tr>
<td>Chang et al. 2008\textsuperscript{12}</td>
<td>19 COPD (FEV\textsubscript{1} 46% predicted), age 69 yrs</td>
<td>Timed Up and Go and postural sway in quiet stance</td>
<td>Static balance in semi-tandem stance with eyes closed</td>
</tr>
</tbody>
</table>

These studies suggest that deficits in balance constitute an important secondary impairment in individuals with COPD. Abnormal balance was identified using both clinical and laboratory measures in individuals with varying degrees of COPD severity. Nevertheless, many knowledge gaps remain in the literature on balance deficits in this population. The underlying mechanisms for reduced postural control in individuals with COPD remain unclear. Many hypotheses have been proposed, including decreased levels of physical activity, peripheral muscle weakness, altered trunk muscle mechanics, hypoxemia, and somatosensory deficits. In addition, it is unclear whether the exercise component of pulmonary rehabilitation, in the absence of specific balance training, might have an effect on balance. A detailed assessment of the relative influence of the different postural control...
systems is likely required to guide the development of effective interventions to optimize balance and fall risk reduction in patients with COPD.

1.2.3.2 Falls in COPD

Many of the common features of COPD constitute well-established risk factors for falls, although there is limited research in this area. In 2009, a review by Roig and colleagues\textsuperscript{89} presented a theoretical framework for identifying fall risk factors among patients with COPD. The findings of the review support a physiological premise for a high susceptibility to falls in COPD due to the presence of multiple fall risk factors. Lower limb muscle weakness and impairments in activities of daily living were considered well-established fall risk factors in patients with COPD, while other intrinsic risk factors, such as gait and balance deficits, malnutrition, depression and medications were deemed possible risk factors requiring further study.\textsuperscript{89}

Studies specifically examining falls in patients with COPD are scarce. A large cross-sectional study of 4,000 elderly women reported that COPD was second only to osteoarthritis in its association with the number of falls.\textsuperscript{19} In a recent prospective cohort study,\textsuperscript{21} individuals with moderate to severe COPD were found to have a projected annual fall rate of 1.2 falls per person- a substantially higher rate than that previously reported for older adults (incidence rate of 0.24).\textsuperscript{20} In this study, previous fall history and a diagnosis of coronary artery disease were the most important predictors of falls. Although the authors failed to note an overall association between fall incidence and reduced health-related quality of life, over six months, fallers with COPD showed a greater decline in dyspnea scores as measured by the Chronic
Respiratory Questionnaire (CRQ) compared to non-fallers.\textsuperscript{21} The relatively short follow-up period in this study likely explains the low impact of falls on overall quality of life.

Taken together, these studies support the need for examining the role of fall prevention strategies for individuals with COPD. Given the relationship between balance and falls in the elderly, it is likely that balance deficits contribute to an increased risk of falling in individuals with COPD. However, no studies have investigated this link to date.

1.3 Summary of research objectives

The observation of balance deficits and an increased fall risk in patients with COPD highlights the need for further research on balance assessment and training with the overarching goal of reducing risk of falls in this population. Studies are needed to investigate the association between balance and falls in COPD, to determine which aspects of balance are most affected, and to examine the impact of interventions. The specific research objectives and hypotheses of this thesis are as follows:

1. To determine the clinical measures that discriminate between fallers and non-fallers in individuals with COPD. We hypothesized that fallers with COPD would be characterized by impairments in functional balance measures, and greater severity of disease. (Chapter 2)

2. To describe the within-subject effects of conventional pulmonary rehabilitation on balance in people with COPD and to determine whether any observed changes in balance are associated with change in exercise tolerance or health-related quality of life. We hypothesized that pulmonary rehabilitation would result in small changes in balance that would be associated with changes in exercise tolerance and quality of life. (Chapter 3)
3. To determine the specific components of postural control that are impaired in individuals with COPD compared to age-matched healthy controls. We hypothesized that subjects with COPD would demonstrate impaired balance in subsystems most reliant on skeletal muscle strength. (Chapter 4)

4. To determine if deficits in balance in COPD are associated with lower extremity muscle strength or physical activity. We hypothesized that lower extremity muscle strength and physical activity would be moderately associated with balance in COPD. (Chapter 4)

5. To develop a feasible and safe balance training program for patients with COPD and to determine the effects of the program on measures of balance and fall risk. We hypothesized that the addition of balance training to pulmonary rehabilitation would be feasible and safe, and would result in superior gains in measures of balance and fall risk compared to pulmonary rehabilitation alone. (Chapter 5)
Chapter 2

2 Impairments in balance discriminate fallers from non-fallers in COPD

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Contributions of the authors: MK Beauchamp developed the research design and protocol, collected and analyzed the data and wrote the manuscript. K Hill contributed to the research design and reviewed the manuscript. RS Goldstein assisted with the overall supervision of the study, research design, subject recruitment and reviewed the manuscript. T Janaudis-Ferreira assisted with data collection and reviewed the manuscript. D Brooks assisted with the overall supervision of the study, research design, and reviewed the manuscript.
2.1 Abstract

**Background:** Preliminary evidence suggests individuals with COPD exhibit deficits in balance. Further investigation of balance and risk of falls is warranted in these patients. The objective of this study was to determine the clinical measures that discriminate fallers from non-fallers among patients with COPD.

**Methods:** A cross-sectional study design was used. Subjects > 60 yrs with COPD attended a single assessment session. One-year incidence of falls was collected via self-report questionnaire. Risk of falls and balance were determined using the Berg Balance Scale (BBS), Timed Up and Go Test (TUG) and the Activity Specific Balance Confidence (ABC) Scale. Exercise tolerance was determined from the Six-Minute Walk Test and functional limitation attributable to dyspnea from the Medical Research Council (MRC) dyspnea scale.

**Results:** Of 39 COPD subjects (FEV1 = 41.5 ± 17.0 % predicted; age 71.1 ± 6.8 yrs) who completed the study, 46% (n = 18) reported at least one fall in the preceding year. Significant differences between fallers and non-fallers were found for the ABC (65.8 ± 18.2 vs. 81.7 ± 11.1; p = 0.002), TUG (17.0 ± 4.9 vs. 14.0 ± 3.1 seconds; p = 0.024), BBS (45.2 ± 5.4 vs. 48.8 ± 5.0; p = 0.042), use of supplemental oxygen (72% vs. 24%; p= 0.002), and MRC dyspnea scale (median 4, range 3 vs. median 3, range 4; p = 0.046).

**Conclusions:** Patients with COPD fall frequently. Standard clinical balance measures discriminate self-reported fallers from non-fallers. These observations draw attention to an important secondary impairment in COPD.
2.2 Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most important causes of death world-wide and is projected to rank third in 2020 in global burden of disease.\textsuperscript{5} Although the primary underlying pathophysiology is pulmonary, associated systemic effects of COPD contribute importantly to the symptoms and disability that characterize this condition. Peripheral muscle dysfunction is associated with reduced functional mobility and exercise capacity in COPD.\textsuperscript{6} In addition, impaired motor control, reaction time and dexterity have been reported in individuals with resting hypoxemia.\textsuperscript{88} Recent studies have also noted reduced balance and coordination in individuals with COPD relative to healthy controls.\textsuperscript{11, 12}

Falls have considerable negative consequences for older adults including morbidity, mortality, and loss of autonomy.\textsuperscript{90} The presence of chronic disease, multiple medications, impaired mobility and muscle weakness are frequently cited risk factors, and balance impairment is one of the most important predictors of falls in older adults.\textsuperscript{16, 38} Despite the fact that individuals with COPD possess many of these risk factors, limited information is available regarding balance and falls in this population.\textsuperscript{91} Furthermore, the high incidence of osteoporosis in these patients\textsuperscript{9} underscores the need for identification of putative risk factors for falls in order to inform the development of both preventive and treatment programs.

The aim of this study was to determine the clinical measures that discriminate between fallers and non-fallers in individuals with COPD. We hypothesized that fallers with COPD would be characterized by impairments in functional balance measures, and greater severity of disease.
2.3 Methods

2.3.1 Participants

Individuals were eligible to participate in this study if they met the following inclusion criteria: (1) physician diagnosis of COPD (FEV$_1$ < 80% predicted and FEV$_1$/FVC < 70% predicted) according to international guidelines$^{92}$; (2) age > 60 years; (3) smoking history >10 pack years and; (4) ability to provide written informed consent. To avoid the potential confounding effect of an exercise training program on fall risk, we recruited patients who had completed less than one week of pulmonary rehabilitation. Individuals with co-morbid conditions likely to jeopardize their safety or influence their balance were excluded. Specifically, exclusion criteria comprised: (1) known cognitive impairment; (2) mechanical ventilation for all or part of the day; (3) neurological or musculoskeletal condition that limited mobility; and (4) symptomatic cardiovascular disease.

2.3.2 Data collection procedures

After study approval by the local Research Ethics Board, consecutive patients enrolled in pulmonary rehabilitation programs between March and August 2008 were approached to attend a single assessment session. After obtaining informed consent, measurements of resting lung function, including forced expiratory volume in one second (FEV$_1$) and carbon monoxide diffusing capacity (D$_L$CO), height, weight and use of supplementary oxygen were retrieved from the patient’s medical chart. All pulmonary function testing was obtained from the same laboratory according to ATS guidelines.$^{93}$ Balance testing and questionnaires were administered by the same registered physical therapist, in a quiet laboratory setting. The order of the tests was
standardized for all subjects; balance and functional mobility tests were completed first, followed by questionnaires and assessment of exercise capacity. Participants were encouraged to rest as needed throughout the assessment session.

2.3.3 Measures

Self-reported falls

The questionnaire component of the Elderly Falls Screening Test (EFST) was utilized to establish the number of times each patient had fallen during the preceding 12 months, using the following standard definition: “A fall would be when you find yourself suddenly on the ground, without intending to get there, after you were either in a lying, sitting or standing position.” The EFST has been shown to have both criterion and predictive validity in elderly individuals residing in the community.

Berg Balance Scale (BBS)

Functional balance was measured using the 14-item BBS. Activities such as transfers, reaching, turning around and single legged stance were graded on a scale ranging from 0 (unable/unsafe) to 4 (independent/efficient/safe), with higher scores indicating greater balance control. The measurement derived using the BBS has demonstrated internal consistency, intra-rater and inter-rater reliability, content validity, construct validity and predictive validity for determining fall risk in older adults. A cut-off score of 46 and below has been identified as a useful score to successfully identify those at risk of falling. Age and gender-specific scores are available in healthy populations.

Timed up and Go (TUG)
The TUG was used to provide a timed measure of balance and functional mobility in our patients.\textsuperscript{96} The test requires the patient to rise from a standard armchair, walk 3 meters at a comfortable pace, walk back to the chair, and sit down. A practice trial was performed (not recorded) and individuals were permitted to use a gait aid if required. Normative data are available for elderly individuals who reside in the community.\textsuperscript{68} The TUG has high intra- and inter-tester reliability and predictive validity for falls in community-living adults.\textsuperscript{95, 96} A cut-off score of 16 seconds or more has been shown to predict falls in community-dwelling elderly.\textsuperscript{97}

**Activity-specific Balance Confidence (ABC) Scale**

The ABC scale requires patients to indicate their confidence in performing 16 activities without losing their balance or becoming unsteady on an 11-point scale (0 to 100\%).\textsuperscript{63} Each item describes a specific activity that requires progressively increased balance control. Greater scores indicate higher balance confidence. The ABC scale has good test-retest reliability, internal consistency and predictive capacity for falls in older adults that reside in the community.\textsuperscript{63, 95}

**Medical Research Council (MRC) dyspnea scale**

The MRC dyspnea scale is a simple and valid method of characterizing patients with COPD in terms of their functional limitation resulting from dyspnea.\textsuperscript{98} The questionnaire comprises five grades (statements) with higher grades indicating greater perceived respiratory disability. Patients were asked to select the statement that best described their limitation.

**Six-Minute Walk Test (6MWT)**

The 6MWT is a self-paced test that quantifies functional exercise capacity in terms of the distance walked in six minutes (6MWD).\textsuperscript{99} The test was performed over a 30 meter level straight
course within an enclosed corridor according to the test protocol described by the American Thoracic Society. During each 6MWT, patients received standardized instructions and encouragement. Two tests were performed to account for possible improvements resulting from familiarization, with the greatest distance recorded. Each 6MWT was separated by a minimum of 30 minutes.

### 2.3.4 Statistical analysis

Statistical analyses were performed using SPSS® (Statistical Package for Social Sciences, version 16.0 for Windows). It was determined that 39 patients were required to yield 80% power ($\alpha = 0.05$) to detect a difference of 3 points in the BBS between fallers and non-fallers using an independent t-test and a standard deviation of 4. A difference of 3 points was chosen as it has been suggested to represent a clinically important difference for this measure. The assumption of normality was assessed by frequency histograms and box plots as well as statistical methods (Shapiro-Wilks test). For all analyses $p$ values $\leq 0.05$ were considered significant. Fallers were defined as those who reported one or more falls in the past year. Variables in fallers were compared with non-fallers using an independent t-test for normally distributed data, the Mann-Whitney U test for non-normally distributed data and ordinal data, and the Chi-Square test for categorical data. A forward stepwise logistic regression was used to determine predictors of falls. Data are expressed as mean $\pm$ standard deviation unless otherwise stated.
2.4 Results

2.4.1 Subjects

Thirty-nine patients (FEV$_1$ 41.5 ± 17.0% predicted; age 71.1 ± 6.8 yrs) completed the study. Their characteristics are summarized in Table 2-1. Eighteen patients (46%) reported at least one fall in the preceding year; with 5 patients (13%) reporting 2 or more falls. Of the 18 patients who used supplementary oxygen, 12 (67%) were on long-term oxygen therapy. To facilitate interpretation of the clinical measures of balance and functional mobility in patients with COPD, Figure 2-1 shows the mean BBS and TUG scores against those derived in a sample of healthy elderly individuals, separated for each decade of life. Fifteen patients (38%) achieved a score ≤ 46 for the BBS and 14 patients (36%) demonstrated scores ≥ the 16 second cut-off for predicting falls with the TUG. No differences in any measures were observed for gender ($p > 0.05$).
**Table 2-1: Subject Characteristics (n = 39)**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men/Women (n)</td>
<td>18/21</td>
</tr>
<tr>
<td>Supplemental oxygen (n,%)</td>
<td>18, 46%</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>71.1 ± 6.8</td>
</tr>
<tr>
<td>FEV&lt;sub&gt;1&lt;/sub&gt; (L)</td>
<td>0.9 ± 0.4</td>
</tr>
<tr>
<td>FEV&lt;sub&gt;1&lt;/sub&gt; (% predicted)</td>
<td>41.5 ± 17.0</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>2.4 ± 0.8</td>
</tr>
<tr>
<td>FVC (% predicted)</td>
<td>77.0 ± 17.0</td>
</tr>
<tr>
<td>D&lt;sub&gt;L&lt;/sub&gt;CO (ml/min/mmHg)</td>
<td>9.8 ± 4.5</td>
</tr>
<tr>
<td>D&lt;sub&gt;L&lt;/sub&gt;CO (% predicted)</td>
<td>51.0 ± 21.2</td>
</tr>
<tr>
<td>MRC Dyspnea scale</td>
<td>median 3, IQR 3</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td>303.3 ± 114.9</td>
</tr>
<tr>
<td>Body Mass Index (kg/m&lt;sup&gt;2&lt;/sup&gt;)</td>
<td>25.7 ± 9.5</td>
</tr>
<tr>
<td>ABC score</td>
<td>74.4 ± 16.6</td>
</tr>
<tr>
<td>BBS score</td>
<td>47.1 ± 5.4</td>
</tr>
<tr>
<td>TUG (sec)</td>
<td>15.4 ± 4.3</td>
</tr>
</tbody>
</table>

**NOTE.** Values are mean ± SD, unless otherwise indicated. Abbreviations: FEV<sub>1</sub>, forced expiratory volume in one second; FVC, forced vital capacity; D<sub>L</sub>CO, carbon monoxide diffusing capacity; MRC, Medical Research Council; IQR, inter-quartile range; 6MWD, six-minute walking distance; ABC, Activity-specific Balance Confidence Scale; BBS, Berg Balance Scale; TUG, Timed Up and Go test.
Figure 2-1: A comparison between a) Berg Balance Scale scores and b) Timed Up and Go scores in subjects with COPD (mean and 95% confidence interval; □) and reference values from healthy elderly (mean and 95% confidence interval; ○) for each decade of life. Reference data from Steffen et al.\textsuperscript{18} where mean and 95% confidence intervals where reported for males and females for each decade of life ranging from 60-90 years.

2.4.2 Comparison of fallers and non-fallers

In order to examine our a-priori hypotheses, we compared measures of functional balance and disease severity between fallers (defined as patients with one or more self-reported falls in the preceding 12 months) and non fallers (Table 2-2). Although multiple comparisons were made, pre-established hypotheses precluded the need for adjustments for type I errors.\textsuperscript{101} In support of
the first hypothesis (i.e., impaired balance in fallers), significant differences were demonstrated between fallers and non-fallers for the ABC (t-test, \( p = 0.002 \)), TUG (t-test, \( p = 0.024 \)), and BBS (t-test, \( p = 0.042 \)). With respect to our second hypothesis (i.e., greater disease severity in fallers), use of supplemental oxygen (chi-square, \( p = 0.002 \)) and MRC dyspnea scale (Mann Whitney U, \( p = 0.046 \)) distinguished fallers from non-fallers. However, no differences were observed between the two groups in FEV\(_1\), DL\(_{CO}\), or 6MWD (\( p > 0.05 \)). Of note, the mean difference in 6MWD between the groups (49 metres) approached the minimally clinically important difference for this measure.\(^{102}\) There was no difference between groups based on gender (\( p > 0.05 \)), though, not surprisingly, age was greater in fallers compared to non-fallers (73.3 ± 6.9 vs. 69.0 ± 6.1, \( p = 0.047 \)).

Table 2-2: Clinical Measures in Fallers and Non-Fallers with COPD

<table>
<thead>
<tr>
<th>Variable</th>
<th>Fallers (n=18)</th>
<th>Non-fallers (n=21)</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABC score</td>
<td>65.8 ± 18.2</td>
<td>81.7 ± 11.1</td>
<td>-15.9</td>
<td>-25.5 to -6.3</td>
<td>0.002*</td>
</tr>
<tr>
<td>Oxygen</td>
<td>n = 13, 72%</td>
<td>n = 5, 24%</td>
<td>-</td>
<td>-</td>
<td>0.002*</td>
</tr>
<tr>
<td>TUG (sec)</td>
<td>17.0 ± 4.9</td>
<td>14.0 ± 3.1</td>
<td>3.1</td>
<td>0.4 to 5.7</td>
<td>0.024*</td>
</tr>
<tr>
<td>BBS score</td>
<td>45.2 ± 5.4</td>
<td>48.8 ± 5.0</td>
<td>-3.5</td>
<td>-7.0 to -0.2</td>
<td>0.042*</td>
</tr>
<tr>
<td>MRC dyspnea</td>
<td>median 4, IQR 3</td>
<td>median 3, IQR 2</td>
<td>-</td>
<td>-</td>
<td>0.046*</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td>278.4 ± 125.7</td>
<td>327.5 ± 100.1</td>
<td>-49.0</td>
<td>-124.0 to 25.9</td>
<td>0.192</td>
</tr>
<tr>
<td>FEV(_1) (% predicted)</td>
<td>42.7 ± 15.8</td>
<td>40.6 ± 18.4</td>
<td>2.1</td>
<td>-9.0 to 13.2</td>
<td>0.704</td>
</tr>
<tr>
<td>DL(_{CO}) (% predicted)</td>
<td>50.1 ± 23.9</td>
<td>51.8 ± 19.1</td>
<td>-1.8</td>
<td>-17.2 to 13.7</td>
<td>0.818</td>
</tr>
</tbody>
</table>

NOTE. Values are mean ± SD, unless otherwise indicated. Abbreviations: ABC, Activity-specific Balance Confidence Scale; TUG, Timed Up and Go test; BBS, Berg Balance Scale; MRC, Medical Research Council; IQR, inter-quartile range; 6MWD, six-minute walking distance; FEV\(_1\), forced expiratory volume in one second; DL\(_{CO}\), carbon monoxide diffusing capacity.

*Significant at \( p < 0.05 \).
An exploratory, forward, step-wise logistic regression was used to identify the variables that predicted falls. Variables included those from Table 2-2 with probability values of $p < 0.05$ (ABC, TUG, BBS, supplemental oxygen and MRC). ABC ($p = 0.033$, odds ratio 0.94) and use of supplemental oxygen ($p = 0.027$, odds ratio 5.83) were retained as independent predictors of falls.

2.4.3 Post-hoc analysis

Given the finding that oxygen use was a predictor of falls, we conducted a post-hoc analysis to explore differences in clinical measures of balance and mobility with patients classified according to their use of supplemental oxygen (Table 2-3). There were significant differences for the TUG (t-test, $p < 0.001$), ABC (t-test, $p = 0.019$), BBS (t-test, $p = 0.028$), and 6MWD (t-test, $p = 0.037$) between patients using supplemental oxygen and those who did not. No differences were observed between the two groups in measures of lung function or age.
Table 2-3: Clinical Measures in Subjects with and without Supplemental Oxygen

<table>
<thead>
<tr>
<th>Variable</th>
<th>Oxygen (n=18)</th>
<th>No Oxygen (n=21)</th>
<th>Mean difference</th>
<th>95% Confidence interval</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TUG (sec)</td>
<td>17.9 ± 4.4</td>
<td>13.2 ± 2.9</td>
<td>4.7</td>
<td>2.3 to 7.0</td>
<td>&lt; 0.001*</td>
</tr>
<tr>
<td>ABC score</td>
<td>67.7 ± 19.6</td>
<td>80.0 ± 11.2</td>
<td>-12.3</td>
<td>-22.5 to -2.1</td>
<td>0.019*</td>
</tr>
<tr>
<td>BBS score</td>
<td>45.1 ± 5.6</td>
<td>48.9 ± 4.7</td>
<td>-3.9</td>
<td>-7.2 to -0.5</td>
<td>0.028*</td>
</tr>
<tr>
<td>6MWD* (m)</td>
<td>264.4 ± 103.3</td>
<td>339.5 ± 113.3</td>
<td>-75.1</td>
<td>-146.0 to -4.4</td>
<td>0.037*</td>
</tr>
<tr>
<td>FEV₁ (% predicted)</td>
<td>39.7 ± 15.6</td>
<td>43.1 ± 18.4</td>
<td>-3.4</td>
<td>-14.6 to 7.8</td>
<td>0.876</td>
</tr>
<tr>
<td>DLO₂ (% predicted)</td>
<td>52.1 ± 24.7</td>
<td>50.2 ± 19.0</td>
<td>1.9</td>
<td>-13.6 to 17.4</td>
<td>0.811</td>
</tr>
</tbody>
</table>

NOTE. Values are mean ± SD. Abbreviations: TUG, Timed Up and Go test; ABC, Activity-specific Balance Confidence Scale; BBS, Berg Balance Scale; 6MWD, six-minute walking distance; FEV₁, forced expiratory volume in one second; DLO₂, carbon monoxide diffusing capacity.

* Significant at p < 0.05.

2.5 Discussion

This is the first study to demonstrate differences in balance, functional mobility and balance confidence between fallers and non-fallers in patients with COPD. The novel findings of this study are: (i) standard clinical measures of functional balance, the BBS and TUG, discriminated between fallers and non-fallers; (ii) impaired balance confidence and the use of supplemental oxygen were significant predictors of falls in this population; and (iii) falls and balance impairments are commonly observed in COPD. Moreover, the results of this work demonstrated that impairments in balance and functional mobility were significantly worse in patients who were prescribed supplementary oxygen compared to those without the requirement for oxygen. These findings highlight the importance of assessing and treating balance in patients with COPD as part of their comprehensive management.
Compared with non-fallers, scores on the BBS and TUG in fallers were 3.5 points lower, and 3.1 seconds longer, respectively, indicative of clinically relevant deficits in measures of balance and functional mobility in patients with COPD who fall.\textsuperscript{95, 100, 103} These deficits are of similar magnitude to previously reported differences in BBS and TUG scores between fallers and non-fallers in other chronic disease populations with established fall risk, such as Parkinson’s and Multiple Sclerosis.\textsuperscript{104, 105} In addition, fallers with COPD in this study achieved mean scores on the BBS and TUG that were consistent with previously established cut-off values\textsuperscript{59, 60, 97} for risk of falls for healthy elderly, however use of these cut-off values for predicting falls in COPD require further validation using prospective studies. Although limited in the COPD literature, there is increasing recognition of balance deficits in this population. Recent work has shown reduced balance and coordination in patients with COPD compared to controls,\textsuperscript{11} as well as acute deficits in static balance following field-based exercise testing.\textsuperscript{12} The current study extends previous observations by considering the frequency of self-reported falls and by using the BBS (a widely used clinical balance tool) to assess functional balance. While current clinical practice guidelines for COPD focus on lower extremity conditioning,\textsuperscript{106} there are no specific recommendations regarding balance training and fall prevention strategies. Recent surveys on pulmonary rehabilitation practices in Canada and in the UK, found that less than 10% of outpatient programs used the TUG for assessing functional mobility.\textsuperscript{107, 108} Given the high observed incidence of falls in COPD, a balance assessment should be part of pulmonary rehabilitation, especially in patients using supplementary oxygen or with low balance confidence.

In this study, oxygen usage both discriminated between fallers and non-fallers, and was a predictor of falls in patients with COPD. Our post-hoc analysis indicated that impairments in
balance and functional mobility, including TUG, were significantly greater in patients who used supplemental oxygen. In contrast, Butcher et al found no differences in TUG between oxygen users and non users, after controlling for FEV₁. The reason for this discordance might relate to the differences in methodologies used to measure TUG between the studies. Specifically, Butcher reported using the fastest of three recorded trials, whereas our investigation utilized the second trial of walking at a “normal walking pace” as outlined by the developers. Further, the current study noted significant between group differences in 6MWD in patients with and without oxygen. As the 6MWD is a surrogate marker for time spent walking during daily life in COPD, it might be that oxygen users were more sedentary, leading to greater impairments in balance. The previous report of an association between oxygen use and low physical activity supports this contention. Other possible explanations for the relationship between falls and oxygen use include decreased motor coordination from cerebral hypoxemia, and the potential physical hazard from ambulatory oxygen equipment.

Balance confidence, or balance self-efficacy, also discriminated fallers from non-fallers and was found to be a predictor of falls in patients with COPD. Fear of falling is increasingly recognized as an important public health concern in older adults with and without a history of falls. The cross-sectional design of our study prevents us from establishing whether impaired balance confidence was a risk factor or a response to a fall. Nevertheless, the ABC scale has merit as a simple assessment tool to identify those patients with COPD at risk of falls. Further, interventions aimed at targeting fear of falls have been shown to be effective in older adults and may be worthwhile in COPD.

Fallers with COPD in this study were characterized by greater functional limitations than non-fallers (MRC 4 versus MRC 3) and lower 6MWD. Although the latter did not reach statistical
significance, the actual difference (49 m 95% CI -124.0 to 25.9) approached the minimal clinically significant change of 54 metres for the 6MWD. As such, the 6MWT may prove useful as a tool to guide fall risk assessment in patients with COPD, however future work is required to determine if a suitable threshold can be determined for predicting falls in these patients. Interestingly, while use of supplemental oxygen distinguished fallers from non-fallers in this study, FEV\textsubscript{1} and DL\textsubscript{CO} did not. These findings suggest that increased fall risk in patients with COPD is more closely related to the disability resulting from the disease rather than the primary impairment in lung function.

In addition to the significant differences in BBS and TUG scores between fallers and non-fallers, individuals with COPD, as a group, exhibited lower BBS and TUG scores (Figure 2-1) relative to age-matched reference values established in older adults functioning independently in the community. In fact, over 35% of our total sample achieved scores below the established cut-offs for risk of falls for the BBS and TUG. These observations are consistent with the report by Butcher and colleagues of impaired balance and coordination in individuals with COPD compared with healthy controls. However, both the current findings and the results by Butcher and colleagues are limited by lack of ability to control for activity levels. It is therefore difficult to determine if the reductions in balance noted in patients with COPD relate to a systemic manifestation of the disease itself or to reduced activity levels as a consequence of progressive lung disease. Future studies are needed in which balance and falls in COPD are considered in light of levels of physical activity.

Certain limitations must be considered when interpreting the results of this study. Our small sample size limits the generalizability of our results to the COPD population and reduces the reliability of our logistic regression. However, the study was powered to detect a three-point
difference in the BBS (power = 0.8). The one-year history of falls described by 46% of our patients was high when referenced against large epidemiological studies reporting retrospective fall incidence between 28 to 35% among community-residing older adults.\textsuperscript{112,113} Larger, prospective studies will yield more precise estimates of fall incidence as they eliminate recall bias which may under-estimate the true incidence.\textsuperscript{114} Nevertheless, the high number of falls in our sample underscores the need to better define this important issue within the context of other risk factors including vision, cognitive function, demographic and environmental factors, medications, physical activity, and muscle strength. In addition, while the primary aim of the current study was to identify factors that characterized fallers in a cohort of patients with COPD, future work would benefit from use of age-matched controls to determine if these factors differ in healthy elderly.

In summary, this study has shown that simple clinical measures of balance can discriminate between fallers and non-fallers with COPD. Patients using supplementary oxygen and those with reduced balance confidence appear to be at particular risk of falling. These findings highlight the importance of an increased risk of falling in COPD and suggest the need for including balance assessment and training, as well as fall prevention strategies within the framework of pulmonary rehabilitation. Future research is warranted to explore the mechanism underlying the observed balance deficits in this population.
3 Effect of pulmonary rehabilitation on balance in persons with COPD


Contributions of the authors: MK Beauchamp developed the research design and protocol, collected and analyzed the data and wrote the manuscript. S O’Hoski assisted with subject recruitment, data collection and reviewed the manuscript. RS Goldstein assisted with the overall supervision of the study, research design, subject recruitment and reviewed the manuscript. D Brooks assisted with the overall supervision of the study, research design, and reviewed the manuscript.
3.1 Abstract

Objectives: To describe the within-subject effects of pulmonary rehabilitation on balance in individuals with chronic obstructive pulmonary disease (COPD) and to determine whether any observed changes in balance were associated with change in exercise tolerance or health-related quality of life.

Design: Single-arm longitudinal study.

Setting: Inpatient pulmonary rehabilitation centre.

Participants: 29 subjects with COPD (mean ± SD; age 69.8 ± 10.3 years; FEV\textsubscript{1} 46.3 ± 22.3% predicted; 59% men or n = 17).

Interventions: A standardized 6-week multidisciplinary pulmonary rehabilitation program (exercise training, breathing exercises, education and psychological support).

Main Outcome Measures: Balance was assessed using the Berg Balance Scale (BBS), Timed Up and Go (TUG) and the Activities-Specific Balance Confidence (ABC) scale. Exercise tolerance was determined from the Six-Minute Walk Test (6MWT) and health-related quality of life from the Chronic Respiratory Questionnaire (CRQ).

Results: Subjects demonstrated small improvements in BBS (2.8 ± 2.8 points; \(P<.001\)) and TUG (-1.5 ± 2.4 seconds; \(P=.003\)) scores, but not in ABC scores (4.8 ± 15.4 points; \(P>.05\)). There was a weak relationship between change in BBS and change in CRQ (\(r = 0.40, P=.045\)) and no relationship with the change in 6MWT.

Conclusions: Pulmonary rehabilitation contributed to minor improvements in balance and had no effect on balance confidence in individuals with COPD. Further work is warranted to determine the optimal intervention for improving balance in this population.
3.2 Introduction

Chronic obstructive pulmonary disease (COPD) is increasingly recognized as a systemic disease associated with a broad array of physical functional limitations. Impairments in peripheral muscle function, mobility and exercise capacity are well established in these patients. However, emerging evidence also suggests that individuals with COPD demonstrate important reductions in balance control which may be associated with an increased fall risk in this population.

Although information regarding postural control in individuals with lung disease is limited, evidence suggests that balance deficits constitute an important secondary impairment in older adults with COPD. Two studies have demonstrated reduced balance performance and coordination in individuals with COPD compared to healthy controls. One study examining the impact of fatigue on physiologic measures of postural sway found that patients with COPD demonstrated impaired static postural control following a six-minute walk test in the absence of visual input (eyes closed condition). In addition, we recently reported that standard clinical balance measures discriminated between fallers and non fallers with COPD, despite the two groups having similar pulmonary function and six-minute walk distances.

The American Geriatrics Society recommends exercise with balance training as an essential component of a multifactorial falls intervention strategy for community dwelling older adults who are at risk of falling. While the exercise component of pulmonary rehabilitation (PR) is considered the cornerstone of rehabilitation for individuals with COPD, it is predominately directed to training peripheral muscles. Balance training and fall prevention strategies are not included in international guidelines for PR and very few programs include any standardized
balance assessment. Although in older adults exercise can improve balance and reduce fall risk, interventions that include exercises to challenge balance have greater effects on fall risk and balance. To date, no study has examined whether the exercise component of standard PR might affect balance, even without targeted training.

Therefore, the objectives of this study were 1) to describe the within-subject effects of conventional PR on balance in individuals with COPD and 2) to determine whether any observed changes in balance were associated with change in exercise tolerance or health-related quality of life.

### 3.3 Methods

#### 3.3.1 Participants

Thirty-eight consecutive patients enrolled in PR were approached for inclusion to the study; five did not meet eligibility criteria and four patients did not complete the 6-week PR program and were therefore excluded. Therefore, 29 older adults with moderate to severe COPD (FEV$_1$ 46.3 ± 22.3% predicted; age 69.8 ± 10.3 yrs) completed the study. Fifty-nine percent of subjects were men (n = 17). Their characteristics are summarized in Table 3-1. Individuals were eligible to participate in this study if they met the following inclusion criteria: (1) physician diagnosis of COPD (FEV$_1$ < 80% predicted and FEV$_1$/FVC < 70% predicted) according to international guidelines; (2) smoking history > 20 pack years and; (3) ability to provide written informed consent. Individuals with co-morbid conditions likely to influence safety or balance were excluded. Specific exclusion criteria comprised: (1) known cognitive impairment; (2)
mechanical ventilation for all or part of the day; (3) neurological or musculoskeletal condition that limited mobility; and (4) symptomatic cardiovascular disease.

3.3.2 Data collection procedures

After study approval by the local Research Ethics Board, consecutive patients enrolled in a 6-week inpatient PR program at West Park Healthcare Centre (Toronto, Canada) between September and December 2009 were approached to attend a pre- and post-rehabilitation assessment session. After obtaining informed consent, measurements of resting lung function, height, weight, and use of supplementary oxygen were retrieved from the patient’s medical chart. Results from assessments of exercise tolerance (Six-Minute Walk Test) and health-related quality of life (Chronic Respiratory Questionnaire) were obtained from the patient’s treating physical therapist. All 5 treating physical therapists had received prior training for administration of the tests according to standardized guidelines. A questionnaire was utilized to establish the number of times each patient had fallen during the preceding 12 months, using the following standard definition: “A fall would be when you find yourself suddenly on the ground, without intending to get there, after you were either in a lying, sitting or standing position.” The Medical Research Council dyspnea scale was used to characterize patients with COPD in terms of their functional limitation resulting from dyspnea. The questionnaire comprises five grades (statements) with higher grades indicating greater perceived respiratory disability; patients are asked to select the statement that best describes their limitation.

Balance testing and questionnaires were administered by the same registered physical therapist (MB) or kinesiologist (SO), in a quiet laboratory setting. At the time of the post-rehabilitation assessment, raters were unaware of the scores of the baseline tests; all data were analyzed only
upon study completion. The order of the tests was standardized for all subjects; balance tests were completed first, followed by questionnaires. If a patient required the use of a gait aid, the same gait aid was used in both assessments. Participants were encouraged to rest as needed throughout the assessment sessions.

3.3.3 Intervention: pulmonary rehabilitation

The PR program consisted of a 6-week inpatient multi-disciplinary program\textsuperscript{119} consistent with clinical practice guidelines put forth by the American College of Chest Physicians.\textsuperscript{1} The rehabilitation program had four main components:

1. Supervised endurance exercise training four to five times a week. After a baseline 6MWT, each patient received an individualized program based on 60-80\% the average speed achieved during the 6MWT (for treadmill exercise or walking), or 60-80\% of the estimation of VO\textsubscript{2} peak from the 6MWT for bicycle training. Training emphasized interval-type exercise; periods of high intensity exercise were alternated with rest periods (i.e., 3 minutes at 80\% VO\textsubscript{2} peak alternated with 2 minutes of relative rest). Exercise duration was progressed until patients were able to tolerate 20-30 minutes of endurance exercise at the highest tolerated symptom level, after which point the speed or intensity was increased by 10-20\%.

2. Lower and upper-extremity strength training three times per week. Muscles trained in the lower extremity included quadriceps, hamstrings, hip flexors, hip abductors and hip extensors. Exercises were completed in sitting and standing with the use of ankle weights for resistance. Upper extremity strength training included biceps, triceps and deltoids using free weights and pectoral muscles using a theraband. The amount of resistance
provided was based on the patient’s ability to complete 15-20 repetitions. Progression included increasing the resistance and the number of sets from 1 set to 2-3 sets as tolerated. During both endurance and resistance training patients were asked to rate their dyspnea and leg fatigue using a visual analogue scale (Borg 0-10) to monitor their exercise intensity.\textsuperscript{120}

3. Breathing exercises daily. Patients received a daily 30-minute class including stretching of major muscle groups and instruction on diaphragmatic and pursed lip breathing.

4. Self management education and psychological and social support were provided through lectures, relaxation classes and recreational activities at least twice a week for 30 minutes.

3.3.4 Measures

The following measures were completed pre- and post-pulmonary rehabilitation.

\textit{Berg Balance Scale (BBS)}

The 14-item BBS\textsuperscript{65} was chosen as the primary outcome in this study as it is the most widely accepted and psychometrically robust clinical measure of balance for older adults.\textsuperscript{121} Activities such as transfers, reaching, turning around and single legged stance were graded on a scale ranging from 0 (unable/unsafe) to 4 (independent/efficient/safe), with higher scores indicating greater balance control. The measurement derived using the BBS has demonstrated internal consistency, intra-rater and inter-rater reliability, content validity, construct validity and predictive validity for determining fall risk in older adults.\textsuperscript{95} A cut-off score of 46 and below has
been identified as a useful score to successfully identify those at risk of falling.\textsuperscript{59, 60} A change of 3.3 (or $\geq$ 4 points) has been suggested to represent a minimal detectable change in elderly patients with baseline BBS scores of 45-56 points.\textsuperscript{100} Minimal detectable change scores for individuals with lower baseline BBS scores range between 5-6 points for community-dwelling older adults.\textsuperscript{100}

\textit{Timed up and Go (TUG)}

The TUG was used to provide a timed measure of balance and functional mobility in our patients.\textsuperscript{96} The test requires the patient to rise from a standard armchair, walk 3 meters at a comfortable pace, walk back to the chair, and sit down. A practice trial was performed (not recorded) and individuals were permitted to use a gait aid if required. The TUG has high intra- and inter-tester reliability and predictive validity for falls in community-living adults.\textsuperscript{95, 96} A cut-off score of 16 seconds or more has been shown to predict falls in community-dwelling elderly.\textsuperscript{97} Reported minimal detectable change scores range from 4 seconds in patients with Alzheimer’s\textsuperscript{122} to as high as 15 seconds in frail elderly patients.\textsuperscript{123}

\textit{Activities-specific Balance Confidence (ABC) Scale}

The ABC scale requires patients to indicate their confidence in performing 16 activities without losing their balance or becoming unsteady on an 11-point scale (0 to 100\%).\textsuperscript{63} Each item describes a specific activity that requires progressively increased balance control. Greater scores indicate higher balance confidence or less fear of falling. The ABC scale has good test-retest reliability, internal consistency and predictive capacity for falls in older adults that reside in the community.\textsuperscript{63, 95} A change of 13\% has been shown to reflect a minimal detectable change for this measure.\textsuperscript{124}
**Six-Minute Walk Test (6MWT)**

The 6MWT is a valid responsive, interpretable self-paced test that quantifies functional exercise capacity in terms of the distance walked in six minutes in patients with COPD.\textsuperscript{125} The test was supervised by a physical therapist over a 30 meter level straight course within an enclosed corridor according to the protocol described by the American Thoracic Society.\textsuperscript{99} During each 6MWT, patients received standardized instructions and encouragement. Two tests were performed to account for possible improvements resulting from familiarization, with the greatest distance recorded. Each 6MWT was separated by a minimum of 30 minutes. The measurement properties of this test are well established in the COPD population.\textsuperscript{99, 126} The minimal clinically important difference for the 6MWT is 54 metres.\textsuperscript{102}

**Chronic Respiratory Questionnaire (CRQ)**

Health-related quality of life was measured using the individualized version of the CRQ.\textsuperscript{127} The CRQ is a disease-specific instrument evaluating four domains that are considered important to individuals with chronic airflow limitation. Subjects are required to quantify events and experiences that have taken place over the two-week period preceding the administration of the questionnaire. It includes twenty questions in four domains: dyspnea, fatigue, emotional function and mastery. The dyspnea domain is “individualized” by allowing patients to choose five activities that cause the greatest shortness of breath. The subject rates dyspnea on these self-selected activities during subsequent administrations of the CRQ. Answers are scored on a seven-point scale ranging from 1 (maximum impairment) to 7 (no impairment). The minimal clinically important difference for the CRQ is a change (improvement or deterioration) of 0.5.\textsuperscript{128} The CRQ is valid, responsive and interpretable when used among patients with COPD.\textsuperscript{127-129}
3.3.5 Statistical analysis

Statistical analyses were performed using SPSS® (Statistical Package for Social Sciences, version 16.0 for Windows). It was determined that 28 patients were required to yield 80% power ($\alpha = .05$) to detect a difference of 3 points or more in the BBS using a paired t-test and a standard deviation of 5.4. The assumption of normality was assessed by frequency histograms and box plots as well as statistical methods (Shapiro-Wilks test). The occurrence of heteroscedasticity (i.e., when the measurement error is dependent on the size of the measurement) was investigated graphically by plotting each individual’s absolute difference in balance scores against his or her mean and by calculating the correlation coefficient. For all analyses $P$ values $\leq .05$ were considered significant. Variables pre- and post-pulmonary rehabilitation were compared using paired t-tests for normally distributed data and the Wilcoxon signed-rank test for ordinal data. However, because the statistical findings were similar for non-parametric and parametric tests and the data were normally distributed, we report the results of the paired t-tests and associated mean difference and 95% confidence intervals for each measure. Change in balance on the BBS was compared to previously reported minimal detectable change scores for this measure using a simple scatter plot. Pearson correlations were conducted to examine the relationship between 1) change in balance and baseline BBS scores and 2) change in balance (BBS and TUG) and response to pulmonary rehabilitation (change in 6MWT and CRQ scores). Data are expressed as mean ± standard deviation unless otherwise stated.
3.4 Results

3.4.1 Subjects

Of the 29 patients who completed the study, twelve (41%) patients reported at least one fall in the preceding year (Table 3-1). Eight (67%) of the 12 fallers had a score ≤ the 46 point cut-off for risk of falls on the BBS; six fallers (50%) had a score ≥ the 16 second cut-off for the TUG. Overall, 11 patients (38%) achieved a score ≤ the 46 point cut-off for risk of falls on the BBS and a score ≥ the 16 second cut-off for the TUG.

Table 3-1: Baseline demographic and functional data of the study participants (n = 29)

<table>
<thead>
<tr>
<th>Variable</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men/Women (n)</td>
<td>17/12</td>
</tr>
<tr>
<td>Supplemental oxygen (n, %)</td>
<td>13, 45%</td>
</tr>
<tr>
<td>Age (yrs)</td>
<td>69.8 ± 10.3</td>
</tr>
<tr>
<td>Body mass index (kg/m²)</td>
<td>29.2 ± 7.8</td>
</tr>
<tr>
<td>FEV₁ (L)</td>
<td>1.2 ± 0.7</td>
</tr>
<tr>
<td>FEV₁ (% predicted)</td>
<td>46.3 ± 22.3</td>
</tr>
<tr>
<td>MRC dyspnea scale</td>
<td>median 3, IQR 3</td>
</tr>
<tr>
<td>6MWT distance (m)</td>
<td>295.4 ± 92.1</td>
</tr>
<tr>
<td>Gait aid use- rollator (n, %)</td>
<td>8, 28%</td>
</tr>
<tr>
<td>BBS score</td>
<td>46.9 ± 7.0</td>
</tr>
<tr>
<td>TUG score (sec)</td>
<td>15.7 ± 5.3</td>
</tr>
<tr>
<td>ABC scale</td>
<td>74.3 ± 17.0</td>
</tr>
<tr>
<td>Fall history (n, %)</td>
<td>12, 41%</td>
</tr>
</tbody>
</table>

Note. Values are mean ± SD unless otherwise indicated.

Abbreviations: FEV₁, forced expiratory volume in one second; MRC, Medical Research Council; IQR, inter-quartile range; 6MWT, Six-minute walk test; BBS, Berg Balance Scale; TUG, Timed Up and Go; ABC, Activities-specific Balance Confidence.
3.4.2 Pulmonary rehabilitation outcomes

Statistically significant improvements were found for 6MWD (mean change 52 m, \( P < .001 \)), the CRQ dyspnea domain (mean change 1.5 units, \( P < .001 \)) and total CRQ scores (mean change 1.4 units, \( P < .001 \)) (Table 3-2).

**Table 3-2:** Effect of pulmonary rehabilitation on balance, exercise tolerance and health-related quality of life.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Pre-rehabilitation</th>
<th>Post-rehabilitation</th>
<th>Mean change</th>
<th>95% Confidence interval</th>
</tr>
</thead>
<tbody>
<tr>
<td>BBS score</td>
<td>46.9 ± 7.0</td>
<td>49.6 ± 5.7</td>
<td>2.8 ± 2.8</td>
<td>1.7 to 3.8</td>
</tr>
<tr>
<td>TUG score (sec)</td>
<td>15.7 ± 5.3</td>
<td>14.2 ± 4.5</td>
<td>-1.5 ± 2.4</td>
<td>-2.4 to -0.5</td>
</tr>
<tr>
<td>ABC scale</td>
<td>74.3 ± 17.0</td>
<td>79.1 ± 16.0</td>
<td>4.8 ± 15.4</td>
<td>-1.0 to 10.7</td>
</tr>
<tr>
<td>6MWT distance(^*) (m)</td>
<td>303.4 ± 84.2</td>
<td>355.8 ± 92.0</td>
<td>52.5 ± 54.0</td>
<td>31.1 to 73.9</td>
</tr>
<tr>
<td>CRQ-dyspnea(^*)</td>
<td>3.0 ± 1.1</td>
<td>4.6 ± 1.3</td>
<td>1.5 ± 1.4</td>
<td>1.0 to 2.1</td>
</tr>
<tr>
<td>CRQ-total(^*)</td>
<td>3.8 ± 1.0</td>
<td>5.2 ± 0.9</td>
<td>1.4 ± 1.0</td>
<td>1.0 to 1.8</td>
</tr>
</tbody>
</table>

Note. Values are mean ± SD. Mean change and 95% confidence intervals associated with paired \( t \)-tests are given for each measure.

Abbreviations: 6MWT, Six-minute walk test; BBS, Berg Balance Scale; TUG, Timed Up and Go; ABC, Activities-specific Balance Confidence; CRQ, Chronic Respiratory Questionnaire.

\(^*\) 6MWT and CRQ data are reported for \( n = 27 \) patients for whom complete data pre- and post-rehabilitation were available

3.4.3 Effect of pulmonary rehabilitation on balance

A comparison of measures of clinical balance and balance confidence pre- and post-PR is provided in Table 3-2. While there was no significant improvement in balance confidence, performance on the BBS and TUG showed small but significant improvements following rehabilitation (mean change 2.8 points, \( P < .001 \); mean change -1.5 sec, \( P = .003 \), respectively). In order to facilitate an understanding of the clinical importance of these changes, a plot of each individual’s absolute difference in BBS scores against his or her mean with minimal detectable
change thresholds is provided in Figure 3-1. No heteroscedasticity was found either graphically (see Figure 3-1) or statistically ($P>.09$). There was a moderate correlation between baseline BBS scores and change in balance ($r=-.60$, $P=.001$).

![Figure 3-1](image)

**Figure 3-1:** The differences between pre- and post-rehabilitation Berg Balance Scale (BBS) scores plotted against their mean with minimal detectable change thresholds with 95% confidence (MDC$_{95}$) for participants with a) baseline scores of 45-56 points ($n = 18$) and b) baseline scores of 35-44 points ($n = 9$). MDC$_{95}$ values from Donoghue et al.$^{25}$ Also note that no heteroscedasticity was found either graphically or statistically ($P>.09$).
3.4.4 Relationship between change in balance and response to pulmonary rehabilitation

There were no relationships between change in balance and change in 6MWD or CRQ dyspnea scores. However, there was a weak relationship between change in BBS scores and change in overall CRQ scores ($r=.40$, $P=.05$).

3.5 Discussion

Although reductions in balance constitute an important secondary impairment in patients with COPD, to our knowledge, this is the first study to report the effects of PR on measures of balance and fall risk in this population. While measures of balance showed modest improvements following rehabilitation, the clinical relevance of these improvements is uncertain. In addition, balance confidence, an increasingly measured and targeted construct in fall prevention programs, did not improve after PR. These observations highlight the need for both assessing balance and fall risk in patients with COPD and evaluating the addition of balance training as part of PR.

The small changes on the BBS and TUG (2.8 points and 1.5 seconds, respectively) achieved by our patients are difficult to interpret in the absence of published minimal clinically important difference (MCID) values. However, minimal detectable change (MDC) scores have been reported for these measures among community-dwelling older adults and in other populations with balance impairment.100, 122, 124 The MDC is an estimate of the smallest change in score that is not due to chance variation in measurement. It differs from the MCID, which is the smallest change considered important by a client or clinician, and thus introduces an element of
subjectivity. A recent investigation of elderly patients undergoing general physical rehabilitation found that the MDC for BBS scores depended on the patient’s starting score.\textsuperscript{100} For example, for individuals with starting scores between 45 and 56 points on the BBS, an improvement of 4 points is required to be 95\% confident that the change was greater than measurement error; for individuals with a baseline BBS between 35-44 points, the MDC is 5 points. In our sample, only 11 patients (38\%) achieved an MDC based on their starting BBS score (Figure 3-1), and the change in TUG scores also did not approach the reported MDC values for this measure.\textsuperscript{122, 124} Therefore, less than half the sample achieved improvements in balance scores that could not be attributable to measurement error. Given that balance confidence also remained unchanged following PR, it is very likely that for most patients PR did not have a meaningful impact on balance or fall risk.

In older adults, fear of falling is associated with an increased risk of falling, restriction of physical activities and a progressive loss of health-related quality of life.\textsuperscript{35-37} A recent study in individuals with COPD demonstrated that fear of falling is a pervasive problem associated with increased levels of anxiety and activity avoidance.\textsuperscript{132} This is of particular concern, given the importance of promoting physical activity in patients with COPD.\textsuperscript{133} In the current study, PR did not have an effect on fear of falling as measured by the ABC scale. In light of the detrimental effects of fear of falling on physical function, interventions to target balance confidence are warranted in individuals with COPD.

Our observed baseline scores for measures of balance performance indicated that more than one in three subjects met the cut-off for an increased risk of falls, with 41\% of our sample reporting at least one fall in the preceding year. Risk factors for falls in COPD include lower limb muscle weakness, impaired activities of daily living and balance deficits.\textsuperscript{89} While current guidelines for
PR recommend progressive resistance exercise for improving peripheral muscle strength in patients with COPD,\textsuperscript{1} recent evidence suggests that strength training may also improve daily task performance, such as stair climbing and sit-to-stand in these individuals.\textsuperscript{134} This highlights the potential role of resistance exercise for improving balance and decreasing fall risk in this population. The relationship between muscle weakness and postural instability is well established in older adults;\textsuperscript{83} it is likely that the small improvements in balance observed in this study were due to the strength training component of PR, albeit of low-intensity. However, higher-intensity strength training (8-10 reps, 2-3 sets) combined with targeted balance training are likely required for exercise programs to have optimal effects on fall risk reduction and balance control.\textsuperscript{86, 118} Given the range of potential sub-components that contribute to poor balance, the specific impairments which contribute to altered postural control need to be addressed.

In this study the improvements in 6MWT and CRQ scores following PR were similar to results reported in a meta-analysis of PR.\textsuperscript{30} This suggests that the small changes in balance scores were not attributable to an ineffective PR program, but more likely to the lack of specific exercises targeted to improve balance control. Changes in BBS scores were only weakly correlated with improvements in CRQ and not associated with improvements in 6MWT distance. These results also underscore the importance of using standardized clinical measures for assessing and monitoring changes in balance among individuals with COPD.

This was a single-arm longitudinal study, and while the within-subject comparisons are an obvious limitation, withholding rehabilitation for control purposes is no longer an option for patients referred for this intervention. Moreover, given that the measured changes were small and unlikely to be of clinical relevance, the absence of a control group does not detract from the
validity of these observations. We did not target participants with a high fall risk or with impaired baseline balance scores and therefore a possible ceiling effect on the BBS may have contributed to the lack of improvement following PR. However, since only four patients achieved a perfect starting score this is unlikely to be the case. In addition, the negative correlation between baseline scores and change in BBS only explained 36% of the variance in this result. In future work, longer follow-up and inclusion of other measures such as lower extremity strength will be necessary to understand changes in balance resulting from rehabilitation interventions.

3.6 Conclusions

In summary, PR was associated with minor changes in standard clinical tests of balance and had no effect on balance confidence in patients with COPD. Measures of exercise tolerance and health-related quality of life cannot be used as surrogate measures to derive balance information. These observations underscore the value of including a balance assessment of patients with moderate and severe COPD, particularly if they have a history of falling. The role of incorporating specific balance training and fall prevention strategies within the framework of PR in order to minimize disability in this population needs to be explored.
4 Impairments in systems underlying control of balance in COPD


Contributions of the authors: MK Beauchamp developed the research design and protocol, collected and analyzed the data and wrote the manuscript. K Sibley contributed to the research design and protocol, assisted with data collection and data cleaning (laboratory measures) and reviewed the manuscript. B Lakhani contributed to the protocol, assisted with data collection and data cleaning (laboratory measures) and reviewed the manuscript. J Romano assisted with subject recruitment, data collection and data cleaning (clinical measures), and reviewed the manuscript. S Mathur contributed to the research protocol, data analysis, and reviewed the manuscript. RS Goldstein assisted with the overall supervision of the study, research design, subject recruitment and reviewed the manuscript. D Brooks assisted with the overall supervision of the study, research design, and reviewed the manuscript.
4.1 Abstract

**Background:** Although balance deficits are increasingly recognized in chronic obstructive pulmonary disease (COPD), little is known regarding the disordered subcomponents underlying control of balance. We aimed to determine the specific components of balance that are impaired in COPD and to investigate the association between balance and peripheral muscle strength and physical activity.

**Methods:** Balance, physical activity and lower extremity muscle strength were assessed in 37 patients with COPD and 20 age-matched healthy controls using the Balance Evaluation Systems Test (BESTest), the Physical Activity Scale for the Elderly (PASE), and an isokinetic dynamometer, respectively. A subset of subjects (20 COPD and 20 controls) underwent a second testing session in which postural perturbations were delivered using a lean-and-release system.

**Results:** Subjects with COPD (age 71 ± 7 yrs; FEV$_1$ 39 ± 16 percent predicted) exhibited significantly lower scores than controls (age 67 ± 9 yrs) on all of the BESTest subscales (all $p < 0.001$). In response to anterior perturbations, subjects with COPD showed a longer time to foot-off ($p = 0.027$), foot-contact ($p = 0.018$), and a longer duration anticipatory phase ($p = 0.008$) compared to controls. Muscle strength ($p = 0.008$) and self-reported physical activity ($p = 0.033$) explained 35% of the variance in balance in subjects with COPD.

**Conclusions:** Individuals with COPD exhibit impairments in all balance subcomponents and demonstrate slower reaction times in response to perturbations. Deficits in balance are associated with reduced physical activity levels and skeletal muscle weakness.
4.2 Introduction

Falls are a leading public health problem in older adults. One in three adults over the age of 65 fall each year\textsuperscript{16, 38, 135} and 20-30\% will suffer moderate to severe injuries that increase their risk of morbidity and mortality.\textsuperscript{34} In the US, the total direct cost of all fall-related injuries is $23.3 billion dollars per year and is expected to reach $54.9 billion by 2020.\textsuperscript{136, 137} A recent prospective study has estimated the incidence of falls in COPD to be 1.2 per person-year\textsuperscript{138} - more than four times the incidence reported in the elderly.\textsuperscript{20} Balance impairment is a major risk factor for falls,\textsuperscript{16, 38} and in particular, the ability to generate a successful postural reaction following a loss of balance determines whether or not an individual will fall.\textsuperscript{139} Indeed, a number of studies suggest that deficits in balance are common in individuals with COPD.\textsuperscript{11, 13, 14, 117} Given the importance of fall prevention, an improved understanding of COPD-related detriments in balance is necessary to guide the development of interventions for this population.

Successful maintenance of balance, or postural control, is a complex skill that requires the integration and coordination of musculoskeletal (i.e., biomechanics, range of motion, flexibility) and neural systems (i.e., motor, sensory and higher-level pre-motor processes) which must be constantly adapted under an array of situations in daily life.\textsuperscript{42, 43} Although some elements of abnormal balance have been identified from clinical and laboratory measures in individuals with varying degrees of COPD severity,\textsuperscript{11, 13, 14, 117} a comprehensive assessment of the systems responsible for these deficits is lacking. Moreover, there is a need to determine the contribution of physical activity and/or peripheral muscle strength to the observed balance deficits in these patients.
The purpose of this study was to use a systems approach to balance assessment to identify the disordered subcomponents underlying control of balance in COPD. Specifically, the two main objectives were to: 1) determine the specific components of postural control that are impaired in individuals with COPD compared to age-matched healthy controls; and 2) determine if deficits in balance in COPD are associated with lower extremity muscle strength or physical activity. We hypothesized that subjects with COPD would demonstrate impaired balance in subsystems most reliant on skeletal muscular strength, and that lower extremity muscle strength and physical activity would be associated with balance.

4.3 Methods

4.3.1 Subjects

We studied 37 individuals with COPD who met the following criteria: diagnosis of COPD according to international guidelines;\textsuperscript{92} smoking history greater than 10 pack years; and ability to provide written informed consent. Exclusion criteria comprised: an inability to communicate; use of medications that might increase risk of falls; neurological or musculoskeletal conditions that limit mobility. In addition, 20 healthy age- and sex-matched controls with normal spirometry (\text{FEV}_1 \geq 80\% \text{ predicted}, \text{FEV}_1/\text{FVC} \geq 0.7) and absence of any health problems that might impair mobility or postural control were recruited from notices posted in community recreation facilities.

4.3.2 Study design

A controlled, cross-sectional study design was used. All subjects underwent a clinical balance performance battery and tests of lower-extremity muscle strength. Pulmonary function results
were retrieved from the clinical record of those with COPD and obtained through simple spirometry in healthy subjects. A subset of subjects (20 COPD and 20 controls) underwent a second testing session in which anterior postural perturbations were delivered using a lean-and-release system and centre of pressure data and muscle onset latencies were recorded with force plates and electromyography, respectively. The protocol was approved by the Joint Bridgepoint/West Park/Toronto Central CCAC Research Ethics Board and the Toronto Rehabilitation Institute Research Ethics Board (#10-001).

4.3.3 Clinical balance measures

Clinical balance tests included the Balance Evaluation Systems Test (BESTest) and the Berg Balance Scale (BBS). A single examiner (MB) completed all evaluations with assistance of a second investigator (JR) as needed for safety during high-level tasks. The BESTest is a 36-item comprehensive clinical balance assessment tool that evaluates 6 subsystems of balance control: 1) biomechanical constraints, 2) postural limits of stability, 3) anticipatory postural adjustments, 4) reactive postural responses, 5) sensory orientation during stance, and 6) dynamic stability during gait, as well as providing an overall balance score (see Table 4-1 for a complete description of the subsystems). Each item is graded on a 4-level ordinal scale from 0 (unable to perform) to 3 (normal performance) as judged by time or performance criteria. Each subsystem category comprises 20% of the total balance score; the BESTest total score is a sum of all the individual items with a maximum of 100 (higher numbers indicate better balance). The test requires minimal equipment and averages approximately 30 minutes to complete. The BESTest has excellent inter-rater reliability and validity, relates to patient’s balance confidence and allows identification of the most affected set of balance deficits.\textsuperscript{62} The 14-item BBS\textsuperscript{140} is a psychometrically robust clinical measure of balance for older adults,\textsuperscript{95,121} in which activities
such as transfers, reaching, turning around and single legged stance are graded on a scale ranging from 0 (unable/unsafe) to 4 (independent/efficient/safe); a perfect score is 56. The BBS requires minimal equipment and can be completed in less than 15 minutes.

**Table 4-1**: Description of subcomponents and outline of items from the Balance Evaluation Systems Test

<table>
<thead>
<tr>
<th>Subcomponent</th>
<th>Description</th>
<th>Items (numbers)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Biomechanical Constraints</td>
<td>Evaluates constraints on standing balance including strength, ROM and posture</td>
<td>Quality of BOS, COM alignment, ankle strength &amp; ROM, hip strength, sit on floor and stand up (1-5)</td>
</tr>
<tr>
<td>2. Stability Limits/Verticity</td>
<td>Includes items for an internal representation of how far the body can move over its BOS, as well as an internal perception of verticality</td>
<td>Verticality and lateral leans, forward and lateral reach (6-8)</td>
</tr>
<tr>
<td>3. Anticipatory Adjustments/Transitions</td>
<td>Includes tasks that require active movement of the body’s COM in anticipation of a transition from one body position to another</td>
<td>Sit to stand, rise to toes, one-legged stance, stair task, standing arm raise (9-13)</td>
</tr>
<tr>
<td>4. Postural Responses</td>
<td>Includes both in-place and compensatory stepping responses to an external perturbation induced by the examiner’s hands</td>
<td>In-place, forward, backward and lateral “push and release” (14-18)</td>
</tr>
<tr>
<td>5. Sensory Orientation</td>
<td>Identifies any increase in postural sway during stance associated with altering visual or somatosensory information</td>
<td>Stance on firm surface and foam surface with eyes open and closed, stance on incline with eyes closed (19-20)</td>
</tr>
<tr>
<td>6. Stability in Gait</td>
<td>Evaluation of stability during walking when balance is challenged</td>
<td>Usual gait speed, change in gait speed, walk with head turns, step over obstacle, TUG, TUG with dual task (21-27)</td>
</tr>
</tbody>
</table>

*Definition of abbreviations:* COM = centre of mass; BOS = base of support; ROM = range of motion; TUG = Timed Up and Go

Balance confidence was assessed with the 16-item Activity-specific Balance Confidence (ABC). Each item describes a specific activity that requires varying difficulties of balance
control. Subjects are asked to indicate their confidence in performing various activities without becoming unsteady. Fall history was determined using a standard definition of a fall: “A fall would be when you find yourself suddenly on the ground, without intending to get there, after you were either in a lying, sitting or standing position.”

4.3.4 Self-reported physical activity

Physical activity was estimated using the Physical Activity Scale for the Elderly (PASE), a valid 12-item self-administered questionnaire of physical activity (0 – 400) that correlates with activity levels measured by accelerometers.

4.3.5 Lower extremity muscle strength

Maximal voluntary isometric contractions were performed in the self-reported dominant limb for the knee extensors/flexors and ankle plantar/dorsi flexor muscle groups, using a Biodex System 4 Dynamometer (Biodex Medical Systems, Inc., 20 Ramsay Road, Shirley, NY 11967, USA). Knee extensor/flexor testing was performed with subjects seated with the hip at 85° and knee flexed to 60°. The axis of rotation of the dynamometer was aligned with the axis of the knee joint and the lever arm secured against the anterior aspect of the leg, proximal to the lateral malleolus. Testing of the plantar/dorsi flexor muscle group was performed with the hips flexed at 85°, the knee flexed at ~ 10° and the ankle joint in neutral. The lateral malleolus was aligned with the axis of the dynamometer, and the foot was secured to the footplate with straps placed over the forefoot and ankle. Proximal stabilization was achieved with straps across the chest, hips and thigh. The torque and position data were analyzed with commercially available software (AcqKnowledge 3.7.1, Biopac Systems Inc.). For each muscle group tested, a warm-up
contraction performed at ~50-75% of perceived maximum effort was followed by 4 maximal efforts (5 seconds each) to obtain peak torque. A one-minute rest was given between trials to minimize fatigue. The highest torque achieved among the 4 maximal trials was used as the peak torque.

To account for the effect of body size on muscle strength, allometric scaling was used according to the following formula: normalised strength = \( \frac{S}{BM^b} \) where S is the absolute strength, BM is body mass, and b is the allometric power exponent that removes the influence of BM. This method is widely regarded as the most appropriate method for scaling of strength to body size. Because muscle strength was recorded as a torque measurement, an allometric exponent of 1 was deemed suitable for this study (see Jaric for arithmetic calculation).

4.3.6 Perturbation-evoked reactions

Compensatory reactions were evoked using a lean-and-release system described in detail elsewhere. Subjects wore a harness with a cable attached posteriorly and were instructed to lean forward from a standardized stance position so that their body weight was supported by the cable. Subjects were encouraged to lean forward with a force of approximately 10\% of their body weight supported by the cable and were given verbal feedback regarding their lean force. Subjects were informed to “respond as safely as possible to maintain balance including taking a step if necessary” in the event of a perturbation. Five perturbation trials were completed with 10-30 second rests between each trial.

Two force plates (50cmX25cm wide; Advanced Medical Technology Inc., Watertown, MA, USA) were mounted in parallel within the platform and third force plate (51cmX46cm; Advanced Medical Technology Inc., Watertown, MA, USA) was located in front of the subject.
to capture footfall. An in-line load cell was fixed within the release cable and recorded the participants’ lean force and provided indication of perturbation onset time. Surface electromyography (EMG) was recorded bilaterally from the medial gastrocnemius (MG) and tibialis anterior (TA). EMG signals were pre-amplified at a gain of 500 and then amplified by 1000 and stored for offline analysis. EMG electrode sites were cleaned with alcohol and abrasive cream and silver/silver chloride electrodes were fixed 1cm apart over each muscle belly. EMG signals were digitally filtered from 20-250Hz (2nd order dual pass Butterworth) and conditioned by removing any DC offset bias and by full wave rectifying the signal. EMG onset latency was defined as the time when the EMG amplitude exceeded five standard deviations of the mean of a 100ms baseline value taken prior to perturbation onset. Individual trial data was averaged for each subject for statistical comparison. Force plate, EMG and load signals were sampled at 1000 Hz.

An anticipatory postural adjustment (APA) was defined as the time when the medio-lateral centre of pressure (ML COP) deviated by 4mm from the pre-perturbation mean ML COP towards the swing limb (calculated for the 200ms prior to the perturbation).50 If present, APA duration was determined as the time between APA onset and the time at which the MLCOP was equal to the MLCOP at APA onset. APA magnitude was the area under the MLCOP curve for the duration of the APA. Foot-off time was the time from perturbation onset at which the vertical load on one force plate was less than 1% of body weight and was expressed relative to perturbation-onset time (i.e., when the load on the load cell was < 2% of body weight). Foot-contact time represents the difference in time between perturbation onset and foot-contact time of the leading limb in the event of a stepping response. Swing time was the foot off time
subtracted from the time that the first foot made contact on the anterior force plate (i.e., > than 2% of body weight).

### 4.3.7 Statistical Analysis

Statistical analyses were performed using SPSS® (Statistical Package for Social Sciences, version 19.0 for Windows). It was determined that a sample size of 20 subjects per group would be required to yield 80% power ($\alpha = 0.05$) to detect a difference of 4 points on the BBS between COPD and controls.$^{100,117}$ In addition a sample of > 30 subjects with COPD was required for multivariate regression with three predictor variables.$^{149}$ The assumption of normality was assessed by graphical and statistical methods. For all analyses an alpha ($p$) value $\leq 0.05$ was considered significant. Independent samples t-tests were used to determine between group differences for continuous variables and chi-squared tests for categorical variables. Pearson’s correlations were used to determine the relationship between 1) physical activity and balance scores and 2) muscle strength and balance scores, in subjects with COPD.

Hierarchical multivariate linear regression was performed using the BESTest total score as the dependant variable and physical activity and muscle strength as predictors. In the first step, age was included in the model independent of statistical significance. In the second step, physical activity and normalised peak torque of the muscle group with the strongest correlation to balance were included in the model.

### 4.4 Results

Subject characteristics are given in Table 4-2. Compared with the healthy control group, the COPD group showed significant expiratory airflow limitation consistent with GOLD stage III
The healthy control subjects had normal spirometry and were well matched for age and sex.

Table 4-2: Subject characteristics for COPD (n = 37) and controls (n = 20)

<table>
<thead>
<tr>
<th>Variable</th>
<th>COPD</th>
<th>Controls</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>71 ± 7</td>
<td>67 ± 9</td>
<td>NS</td>
</tr>
<tr>
<td>BMI</td>
<td>28.9 ± 10.5</td>
<td>24.8 ± 3.4</td>
<td>NS</td>
</tr>
<tr>
<td>FEV₁ percent predicted</td>
<td>39.4 ± 16.3</td>
<td>96.9 ± 15.9</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>FEV₁/FVC percent predicted</td>
<td>40.5 ± 15.1</td>
<td>83.8 ± 10.9</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>No of men, %</td>
<td>17, 46%</td>
<td>8, 40%</td>
<td>NS</td>
</tr>
<tr>
<td>MRC dyspnea</td>
<td>3.3 ± 1</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>No with fall history, %</td>
<td>19, 51%</td>
<td>7, 35%</td>
<td>NS</td>
</tr>
<tr>
<td>No on oxygen, %</td>
<td>13, 35%</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

Definition of abbreviations: BMI = body mass index; FEV₁ = forced expiratory volume in one second; FVC = forced vital capacity; MRC = Medical Research Council.

Results from the clinical balance tests, strength and physical activity measures are shown in Table 4-3. Subjects with COPD demonstrated reduced balance scores on each component of the BESTest with marked deficits (> 30% reduction) in biomechanics, transitions and gait (Figure 4-1). Lower BBS, balance confidence scores and physical activity levels were also evident in subjects with COPD compared to controls (p’s < 0.001). Normalised peak torque for the knee extensors, flexors and ankle plantarflexors and dorsiflexors were reduced in subjects with COPD compared to controls (p’s ≤ 0.002).
**Table 4-3:** Balance, strength and physical activity measures in subjects with COPD (n = 37) compared to controls (n = 20)

<table>
<thead>
<tr>
<th>Variable</th>
<th>COPD</th>
<th>Controls</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BESTest total (%)</td>
<td>70.7 ± 11.3</td>
<td>91.9 ± 4.0</td>
<td>21.3</td>
<td>17.1 to 25.4</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>BBS</td>
<td>48.7 ± 5.7</td>
<td>54.9 ± 1.8</td>
<td>6.2</td>
<td>4.1 to 8.2</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>ABC</td>
<td>75.8 ± 17.9</td>
<td>95.8 ± 4.7</td>
<td>20.0</td>
<td>13.7 to 26.3</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>PASE</td>
<td>95.9 ± 67.8</td>
<td>185.4 ± 91.8</td>
<td>89.5</td>
<td>46.7 to 132.3</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>*KE peak torque (Nm/kg)</td>
<td>1.29 ± 0.44</td>
<td>1.74 ± 0.40</td>
<td>0.44</td>
<td>0.20 to 0.68</td>
<td>0.001</td>
</tr>
<tr>
<td>*KF peak torque (Nm/kg)</td>
<td>0.71 ± 0.25</td>
<td>1.04 ± 0.24</td>
<td>0.33</td>
<td>0.20 to 0.47</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>*PF peak torque (Nm/kg)</td>
<td>0.97 ± 0.34</td>
<td>1.34 ± 0.48</td>
<td>0.37</td>
<td>0.14 to 0.59</td>
<td>0.002</td>
</tr>
<tr>
<td>*DF peak torque (Nm/kg)</td>
<td>0.32 ± 0.11</td>
<td>0.46 ± 0.12</td>
<td>0.14</td>
<td>0.07 to 0.21</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

*Definition of abbreviations:* BESTest = Balance Evaluation Systems Test; BBS = Berg Balance Scale; ABC = Activities-Specific Balance Confidence Scale; PASE = physical activity scale for the elderly; KE = knee extensors; KF = knee flexors; PF = ankle plantarflexors; DF = ankle dorsiflexors. * Values are normalised peak torque.
Figure 4-1: Scores on each of the components of the Balance Evaluation Systems Test in subjects with COPD (dots) vs. controls (crosses). All comparisons were significant at p < 0.001.

Characteristics of compensatory stepping responses evoked by anterior perturbations in subjects with COPD (n = 20, age 71 ± 8 yrs, FEV$_1$ 44.0 ± 19.5 % predicted) compared to controls (n = 20, age 67 ± 9 yrs, FEV$_1$ 96.9 ± 15.9 % predicted) are shown in Table 4-4. Subjects with COPD showed a longer time to foot-off (p = 0.027) and foot-contact (p = 0.018) relative to perturbation onset. In the COPD group, physical assistance from the assessor was required in 12 trials compared to 2 trials for controls. There was no difference between groups in the frequency of anticipatory postural adjustments (APAs), however subjects with COPD exhibited a longer APA duration (p = 0.008) compared to controls. Analysis of EMG data did not reveal any differences in muscle onset latencies between the two groups except for a faster right TA onset in COPD compared to controls (97.2 ms vs. 108.9 ms, p = 0.022).
Table 4-4: Compensatory stepping responses evoked by anterior perturbations in subjects with COPD (n = 20) compared to controls (n = 20)

<table>
<thead>
<tr>
<th>Variable</th>
<th>COPD</th>
<th>Controls</th>
<th>Mean difference</th>
<th>95% CI</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot off time (ms)</td>
<td>372 ± 78</td>
<td>323 ± 51</td>
<td>49</td>
<td>6 to 91</td>
<td>0.027</td>
</tr>
<tr>
<td>Foot contact time (ms)</td>
<td>500 ± 89</td>
<td>434 ± 77</td>
<td>66</td>
<td>12 to 120</td>
<td>0.018</td>
</tr>
<tr>
<td>Swing time (ms)</td>
<td>128 ± 28</td>
<td>111 ± 32</td>
<td>18</td>
<td>-2 to 37</td>
<td>0.076</td>
</tr>
<tr>
<td>APA duration (ms)</td>
<td>192 ± 52</td>
<td>146 ± 45</td>
<td>46</td>
<td>13 to 79</td>
<td>0.008</td>
</tr>
<tr>
<td>Integrated APA size (mm.ms)</td>
<td>339 ± 253</td>
<td>252 ± 154</td>
<td>86</td>
<td>-54 to 226</td>
<td>0.219</td>
</tr>
</tbody>
</table>

Definition of abbreviations: APA = anticipatory postural adjustment.

Results from the correlation analysis are given in Table 4-5. Self-reported physical activity was positively associated with BBS scores (p = 0.007) (Figure 4-2), total BESTest scores (p = 0.008) (Figure 4-3), BESTest biomechanics (p = 0.04), transitions (p = 0.027), and reactive sub-scores (p = 0.003). Measures of lower extremity muscle strength were associated with BBS and BESTest total scores (Figure 4-4), and with five of the six BESTest sub-scores (biomechanics, transitions, reactive, sensory and gait) (see Table 4-5). In multivariate linear regression, the model including age, knee flexor muscle strength and self-reported physical activity explained 35% of the variance in BESTest score (p < 0.001). Both knee flexor muscle strength (p = 0.008) and physical activity (p = 0.033) were independently associated with BESTest score.
**Table 4-5:** Associations between self-reported physical activity and muscle strength with balance in patients with COPD (n = 37)

<table>
<thead>
<tr>
<th>Variable</th>
<th>PASE</th>
<th>KE peak torque (Nm/kg)</th>
<th>KF peak torque (Nm/kg)</th>
<th>PF peak torque (Nm/kg)</th>
<th>DF peak torque (Nm/kg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>BESTest total</td>
<td>0.40**</td>
<td>0.42**</td>
<td>0.43**</td>
<td>0.064</td>
<td>0.27</td>
</tr>
<tr>
<td>BESTest Biomechanics</td>
<td>0.30*</td>
<td>0.28*</td>
<td>0.23</td>
<td>0.12</td>
<td>0.16</td>
</tr>
<tr>
<td>BESTest Stability</td>
<td>0.16</td>
<td>0.02</td>
<td>0.15</td>
<td>0.01</td>
<td>0.12</td>
</tr>
<tr>
<td>BESTest Transitions</td>
<td>0.32*</td>
<td>0.22</td>
<td>0.33*</td>
<td>0.11</td>
<td>0.15</td>
</tr>
<tr>
<td>BESTest Reactive</td>
<td>0.45**</td>
<td>0.17</td>
<td>0.19</td>
<td>0.02</td>
<td>0.29*</td>
</tr>
<tr>
<td>BESTest Sensory</td>
<td>0.26</td>
<td>0.34*</td>
<td>0.41**</td>
<td>0.22</td>
<td>0.32*</td>
</tr>
<tr>
<td>BESTest Gait</td>
<td>0.26</td>
<td>0.41**</td>
<td>0.41**</td>
<td>-0.10</td>
<td>0.18</td>
</tr>
<tr>
<td>BBS</td>
<td>0.41**</td>
<td>0.24</td>
<td>0.28*</td>
<td>0.02</td>
<td>0.31*</td>
</tr>
</tbody>
</table>

*Definition of abbreviations:* BESTest = Balance Evaluation Systems Test; BBS = Berg Balance Scale; PASE = physical activity scale for the elderly; KE = knee extensors; KF = knee flexors; PF = ankle plantarflexors; DF = ankle dorsiflexors.

* Significant at p < 0.05
** Significant at p < 0.01
Figure 4-2: Association between Physical Activity Scale for the Elderly (PASE) scores and a) Balance Evaluation Systems Test (BESTest) and b) Berg Balance Scores in subjects with COPD.
**Figure 4-3**: Association between normalised knee extensor (KE) peak torque and a) Balance Evaluation Systems Test (BESTest) and b) Berg Balance Scores in subjects with COPD.
Figure 4.4: Association between normalised knee flexor (KF) peak torque and a) Balance Evaluation Systems Test (BESTest) and b) Berg Balance Scores in subjects with COPD.

4.5 Discussion

The novel findings of this study are (i) individuals with COPD demonstrate reductions in all six subcomponents of postural control compared to age-matched controls, with marked deficits in biomechanics, transitions and gait, (ii) in response to perturbations, individuals with COPD have a delayed reaction time for balance recovery compared to controls, and (iii) physical activity and lower extremity muscle strength are both associated with balance in COPD.
Only two previous studies have documented reduced performance on clinical balance tests in patients with COPD compared to controls;\textsuperscript{11,13} our work extends these observations by using well-validated measures and is the first study to systematically evaluate the underlying systems responsible for these deficits. It is difficult to compare our results to previous work as the measures used differed. However, deficits in BBS scores in subjects with COPD (6.2 points) exceeded previously reported differences in BBS scores between self-reported fallers and non-fallers with COPD (3.5 points),\textsuperscript{117} and were consistent with clinically important thresholds previously identified for this measure in older adults (4 points)\textsuperscript{100} and those with stroke (6 points).\textsuperscript{150} Although the BBS is an established measure for the determination of fall risk, we also selected the BESTest, a comprehensive assessment tool that assesses six different balance control subsystems, to identify the underlying postural control systems responsible for poor balance in COPD. While our subjects exhibited deficits in each of the six subsystems,\textsuperscript{151} the deficits were most pronounced in the subsystems of biomechanics, transitions and gait, when compared to controls (Figure 4-1). These deficits are of similar magnitude to those reported in populations with neuromuscular disease\textsuperscript{151} and suggest that individuals with COPD are at greater risk of falling when walking and when performing tasks that require anticipatory postural adjustments or reliance on the musculoskeletal system. Of note, patients were cognisant of their balance deficits reflected in their low subjective balance self-efficacy scores. As conventional pulmonary rehabilitation alone does not address balance impairments,\textsuperscript{152} it may be useful to evaluate the impact of including specific balance exercises within the rehabilitation program. In particular, our results suggest that the optimal training program should include an emphasis on functional lower extremity strength training, gait training under challenging conditions (e.g.,
obstacles, secondary cognitive tasks) and training to increase stability during postural transitions (e.g., sit-to-stand, changes in base of support, stair climbing).

In the current study we include measurements of reactive postural control in response to external postural perturbations. The ability to maintain balance in daily life stems from a combination of anticipatory and compensatory postural control strategies. While anticipatory postural control lessens the effect of a predictable disturbance such as a voluntary movement, compensatory control is the only recourse in the event of an unexpected perturbation. Measurement of reactive control is therefore fundamental to determining fall risk outside of the laboratory. A key finding in this study was the delayed foot-off and foot-contact times in response to perturbations suggesting that individuals with COPD have an increased risk of falls due to an inability to respond quickly in circumstances of instability. In addition, the reaction time values we observed in patients with COPD are similar to those reported for patients with elevated fall risk, although using a different perturbation paradigm. The absence of slower muscle onset latencies in subjects with COPD compared to controls suggests that these impairments in response time are not related to a central signalling issue, but rather to deficits at the level of the muscle. Skeletal muscle dysfunction may well account for the decreased ability to perform fast and powerful muscle contractions in response to perturbations. In fact, muscle power (the product of force and velocity) is increasingly recognized as an important determinant of balance and fall risk in older adults, and is an area worthy of study in COPD.

Another explanation for the slower foot-off times in subjects with COPD may be the longer anticipatory postural adjustment (APA) durations compared to controls. APAs are typically present during volitional stepping and are characterized by an initial mediolateral centre-of-pressure shift toward the swing limb that drives the centre-of-mass toward the stance limb in
preparation for foot-off.\textsuperscript{49} However, in response to unpredictable perturbations it has been shown that the anticipatory phase is disrupted by the need to react rapidly to the instability imposed by the perturbation, and in healthy individuals, APAs are often absent during rapid compensatory stepping reactions.\textsuperscript{50} We observed that subjects with COPD showed a longer anticipatory phase than control subjects, which may impede their ability to react rapidly in response to a perturbation. Together with the BESTest results for reactive control, these findings indicate that balance exercises for patients with COPD should also include perturbation-based training.

In this study, lower extremity muscle strength and self-reported physical activity were moderately associated with measures of balance in patients with COPD (Figure 4-2, Figure 4-3, Figure 4-4). Although reductions in physical activity\textsuperscript{110,158} and lower extremity muscle strength\textsuperscript{159} have been shown previously, this is the first study to explore the relationship between these measures and control of balance in these patients. Muscle weakness is a well-established risk factor for falls and impaired balance in the general population.\textsuperscript{83,160} The relationship between physical activity and fall risk has been less studied, however there is some evidence to suggest that sedentary older adults have more difficulty discriminating and integrating sensory information than their more active peers.\textsuperscript{161} Therefore it is possible that sedentary lifestyle in individuals with COPD contributes to impairments in balance independent of loss of muscle strength from disuse. However, prospective studies are needed to determine the direction of the association between balance and physical activity and muscle strength in this population. In addition, while our findings provide additional support for the role of resistance training and for encouraging regular physical activity in patients with COPD, clearly other factors impact on balance and should be explored.
Certain limitations need to be addressed when interpreting the results of this study. Because it was a cross-sectional study, no causality or directionality of the findings can be inferred. In addition, although our sample size was sufficient to detect differences between groups in most measures, larger prospective studies are required to confirm the relationships among objective measures of physical activity, peripheral muscle strength, and other factors that may impact on balance, such as muscle power and medications.

In summary, we note that compared with age-matched controls, individuals with COPD have reduced performance in all subcomponents of balance including impaired balance recovery in response to perturbations. These deficiencies in balance are associated with low self-reported physical activity levels and lower extremity muscle weakness. Given the association between impaired balance and an increased risk of falls in COPD, a detailed balance evaluation should be offered to at risk individuals. There is a clear need for future research to evaluate the role of balance training as part of the comprehensive management of patients with COPD.
Chapter 5

5 Preliminary results of a randomized controlled trial of balance training during pulmonary rehabilitation in individuals with COPD


Contributions of the authors: MK Beauchamp developed the research design and protocol, collected and analyzed the data and wrote the manuscript. T Janaudis-Ferreira contributed to the research design and protocol. J Romano assisted with subject recruitment, data collection and delivery of the intervention. L Woon assisted with delivery of the intervention. RS Goldstein assisted with the overall supervision of the study, research design, subject recruitment and reviewed the manuscript. D Brooks assisted with the overall supervision of the study, research design, and reviewed the manuscript.
5.1 Abstract

**Objective:** Impairments in balance are increasingly recognized among the important secondary impairments in COPD. The main purpose of this study was to investigate the feasibility and effect of a balance training program on measures of balance and fall risk in patients with COPD enrolled in pulmonary rehabilitation.

**Methods:** Patients were randomly assigned to an intervention or control group. The intervention group underwent balance training three times a week for 6 weeks in addition to pulmonary rehabilitation. The control group received only the 6-week pulmonary rehabilitation program. Clinical balance measures included the Berg Balance Scale (BBS), the Balance Evaluation Systems Test (BESTest) and the Activities-Specific Balance Confidence (ABC) scale. The SF-36 physical function subscale (PF-10) and 30-second chair-stand test were used to measure self-reported physical function and lower-extremity muscle strength, respectively.

**Results:** Sixteen patients with COPD (mean FEV$_1$ 39% predicted) completed the study. Mean compliance to the balance training program was 87.3% and no adverse events were reported. Performance on the BBS and BESTest was significantly improved in the intervention group (n = 7) compared to controls (n = 9) (p < 0.01). No significant between-group differences were found in change scores on the ABC scale (p = 0.4), or 30-second chair-stand (p = 0.07). The improvement in PF-10 was borderline statistically significant (p = 0.05) in favour of the intervention group.

**Conclusions:** Preliminary results support the feasibility and effectiveness of balance training for improving balance performance in patients with moderate to severe COPD.
5.2 Introduction

Chronic obstructive pulmonary disease (COPD) is one of the most important causes of death in North America, and is projected to rank third in 2020 in global burden of disease.\textsuperscript{5, 92} While treatment of COPD has traditionally focused on lung function, secondary manifestations of the disease are increasingly recognized. Impairments in peripheral muscle function, mobility and exercise capacity are well established in these patients.\textsuperscript{6, 7, 116} In addition, a growing body of evidence suggests that individuals with COPD demonstrate important deficits in balance control that may be associated with an increased risk of falls.\textsuperscript{11-14, 117, 162}

A number of studies have documented impaired balance control in patients with COPD compared to age-matched controls.\textsuperscript{11, 13-15, 163} These balance deficits have been demonstrated using both clinical and objective laboratory measures of balance in patients with varying COPD severity.\textsuperscript{164} Of note, two recent studies found that patients with COPD exhibit impaired balance recovery reactions in response to externally applied perturbations.\textsuperscript{15, 163} This is of particular relevance to fall risk given that the majority of falls occur as a result of unpredictable balance disturbances; the ability to generate a successful balance reaction in response to a postural disturbance is critical in determining fall risk.\textsuperscript{139} Indeed, we have previously shown that impairments in balance successfully identified patients with COPD with a history of falling.\textsuperscript{117}

Falls are a common and costly problem among older adults. In the United States alone, over $20 billion dollars are spent on fall-related injuries each year.\textsuperscript{136} Although not extensively studied to date, there is recent evidence to suggest an increased incidence of falls in individuals with COPD. A large cross-sectional study reported that COPD was second only to osteoarthritis in its association with the number of falls in elderly women.\textsuperscript{19} In a recent prospective study,
individuals with COPD were found to have an estimated annual fall rate of 1.2 falls per person—a substantially higher rate than that previously reported for older adults (incidence rate of 0.24). Given the importance of balance as a modifiable risk factor for falls, there is a need for research to examine the effects of interventions to improve balance in individuals with COPD.

Exercise with balance training is an established component of any falls intervention strategy for older adults at risk of falling. While exercise training is considered the cornerstone of pulmonary rehabilitation, it is predominately focused on increasing endurance. Balance training and fall prevention strategies are not included as part of international guidelines for pulmonary rehabilitation and very few programs include any standardized balance assessment. We recently reported that a conventional pulmonary rehabilitation program, in the absence of any specific balance training, resulted in only minor improvements in balance. The primary aim of this study, therefore, was to evaluate a tailored intervention to improve balance and reduce risk of falls in patients with COPD enrolled in pulmonary rehabilitation.

5.3 Methods

5.3.1 Study design

This was a prospective, single-blind, randomized controlled trial. Patients were randomly (in blocks of four) assigned to an intervention or control group using a computer generated randomization list. Randomization was stratified according to the presence or absence of the use of supplemental oxygen at rest. Allocation was concealed as the sequence was kept in opaque envelopes by an investigator who was not involved in data collection. After the pre-assessment session, the trainer drew the envelope and scheduled patients allotted to the intervention group
for the balance training sessions. Outcome measures were collected prior to and within two days of completing the 6-week exercise intervention for all patients; the outcome assessor was a registered physiotherapist (MB) with extensive experience administering the balance tests. The outcome assessor remained blind to group allocation and patients were not directly informed of their treatment allocation. Subjects were told, “Depending on which group you are allocated to, some of the exercises in your program will differ. We think that one type of exercise will have a greater effect on balance but we do not know for sure.” Patients allotted to the intervention group exercised in groups of 2-3 at a different time and location than control subjects and were told not to discuss their exercises with their peers or outcome assessor. Approval for this study was obtained from the Bridgepoint/West Park research ethics board, and written informed consent was obtained from each participant prior to inclusion in the study.

5.3.2 Study population

Consecutive patients with stable COPD were recruited from the in-patient pulmonary rehabilitation program at West Park Healthcare Centre. Individuals were considered eligible for the study if they met the following criteria: a diagnosis of COPD; a self-reported decline in balance, or fall in the last 5 years, or a recent near fall; and smoking history greater than 10 pack years. Individuals were excluded if they have co-morbid conditions thought to jeopardize their safety or influence their balance. Specifically, exclusion criteria comprised: an inability to communicate because of language skills, hearing or cognitive impairment; and evidence of a neurological or musculoskeletal condition that severely limited mobility and postural control.
5.3.3 Intervention

Patients assigned to the intervention group underwent balance training three times a week for 6 weeks, for a targeted total of 18 sessions. Training sessions lasted approximately 30 minutes and were delivered by a physiotherapist and trained research assistant. We used a circuit training approach with different stations designed to target specific areas of impairment. Participants worked through four stations in small groups (2-3 patients). However, they received individualized exercise prescription regarding the level of difficulty and the approach to exercise progression. The content of the balance training program was developed based on our work to date, the American Geriatrics Society guidelines for fall prevention, and consultation with experts (see Appendix 3 for a detailed outline of the intervention). The four balance stations consisted of: 1) Stance exercises (e.g., single leg stance, tandem stance, and standing on uneven surfaces); 2) Transition exercises (e.g., sit-to-stands from chair and floor, stair tapping); 3) Gait exercises (e.g., walking in parallel bars over obstacle courses, walking and kicking a ball, tandem walking); and 4) Functional strengthening (e.g., toe and heel raises, squats, step-ups, and core work on stability ball). When a participant was able to complete a task independently and with little instability, we progressively increased the difficulty level by introducing more challenging conditions (e.g., eyes closed, addition of a secondary cognitive task, faster speed, manual perturbations, and increased repetitions). Prior to beginning the trial, we pilot tested the balance training program on two patients with COPD to determine 1) equipment needs for safety of participants and 2) feasibility of the balance exercise program with respect to a 30-minute time-frame.
The balance training program occurred concurrently with pulmonary rehabilitation, which included: 1) Supervised endurance exercise training five times a week; 2) Lower and upper extremity strength training three times a week; 3) Daily breathing exercises; and 4) Self-management education and psychological and social support. For a full description of the pulmonary rehabilitation program please see Beauchamp et al. 2010.\textsuperscript{152}

5.3.4 Control group

Patients assigned to the control group received the usual pulmonary rehabilitation program provided at our centre as described above.

5.3.5 Primary outcome measures

\textit{Berg Balance Scale (BBS):} The 14-item BBS\textsuperscript{140} was chosen as a primary outcome in this study as it is one of the most widely accepted and psychometrically robust clinical measure of balance for older adults.\textsuperscript{121} Activities such as transfers, reaching, turning around and single legged stance are graded on a scale ranging from 0 (unable/unsafe) to 4 (independent/efficient/safe), with higher scores indicating greater balance control. The measurement derived using the BBS has demonstrated internal consistency, intra-rater and inter-rater reliability, content validity, construct validity and predictive validity for determining fall risk in older adults.\textsuperscript{95} A change of 3.3 (or ≥ 4) points has been suggested to represent a minimal detectable change in elderly patients with baseline BBS scores of 45-56 points.\textsuperscript{100} Minimal detectable change scores for individuals with lower baseline BBS scores range between 5-6 points for community-dwelling older adults.\textsuperscript{100}
The Balance Evaluation Systems Test (BESTest): The BESTest is a recently developed comprehensive, clinical balance assessment tool that evaluates six subsystems of balance control: biomechanical, stability limits/verticality, anticipatory postural adjustments for postural transitions, reactive postural response strategies, weighting of sensory information for orientation, and postural stability during gait. The BESTest has excellent inter-rater reliability and validity, relates to patient's balance confidence and allows therapists to focus their rehabilitation strategy on the most affected set of balance deficits.  

5.3.6 Secondary outcome measures

Balance confidence: The Activities-Specific Balance Confidence (ABC) scale requires patients to indicate their confidence in performing 16 activities without losing their balance or becoming unsteady on an 11-point scale (0 to 100%). Each item describes a specific activity that requires progressively increased balance control. Greater scores indicate higher balance confidence. The ABC scale has good test-retest reliability, internal consistency and predictive capacity for falls in older adults that reside in the community. A change of 13% has been shown to reflect a minimal detectable change for this measure.

Self-reported physical function: The physical function (PF-10) scale of the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36v2) was used to examine perceived limitations in overall physical functioning. The PF-10 assesses the effect of physical health on self-reported physical performance ranging from basic activities of daily living to vigorous physical activity. Responses from each of the 10 items are scored on a 3-point Likert scale (yes, limited a lot; yes, limited a little; and no, not limited at all); scores range from 0 to 100 with higher scores
indicating better function. The PF-10 has been widely used with good construct validity and sensitivity to change.\textsuperscript{166}

*Functional strength:* The repeated chair stand test (number of sit to stands the subject can complete in a 30 second time period) was used as a measure of functional lower body strength. The reliability and validity of this measure has been previously evaluated in community-dwelling older adults\textsuperscript{167} and in people with COPD\textsuperscript{168} and it has been shown to be correlated to maximal voluntary force from a seated leg press.\textsuperscript{167, 168}

*Exercise capacity:* The Six-Minute Walk Test (6MWT) is a valid, responsive and interpretable self-paced test that quantifies functional exercise capacity in terms of the distance walked in six minutes in patients with COPD.\textsuperscript{99} The test was performed by the patient’s treating physiotherapist according to the protocol described by the American Thoracic Society.\textsuperscript{99} The measurement properties of this test are well established in the COPD population.\textsuperscript{99, 126}

5.3.7 Descriptive measures

At baseline, recent measurements of height and weight were retrieved from the clinical record, as were pulmonary function results, age, sex, smoking history, use of walking aid, and medications. Functional limitation from dyspnea was quantified using the Modified Medical Research Council (MRC) scale\textsuperscript{98} and the questionnaire portion of the EFST\textsuperscript{94} was used to collect data on fall history of the participants. Feasibility measures included patient attendance and adherence and monitoring of adverse events. In addition, to measure perceived change in balance status, we used a global balance transition item in which participants were asked to rate the amount of change they experienced in their balance over a 6-week period on a 5-point Likert scale (much better; a little better; no change; a little worse; or much worse).
5.3.8 Statistical analysis

Data were analyzed using SPSS, version 20.0 (SPSS Inc; Chicago, Illinois). The distribution of data was evaluated using the Shapiro-Wilks test and frequency histograms; thereafter, between-group comparisons of baseline data were undertaken using either an independent t-test (for normally distributed data) or the Mann-Whitney U Test (for non-parametric data). Independent t-tests of the difference scores were conducted to analyze between-group differences. Analysis was performed on an intention-to-treat basis and p values < 0.05 were considered significant. We determined that a sample size of 38 (19 per group) would yield 80% power (alpha = 0.05) to detect a difference of 4 points (the minimal detectable change)\textsuperscript{100} in Berg Balance score between the treatment and control groups using an independent t-test. This sample size was also deemed adequate to detect a 10-point difference on the BESTest. To date, data collection has been completed on 16 subjects and these data are reported here. Data collection remains ongoing to meet the targeted sample size.

5.4 Results

As of March 31\textsuperscript{st} 2012, 17 patients with moderate to severe COPD have been enrolled in the trial, of whom 16 completed the post-test assessments and were included in the analysis (Figure 5-1). Baseline characteristics of the sample are provided in Table 5-1. No significant between-group differences were noted in any of the baseline characteristics or outcome variables.
Figure 5-1: Study flow as of 03/31/2012

Table 5-1: Subject characteristics at baseline (n = 17)

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group (n=9)</th>
<th>Intervention group (n=8)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>69.7 ± 9.8</td>
<td>74.1 ± 4.7</td>
</tr>
<tr>
<td>BMI</td>
<td>25.1 ± 8.4</td>
<td>23.8 ± 5.1</td>
</tr>
<tr>
<td>FEV₁ % predicted</td>
<td>35.0 ± 17.6</td>
<td>44.4 ± 18.4</td>
</tr>
<tr>
<td>FEV₁/FVC % predicted</td>
<td>38.8 ± 13.4</td>
<td>40.3 ± 9.9</td>
</tr>
<tr>
<td>No. of men, %</td>
<td>3, 33</td>
<td>5, 63</td>
</tr>
<tr>
<td>MRC dyspnea</td>
<td>3.9 ± 0.8</td>
<td>3.6 ± 1.3</td>
</tr>
<tr>
<td>No. with fall history, %</td>
<td>4, 44</td>
<td>4, 50</td>
</tr>
<tr>
<td>No. on oxygen, %</td>
<td>4, 44</td>
<td>4, 50</td>
</tr>
</tbody>
</table>

Definition of abbreviations: BMI = body mass index; FEV₁ = forced expiratory volume in one second; FVC = forced vital capacity; MRC = Medical Research Council.
5.4.1 Feasibility

Subjects in the intervention group attended a mean of 15.7 ± 1.8 balance training sessions (out of a total possible of 18) achieving an overall compliance rate of 87.3% ± 10%. No adverse events were reported. The one drop-out in the intervention group was due to medical reasons unrelated to the study.

5.4.2 Between-group findings

Table 5-2 shows the results for the outcomes of interest. Compared with the changes observed in the control group, the magnitude of improvement in the intervention group was greater for the BBS (p = 0.009) and BESTest (p = 0.008) (see Figure 5-2 and Figure 5-3).

Table 5-2: Outcome measures for control and intervention groups (n = 16)

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Control group (n=9)</th>
<th>Intervention group (n=7)</th>
<th>Mean Difference (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Pre-test</td>
<td>Post-test</td>
<td>Change</td>
</tr>
<tr>
<td>BBS</td>
<td>45.7 ± 7.1</td>
<td>47.7 ± 4.9</td>
<td>2 ± 4.9</td>
</tr>
<tr>
<td>BESTest</td>
<td>67.9 ± 12.1</td>
<td>74.4 ± 9.8</td>
<td>6.5 ± 5.1</td>
</tr>
<tr>
<td>ABC scale</td>
<td>61.2 ± 24.8</td>
<td>82.9 ± 12.1</td>
<td>21.8 ± 73.5</td>
</tr>
<tr>
<td>PF-10</td>
<td>20.6 ± 13.1</td>
<td>25.0 ± 19.7</td>
<td>4.4 ± 16.3</td>
</tr>
<tr>
<td>Chair-stand</td>
<td>5.0 ± 5.2</td>
<td>9.0 ± 4.9</td>
<td>4.0 ± 4.2</td>
</tr>
<tr>
<td>6MWD</td>
<td>278.3 ± 73.3</td>
<td>364.0 ± 90.4</td>
<td>85.7 ± 57.0</td>
</tr>
</tbody>
</table>

Definition of abbreviations: BBS = Berg Balance Scale; BESTest = Balance Evaluation Systems Test; ABC = Activities-Specific Balance Confidence; PF-10 = Physical Function scale of the SF-36; 6MWD = Six-minute walk distance.

*Significant at p < 0.01

The improvement in PF-10 scores in the intervention group compared to controls was of borderline statistical significance (p = 0.05), and there was a trend toward greater repetitions on
the chair-stand test in favour of the treatment group (p = 0.07). No between-group differences were found for changes in the ABC score (p = 0.4) or 6MWD (p = 0.5). All 7 patients in the intervention group perceived their balance as “much better” after training. In the control group, only 1 patient reported their balance as “much better”; 4 patients reported their balance as “a little better”; and 4 patients reported no change in balance.

Figure 5-2: Change in Berg Balance Scores (BBS) in a) the control group and b) the intervention group
Figure 5-3: Change in the Balance Evaluation Systems Test (BESTest) in a) the control group and b) the intervention group

5.5 Discussion

Impairments in balance are increasingly recognized as an important physical functional limitation in individuals with COPD.\textsuperscript{11, 12, 14, 15, 117, 163, 164} To our knowledge, this is the first randomized controlled trial to evaluate the effects of an intervention aimed to address these deficits in patients with COPD. Our preliminary findings indicate that the addition of balance training to pulmonary rehabilitation significantly improved measures of functional balance compared to pulmonary rehabilitation alone. In addition, we found the thrice-weekly training program was feasible and well-tolerated for patients with moderate to severe COPD undergoing pulmonary rehabilitation.
In this study, balance training resulted in significant improvements on our primary measures of balance and fall risk, the BBS and BESTest. Compared with subjects in the control group, the intervention group demonstrated a 7.6 point greater improvement in BBS scores after the 6-week balance training program. The magnitude of difference between groups on the BBS is likely clinically important as it exceeds the minimal detectable change for this measure in older adults,\(^{100}\) the 3.5 point difference we previously reported between fallers and non-fallers with COPD,\(^{117}\) as well as the 6.2 point difference we recently found between COPD patients and age-matched controls.\(^{163}\) The change in BESTest scores in the intervention group also suggests a clinically relevant difference based on our previous work.\(^{163}\) Of note, the greater improvement in balance in the intervention group was perceptible to patients as all those in the intervention group reported a large improvement in balance after training, compared to only one patient in the control group. Our results in COPD are consistent with previous meta-analyses in the elderly indicating that exercise programs with a focus on balance, gait, strengthening and functional tasks have the greatest effects on measures of balance and fall risk.\(^{82, 118}\) Given the importance of balance control to daily physical function and the established link between balance deficits and fall risk,\(^{16, 17, 38-40}\) our findings support the inclusion of balance training as part of pulmonary rehabilitation for improving balance and reducing fall risk in patients with COPD.

Despite the large improvements in measures of balance performance favouring the intervention group in this study, we did not find a between-group difference in balance self-efficacy scores as measured by the ABC scale. Several reasons may account for this finding. First, it is possible that patients in the intervention group gained further insight into their balance deficits by nature of participating in an intervention with challenging balance tasks thereby attenuating their balance confidence after training. Second, based on our results in Table 5-2, it appears that both
the intervention and control groups showed large (17-20 points) within-subject improvements in balance confidence after 6-weeks. The finding of improved balance confidence in our control subjects contrasts with a previous study in which we failed to find an effect of a conventional pulmonary rehabilitation on balance confidence in COPD patients. However, in the current trial, we targeted patients with self-reported balance problems and recent fall history, which may well explain the differing results. Indeed, baseline balance confidence scores in this trial (mean ABC score of 61%) were lower than in our previous study (74%); therefore, a ceiling effect on the ABC scale may have accounted for the lack of improvement with conventional pulmonary rehabilitation in our previous study. Finally, it is also possible that, in addition to balance training, other types of interventions such as fall prevention education and specific psychosocial components are necessary to optimize improvements in balance self-efficacy.

Preliminary results from this study suggest that balance training is associated with superior gains in self-reported physical function and a trend towards improved functional strength in patients with COPD. Although the improvement in the PF-10 reported in our intervention group compared with controls was borderline statistically significant ($p = 0.05$), the between-group difference of 14.8 points exceeds the minimal clinically important difference (MCID) for this measure established in patients with COPD. Similarly, the trend towards a 3-repetition difference in the 30-second chair-stand favouring the intervention group ($p = 0.07$) is also consistent with the MCID for this measure established in older adults with musculoskeletal conditions. Thus, the addition of balance training to pulmonary rehabilitation may confer larger relative effects on both self-reported and objective measures of physical function. Together with the observed improvements in balance performance, this study provides
compelling support for the inclusion of balance training as part of pulmonary rehabilitation for optimizing gains in physical function in patients with COPD.

The results of this study must be interpreted in light of numerous limitations. While we report improvements in balance after just 6 weeks of training, we are not able to comment on the long-term persistence of these effects. Given the diminishing effect of exercise training in patients with COPD in the year following pulmonary rehabilitation,\textsuperscript{174} it is likely that extended interventions are needed to maintain balance as well. In addition, guidelines for fall prevention recommend ongoing balance training (≥ 6 months in duration) to achieve the most favorable effects on reducing falls in older adults.\textsuperscript{16, 84} Future work with longer-follow-up and greater exercise dose will be necessary to investigate the effects of balance training on reducing falls in this population. As we did not include a sham exercise training control group, it is possible that increased attention in the treatment group accounted for some of the self-reported improvements in function and balance. Finally, the generalizability of our findings to all patients with COPD is limited as we targeted at-risk patients and exclusively those enrolled in pulmonary rehabilitation.

In summary, preliminary results from this study demonstrate that balance training is feasible and effective for improving balance performance and self-reported physical function in patients with moderate to severe COPD participating in pulmonary rehabilitation. Balance training should be offered to patients with COPD presenting with balance deficits and increased fall risk. Future work is warranted to determine the long-term effects of balance training for reducing the rate of falls in this population.
Chapter 6

6 Discussion and conclusion

6.1 Overview of findings

The studies in this thesis contribute important new knowledge to the literature on balance assessment and treatment in patients with COPD. Specifically, the novel findings of this thesis are:

1) Individuals with COPD who report a positive fall history are characterized by impairments in balance;

2) Pulmonary rehabilitation, in the absence of specific balance training, has small effects on improving balance performance and no effect on improving balance confidence;

3) Compared to age-matched controls, patients with COPD have impaired balance in all postural control subsystems;

4) Biomechanics, transitions and gait were the most impaired balance control subsystems in patients with COPD;

5) Patients with COPD have slower balance recovery reactions in response to externally applied perturbations;

6) Deficits in balance in patients with COPD are associated with lower extremity muscle weakness and lower levels of physical activity;
7) The addition of tailored balance training exercises to conventional pulmonary rehabilitation is effective for improving balance in patients with COPD.

These findings highlight an important secondary impairment in patients with COPD that may contribute to an increased fall risk in this population. Furthermore, our results suggest that the observed balance deficits are amenable to therapy; the addition of balance training to pulmonary rehabilitation is a feasible and effective option for improving measures of balance and fall risk in patients with COPD.

6.2 Balance assessment in COPD

COPD is increasingly recognized as a systemic disease associated with a number of physical functional limitations. In addition to limitations in lower extremity function, exercise performance, and muscle strength, this thesis has highlighted that deficits in balance constitute an important functional impairment in these patients.

In chapter 2, we showed that patients with COPD who reported a history of one or more falls in the previous year had reduced scores on the BBS, TUG and ABC scale compared to those without a history of a fall. Furthermore, the use of supplemental oxygen and more severe MRC dyspnea score also characterized fallers with COPD, while measures of airflow limitation, such as FEV\textsubscript{1}, did not. The finding of greater functional limitation in fallers with COPD is important in context of recent work on the development of secondary disability in COPD. COPD is one of the leading causes of disability in North America and individuals with COPD have a 10-fold greater risk of disability compared with the general population. Physical functional limitations, including deficits in standing balance, have been shown to have a greater
impact on the development of disability than airway obstruction in COPD.\textsuperscript{26} Indeed, exercise tolerance, health-related quality of life, and performance of daily activities, are commonly impaired disproportionately to the lung function impairment in individuals with COPD.\textsuperscript{27} Taken together, these findings support the need to extend the focus on respiratory impairment in patients with COPD, to include the comprehensive assessment and management of the various non-respiratory impairments, such as dysfunctional balance.

In our post-hoc analysis in Chapter 2, we compared balance in patients with COPD based on their requirement for supplemental oxygen.\textsuperscript{117} We found more impaired balance scores on the BBS, TUG and ABC in those using supplemental oxygen, but no differences in measures of lung function severity (i.e., FEV\textsubscript{1} or D\textsubscript{L}CO). These findings are somewhat in contrast to previous work by Butcher et al.,\textsuperscript{11} which showed that deficits in balance (as measured by the CB&M and TUG) in patients with COPD were associated with reduced pulmonary function. In this study, it was initially found that patients with COPD on oxygen had more impaired balance than those who were not on oxygen, and that both groups of patients with COPD had more impaired balance compared to controls. However, after the authors controlled for FEV\textsubscript{1} in their analysis, these differences disappeared, suggesting that the functional balance deficits were likely attributable to disease severity and not the requirement for supplemental oxygen. While we cannot directly compare our findings with those from Butcher et al. because of the differences in methodology, it is interesting to note these conflicting results. One possible theory for reduced functional balance in patients with COPD using supplemental oxygen, also proposed by Butcher et al., may relate to lower physical activity levels in these patients. While we did not specifically measure physical activity in this particular study (Chapter 2), 6MWT distance, a marker of physical activity in COPD,\textsuperscript{109} was significantly lower in patients using supplemental oxygen.
Indeed, our results in Chapter 4 lend support to this theory as scores on the BBS and BESTest were correlated with physical activity scores in patients with COPD, albeit only moderately.\textsuperscript{163}

In Chapter 4, we include an in-depth assessment of balance in patients with COPD compared with age-matched controls.\textsuperscript{163} Our results extend previous observations of impaired balance in patients with COPD,\textsuperscript{11, 13-15} while contributing new evidence on the specific balance subsystems most affected in this population. While patients with COPD exhibited impairments in each of the postural control subsystems evaluated with the BESTest, in agreement with our hypothesis, these deficits were most marked in the balance control subsystems of biomechanics, transitions and gait. These subsystems could arguably be considered the systems most reliant on the musculoskeletal system (for example, in contrast to sensory organization); given that skeletal muscle dysfunction is well established in COPD,\textsuperscript{6} these results are not surprising. Nonetheless, the finding that all postural control systems were impaired suggests that there is no single reason that accounts for the balance deficits in COPD but rather, a combination of factors is likely. For example, there are reports of somatosensory deficits in patients with COPD, such as polyneuropathy,\textsuperscript{177, 178} which may contribute to impaired postural control, particularly with respect to sensory orientation. In addition, while we found that lower extremity muscle strength and self-reported physical activity were moderately associated with balance in our COPD patients, these factors only explained part of the variance in balance scores, indicating the need to examine other variables in future work.

The finding in Chapter 4 that overall performance on the BBS and BESTest was associated with lower extremity muscle strength in patients with COPD is in line with studies in older adults\textsuperscript{83} but does not support findings from a recent study in COPD by Roig et al.\textsuperscript{15} In this study, individuals with moderate to severe COPD were compared to age-matched controls using the
Sensory Organization Test (SOT) and knee extensor torque was assessed with an isokinetic dynamometer. In the SOT, individuals stand on force plates in a visual surround system, and the system then modifies the support surface by either tilting the force plate or moving the visual background, to assess somatosensory and visual inputs, respectively. Roig et al. found a reduction in overall performance on the SOT in patients with COPD compared with controls, however, in contrast to our results, knee extensor muscle strength was not associated with test scores among the COPD subjects. Several reasons may account for these differing results. First, we investigated the association between muscle strength and measures of functional balance (i.e., the BESTest and the BBS). It could be argued that the SOT considers only one aspect of balance (sensory organization), and it is possible that muscle strength does not contribute equally to all balance systems. Second, as Roig et al. point out, their study was likely underpowered to investigate this association. Third, we used allometric scaling to account for the effect of body size on muscle strength instead of using raw values. Finally, while both studies included patients with moderate to severe COPD, the study by Roig et al. excluded patients using supplemental oxygen and their sample had less severe airway obstruction (FEV$_1$ 47% predicted vs. 41 % predicted in our study).

In Chapter 4, we also present the results of compensatory reactions to external perturbations in patients with COPD. The inclusion of this type of measure is an important contribution of this thesis given that the successful execution of change-in-support reactions are critical to fall prevention in daily life.$^{43,47,48}$ We showed that patients with COPD are slower to initiate stepping reactions compared with age-matched controls in response to large and unpredictable perturbations.$^{163}$ In studies of the effect of aging on change-in-support reactions, older adults have been shown to be more likely to initiate a stepping or grasping reaction at lower thresholds
of instability and to take multiple steps to recover their balance in response to perturbations. Of note, most studies have failed to show an age-related delay in the onset timing of these balance recovery reactions. Therefore, our finding of a delay in initiation of the stepping reaction in patients with COPD suggests that this impairment is not simply an amplification of age-related processes, but perhaps a disease-specific alteration. Of interest, we did not find slower muscle onset latencies in our COPD patients, suggesting that the delayed stepping response is not a result of a central signaling issue, but instead, some disturbance at the muscle level itself. One possibility pertains to delays in voluntary muscle activation, which have been recently shown in the quadriceps muscle of patients with COPD and could help to explain our findings. Furthermore, although we were unable to assess muscle power in our study, there is recent work to suggest that patients with COPD exhibit deficits in leg muscle power which may be of particular relevance to balance and fall risk.

The proportion of patients with COPD who reported one or more falls in this thesis ranged from 41% (Chapter 3) to as high as 51% (Chapter 4). These incidence rates, although likely subject to recall bias, are considerably higher than those reported in older adults and in line with results from two other studies showing a high fall incidence in patients with COPD. Given that balance deficits characterized fallers with COPD (Chapter 2), there is a need for clinicians to consider assessing balance in patients with COPD who may be vulnerable. In a survey of Canadian pulmonary rehabilitation programs, it was found that only very few programs included a standardized balance assessment. Given our results and the established link between balance impairment and fall risk, we would recommend balance screening as part of the routine assessment of COPD patients admitted for rehabilitation, and in particular, for those with more severe symptoms and with a recent fall history.
6.3 Balance training in COPD

While exercise is a major component of pulmonary rehabilitation, current guidelines for exercise prescription in COPD do not include recommendations for the inclusion of balance-specific exercises. Results from Chapter 3 and Chapter 5 of this thesis provide support for including balance training as part of the exercise component of rehabilitation to optimize gains in balance and mobility in patients with COPD. Furthermore, although we did not specifically examine the effects of balance training on falls in COPD, guidelines for fall prevention in community-dwelling older adults\textsuperscript{16} recommend balance training for fall risk reduction in individuals who may be at risk.

In Chapter 3, we demonstrated that a conventional pulmonary rehabilitation program, including primarily aerobic and resistance exercise, resulted in only small improvements in measures of balance and fall risk in patients with COPD.\textsuperscript{152} In contrast, preliminary results from our randomized controlled trial (Chapter 5), demonstrated that the inclusion of balance-specific training three times/week for 30 minutes is feasible and resulted in considerable gains in measures of postural control and physical function. Importantly, these gains were perceptible to patients as evidenced by their global balance transition ratings. These results are in agreement with systematic reviews in the elderly demonstrating greater relative effects on balance from exercise training programs with balance-specific exercises.\textsuperscript{82, 84}

To our knowledge, the randomized controlled trial in Chapter 5 is the first study to evaluate the effects of a balance training program for patients with COPD. Given that balance deficits appear to be a common problem in this population (Chapter 2 and Chapter 4), the inclusion of simple balance exercises as part of comprehensive rehabilitation should be considered. The balance
training program included in Chapter 5 (Appendix 3) serves as a template for an effective training program that could be adapted and used by clinicians for individual patients.

### 6.4 Limitations and future directions

The findings of this thesis should be considered in light of several limitations. First, none of the balance measures have been validated in individuals with COPD. This limits the interpretability of our findings, particularly in Chapter 3 and Chapter 5, where we evaluated the impact of interventions. Nonetheless, the balance measures have been validated in various other populations with and without balance impairments. In addition, while we included global ratings of change in our randomized controlled trial to help facilitate the interpretation of our findings, there is also a need to establish the minimal clinically important difference for these measures, both in the elderly and in COPD. Future work is warranted to evaluate the psychometric properties of clinical balance tools such as the BBS and BESTest in patients with COPD.

Second, the cross-sectional nature of the studies in Chapter 2 and Chapter 4 limit our understanding of the direction of the association between 1) balance and fall risk (Chapter 2) and 2) muscle strength and physical activity and balance (Chapter 4). Falls were also captured retrospectively in all studies included in this thesis; recall bias therefore likely underestimated the true incidence of falls in our samples. Prospective studies are needed, in particular to determine whether balance deficits, muscle weakness or physical activity levels can predict falls in patients with COPD.

The third main limitation in this thesis is the perturbation paradigm used in Chapter 4. While the inclusion of perturbation-evoked reactions is a major strength of this work, the lean and release
system we used to deliver the perturbations was limited by the ability to deliver only a unidirectional (anterior) perturbation. Furthermore, previous studies have shown the potential for subjects to adapt and improve their response with repeated exposure to perturbations,\textsuperscript{153} therefore future studies would benefit from the use of a perturbation system that could deliver rapid and unpredictable perturbations in all directions. We also did not include a kinematic analysis of stepping trajectory which may have helped to further characterize the stepping response in patients with COPD compared with controls.

The fourth major limitation in this thesis pertains to the short follow-up time of the balance training intervention (Chapter 5). Although we found positive effects after just 6 weeks of balance training in patients with COPD, it is unclear how long these benefits persist in the absence of continued supervised training. Future work is needed to establish the medium and long-term effects of this type of intervention and, whether or not the improved performance on measures of balance and fall risk translate into a reduced number of falls.

Finally, while this thesis offers new information regarding balance assessment and treatment in patients with COPD, there remain several important questions for further investigation. More work is needed to elucidate the multifactorial physiological mechanisms underlying the observed deficits in postural control in patients with COPD. In particular, the contribution of muscle power, medications, comorbidities, cognition, hypoxemia and polyneuropathy to balance and falls in COPD represent exciting areas for further research. Given the devastating consequences of falls, a final important area for future investigation is the development and evaluation of adjunct fall prevention strategies in patients with COPD, such as fall risk education, mobility aids, and environmental modification.
6.5 Concluding remarks

This thesis contributes new evidence to the emerging field of balance assessment and treatment in patient with COPD. Impairments in balance constitute an important and modifiable secondary impairment in patients with COPD that may be related to an increased risk of falling in this population. In light of recent work highlighting a high fall incidence in patients with COPD, balance assessment and treatment of individuals who may be at risk is warranted. Balance training, with a focus on gait, functional tasks and lower-extremity strengthening, can be safely incorporated into existing pulmonary rehabilitation programs and confers short-term benefits in objective measures of balance performance and self-reported physical function.
References


Appendix 1- Ethics approval letters for studies 1-4
March 7, 2008

Dr. Dina Brooks
Respiratory Medicine
82 Buttonwood Ave
Toronto, M6M 2J5

Dear Dr. Brooks:

I am writing to confirm you that your protocol entitled, “Fall risk assessment in individuals with chronic pulmonary disease (COPD)” has received full ethical approval and you may proceed with data collection.

Please note that should you wish to make any further changes to the approved project, they must be submitted for consideration to the board prior to amending the protocol. Address any proposed changes to: Chair, Joint Research Ethics Board, c/o Dragana Markovic, Bridgepoint Center for Research, Education and Policy. Note also that any and all adverse events must immediately be reported to the research office.

Finally, all research conducted at Bridgepoint Health, West Park Healthcare Centre or the Toronto Central Community Care Access Centre is subject to ongoing monitoring that includes the submission, in writing, of an annual status report of project activities to the board. Upon completion of the project, please advise the board promptly in writing.

Best wishes for the progress of this work.

Yours very truly,

Ron Heslegrave, PhD
Chair, Joint Bridgepoint / West Park / Toronto Central CCAC Research Ethics Board
Notification of JREB Approval

June 15, 2009

Dr. Dina Brooks
Respiratory Medicine
West Park Healthcare Centre
82 Buttonwood Avenue
Toronto, ON M6M 2J5

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Dear Dina:

I am writing to confirm that your protocol entitled, “Balance Impairment in COPD and the effect of pulmonary rehabilitation on the recovery of balance” has received full ethical approval and you may proceed with data collection.

If, during the course of the research, there are any serious adverse events, any confidentiality concerns, changes in the approved protocol or consent form, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the JREB. In the event of a privacy breach, you are responsible for reporting the breach to the JREB (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the JREB requires reports of inappropriate/unauthorized use of the information.

The Joint Bridgepoint-West Park-Toronto Central Community Care Access Centre Research Ethics Board (JREB) operates in compliance with the Tri-Council Policy Statement, ICH/GCP Guidelines, the Ontario Personal Health Information Protection Act, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Should you wish to make any further changes or revisions to any aspect or portion of the approved project, they must be submitted for consideration to the board prior to amending the protocol. Address any proposed changes to: Joint Research Ethics Board, c/o Dale Min, Bridgepoint Health, 14 St. Matthews Rd., Toronto, ON, M4M 2B5.
Finally, all research conducted at Bridgepoint Health, West Park Healthcare Centre or the Toronto Central Community Care Access Centre is subject to ongoing monitoring that includes the submission, in writing, of an annual status report of project activities to the board. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The JREB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Best wishes for the progress of this work.

Yours very truly,

Ron Heslegrave, PhD
Chair, Joint Bridgepoint / West Park / Toronto Central CCAC Research Ethics Board
Notification of JREB Approval

December 1, 2009

Dr. Dina Brooks
Respiratory Medicine
West Park Healthcare Centre
82 Buttonwood Avenue
Toronto, ON M6M 2J5

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<td>JREB Application Form, Study Protocol and Informed Consent Form and all other appendices (Versions sent to JREB on Nov. 19, 2009)</td>
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Dear Dr. Brooks:

I am writing to confirm that your protocol entitled, “Characterization of Balance Impairments in Individuals with Chronic Obstructive Pulmonary Disease” has received full ethical approval and you may proceed with data collection.

If, during the course of the research, there are any serious adverse events, any confidentiality concerns, changes in the approved protocol or consent form, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the JREB. In the event of a privacy breach, you are responsible for reporting the breach to the JREB (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the JREB requires reports of inappropriate/unauthorized use of the information.

The Joint Bridgepoint-West Park-Toronto Central Community Care Access Centre Research Ethics Board (JREB) operates in compliance with the Tri-Council Policy Statement, ICH/GCP Guidelines, the Ontario Personal Health Information Protection Act, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Should you wish to make any further changes or revisions to any aspect or portion of the approved project, they must be submitted for consideration to the board prior to amending the protocol. Address any proposed changes to: Joint Research Ethics Board, c/o Dale Min, Bridgepoint Health, 14 St. Matthews Rd., Toronto, ON, M4M 2B5.
Finally, all research conducted at Bridgepoint Health, West Park Healthcare Centre or the Toronto Central Community Care Access Centre is subject to ongoing monitoring that includes the submission, in writing, of an annual status report of project activities to the board. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The JREB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Best wishes for the progress of this work.

Yours very truly,

Ron Heslegrave, PhD
Chair, Joint Bridgepoint / West Park / Toronto Central CCAC Research Ethics Board
May 21, 2010

Dr. Dina Brooks
TRI - University Centre
550 University Avenue
Toronto, Ontario
M5G 2A2

Dear Dr. Brooks:

RE: TRI REB # 10-001
Characterization of balance impairments in individuals with chronic obstructive pulmonary disease (COPD)

The Toronto Rehabilitation Institute Research Ethics Board has reviewed the above-named submission. Any concerns and requested revisions have been addressed to the satisfaction of the REB. The protocol and the consent form received on May 11, 2010 are approved for use for the next 12 months. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The REB must also be notified of the completion or termination of this study and a final report provided.

The following documents are also approved for use:
Appendix 3: Date Collection Forms
Appendix 4: Advertisement for controls

If, during the course of the research, there are any serious adverse events, changes in the approved protocol or consent form or any new information that must be considered with respect to the study, these should be brought to the immediate attention of the Board.

Best wishes for the successful completion of your project.

Yours sincerely,

[ ] Paul Oh MD, MSc, FRCPC, FACP
Chair, Research Ethics Board
Toronto Rehabilitation Institute

May 21, 2010
Date of Initial REB Approval

May 21, 2011
Expiry Date of REB Approval

TRI REB conforms with the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans and Ontario Privacy Legislation PIPPA
Notification of JREB Approval

June 1, 2011

Dr. Dina Brooks
West Park Healthcare Centre
82 Buttonwood Avenue
Toronto, ON M6M 2J5

<table>
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Dear Dr. Brooks:

I am writing to confirm that your protocol entitled, “A Randomized Controlled Trial of Balance Training in Individuals with COPD” has received full ethical approval and you may proceed with data collection.

If, during the course of the research, there are any serious adverse events, any confidentiality concerns, changes in the approved protocol or consent form, or any new information that must be considered with respect to the project, these should be brought to the immediate attention of the JREB. In the event of a privacy breach, you are responsible for reporting the breach to the JREB (in accordance with Ontario health privacy legislation – Personal Health Information Protection Act, 2004). Additionally, the JREB requires reports of inappropriate/unauthorized use of the information.

The Joint Bridgepoint-West Park-Toronto Central Community Care Access Centre Research Ethics Board (JREB) operates in compliance with the Tri-Council Policy Statement, ICH/GCP Guidelines, the Ontario Personal Health Information Protection Act, and Part C, Division 5 of the Food and Drug Regulations of Health Canada.

Should you wish to make any further changes or revisions to any aspect or portion of the approved project, they must be submitted for consideration to the board prior to amending the protocol. Address any proposed changes to: Joint Research Ethics Board, c/o Ruby Paner, West Park Healthcare Centre, 82 Buttonwood Avenue, Toronto, ON, M6M 2J5

Finally, all research conducted at Bridgepoint Health, West Park Healthcare Centre or the Toronto Central Community Care Access Centre is subject to ongoing monitoring that includes...
the submission, in writing, of an **annual** status report of project activities to the board. If the study is expected to continue beyond the expiry date, you are responsible for ensuring the study receives re-approval. The JREB must be notified of the completion or termination of this study and a final report provided. As the Principal Investigator, you are responsible for the ethical conduct of this study.

Best wishes for the progress of this work.

Yours very truly,

Ron Heslegrave, PhD
Chair, Joint Bridgepoint / West Park / Toronto Central CCAC Research Ethics Board
Appendix 2- Consent forms for studies 1-4
Participant Information and Consent Form

Study title: Fall Risk Assessment in COPD

The investigation team includes the following:
- Dr. Dina Brooks, Research Associate, West Park (416 978 1739)
- Dr. Kylie Hill, Research Fellow, West Park (416 243 3600 ext. 2293)
- Dr. Roger Goldstein, Respirologist, West Park (416 243 2179)
- Marla Beauchamp, PhD student, West Park (416 243 3600 ext. 3665)

1. Introduction
The purpose of this study is to determine the risk of falling in 40 individuals with COPD and to compare the results to individuals without COPD of the same age.

2. Process
If you agree to participate in this study, one of the investigators will collect information from your medical notes about your lung disease and exercise capacity. Specifically, we will record the results of your most recent breathing tests and walking tests that you did at West Park as well as the medications that you are taking.

For this study, you will be asked to attend one testing session and to wear a sensor arm band during the days of one full week. The testing session will last about 2 hours and 30 minutes. During this testing session you will be asked to complete the following tasks under the supervision of an investigator:
- **Berg Balance Test:** This will involve performing a series of tasks designed to challenge your balance.
- **Timed Up and Go:** This test involves standing up from a chair, walking 3 metres, and then returning to the chair.
- **Elderly Falls Screening Test:** This will involve watching how you walk and timing your walking pace while you walk just over 5 metres.
- **Two six-minute walk tests:** This involves walking as far as you can in six minutes. You will have at least a 30 minute rest in between the tests. If you have recently completed a six-minute walk test as part of your pulmonary rehabilitation program then we will only ask you to do one six-minute walking test.
- **Complete questionnaires** asking information about your symptoms, balance confidence, history of falls, and mood.

During each of the walking tests we will measure your heart rate and breathing responses. This will involve you wearing a heart sensor around your chest to monitor your heart rate and a small sensor attached to your forehead to monitor your oxygen levels.

At the end of the testing session we will show you how to use a sensor arm band that will collect information about how much energy you use during the day. We will ask that you take the sensor arm band with you to wear around your right arm during the day for 1 full week. You will be given the investigator’s telephone number should you experience any difficulty during the week. The investigator that gave you the arm band will also call you at an agreed upon time to make sure that you are not having any difficulty with the arm band. At the end of the week, we will arrange to collect the arm band from you.
3. Discomforts and Risks
The six-minute walk test is the most common test of “walking capacity” in Canada. It is done before and after pulmonary rehabilitation (exercise programs) at West Park and is generally considered to be safe. During the test, we will ask you to try as hard as you can. Therefore, it is normal for you to feel short of breath and fatigued (tired) during the test. However, any breathlessness and fatigue will be short-lived and you should feel fully recovered within 30 minutes of finishing each test. If you are not used to walking, the muscles in your legs might be a little sore for a few days. This is also normal.

Because we will be asking you to try as hard as you can during all the tests, there is a small risk that something might go wrong (for example, you have problems with your heart or you may fall and injure yourself). To minimize any risk during these tests, we will do the following: (i) make sure that you do not decrease your oxygen levels too much during exercise, (ii) ask you about heart disease and stop you from participating in the study if you have serious problems with your heart, (iii) monitor your heart rate during the test using a special sensor, (iv) ask you to stop the test if you experience any chest pain or dizziness and, (v) supervise all tests and make sure that a doctor is available to help if needed. Also, we will stop you from participating in the study if you experience any chest pain that is likely to be from your heart during the test.

We may use adhesive tape to attach the oxygen sensor during the exercise tests and an elastic strap to attach the heart rate sensor to your chest. Although we will not include anyone in this study who has a known allergy to adhesive tape, there is a small chance that your skin may still be irritated by the tape or the elastic strap. However, it is expected that any skin irritation will resolve within 24 hours.

The tests of balance used in this study are tests that are sometimes used in rehabilitation programs in Canada. However, because we will are challenging your balance during these tests, there is a small risk of falling during these tests. To minimize this risk a registered physiotherapist will be present during all testing sessions and we will be watching you closely so that we may provide any necessary assistance should you lose your balance. Also, you are permitted to refuse to perform any balance task that we ask you to do if you feel unsafe or unable to complete the task.

As part of your participation in this study we require that you inform the researcher if you experience any symptom that concerns you either during the walking tests or at home during the day following the tests. Specifically, you must tell the researcher if you experience any dizziness, chest palpitations, nausea, chest, neck or arm pain. In the unlikely event that you suffer a physical injury as a direct result of participating in the study, you will obtain medical care in the same manner as you would ordinarily obtain any other medical treatment.

4. Benefits
You will not directly benefit from participating in this study. However, we hope that the results of this study will help health care workers to identify patients that are at risk of falling and to provide the appropriate interventions to minimize this risk.

5. Data Storage and Confidentiality
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and identifying personal information will not be used on any of the data collection forms. In addition to the researchers involved in this study, individuals from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be granted access to the information collected during this study.
6. Voluntary Participation
Your participation in this study is strictly voluntary. You are able to withdraw at any time before, during, or after the study. If you should decline to participate, it will not affect your therapeutic relationship with the investigators/facility.

7. Expenses
We will cover any expense directly associated with attending the assessment sessions, such as gas and parking costs (up to $15). We will also cover the cost of returning the sensor arm band to West Park.

9. Questions and Concerns
If you have any questions or concerns, please contact Dr. Dina Brooks at 416-978 -1739 or Marla Beauchamp at 416-243-3600 Ext. 3665. This study has been approved by the Research Ethics Board at West Park. If you have any concerns regarding the ethics of the study, please contact Dragana Markovic at Bridgepoint Center for Research, Education and Policy at 416-461-8251 Ext. 2343.

10. Consent
The researcher whose name appears below has explained the study to me. I have also read the information above that the researcher has given me. I understand the possible risks and discomforts, and I understand that my participation in this study is voluntary and that I can stop being a part of this study at any time without affecting my therapeutic relationship with the investigators/facility.

I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I agree to be part of this study.

______________________  ________________
Patient name                  Patient signature

______________________  ________________
Person obtaining consent     Person obtaining consent signature

_____________________
Today’s date
Participant Information and Consent Form

Study title:
Balance impairment in COPD and the effect of pulmonary rehabilitation on balance

The investigation team includes the following:
- Dr. Dina Brooks, Research Associate, West Park (416 978 1739)
- Dr. Roger Goldstein, Respirologist, West Park (416 243 2179)
- Marla Beauchamp, PhD student, West Park (416 243 3600 ext. 3665)

Introduction
The purpose of this study is to determine the effect of traditional pulmonary rehabilitation on balance.

Process
If you agree to participate in this study, one of the investigators will collect information from your medical notes about your lung disease and exercise capacity. Specifically, we will record the results of your most recent breathing tests and walking tests that you did at West Park as well as the medications that you are taking.

For this study, you will be asked to attend two testing sessions, one at the beginning of rehabilitation and one near the end. The testing session will last about 1 hour. During this testing session you will be asked to complete the following tasks under the supervision of an investigator:
- Berg Balance Test: This will involve performing a series of tasks designed to challenge your balance.
- Timed Up and Go: This test involves standing up from a chair, walking 3 metres, and then returning to the chair.
- Complete a questionnaire asking information about your balance confidence.

Discomforts and Risks
The tests of balance used in this study are tests that are sometimes used in rehabilitation programs in Canada. However, because we will are challenging your balance during these tests, there is a small risk of falling during these tests. To minimize this risk a registered physiotherapist will be present during all testing sessions and we will be watching you closely so that we may provide any necessary assistance should you lose your balance. Also, you are permitted to refuse to perform any balance task that we ask you to do if you feel unsafe or unable to complete the task. As part of your participation in this study we require that you inform Marla Beauchamp at 416-243-3600 ext. 3665 if you experience any symptom that concerns you either during the tests or during the day following the tests. Specifically, you must tell the researcher if you experience any dizziness, irregular heart beat, upset stomach, chest, neck or arm pain. In the unlikely event that you suffer a physical injury as a direct result of participating in the study, you will obtain medical care in the same manner as you would ordinarily obtain any other medical treatment.

Benefits
You will not directly benefit from participating in this study. However, we hope that the results of this study will help health care workers to identify which components of balance they should train to minimize the risk of falls in COPD.

Data Storage and Confidentiality
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded...
and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and identifying personal information will not be used on any of the data collection forms. In addition to the researchers involved in this study, individuals from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be granted access to the information collected during this study.

Voluntary Participation
Your participation in this study is strictly voluntary. You are able to withdraw at any time before, during, or after the study. Should you wish to withdraw from this study please contact one of the members of the research team listed at the top of this form. If you should decline to participate, it will not affect your therapeutic relationship with the investigators/facility.

Questions and Concerns
If you have any questions or concerns, please contact Dr. Dina Brooks at 416-978-1739 or Marla Beauchamp at 416-243-3600 Ext. 3665. This study has been approved by the Research Ethics Board at West Park. If you have any concerns regarding the ethics of the study, please contact Dr. Ron Heslegrave, Joint Research Ethics Board Chair, at Bridgepoint Health, 14 St. Matthews Rd., Toronto, ON, M4M 2B5 (416) 461-8252 Ext. 2343.

Consent
The researcher whose name appears below has explained the study to me. I have also read the information above that the researcher has given me. I understand the possible risks/discomforts, and I that my participation in this study is voluntary and that I can stop being a part of this study at any time for any reason without affecting my therapeutic relationship with the investigators/facility. I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I agree to be part of this study.

______________________
Patient name

______________________
Patient signature

______________________
Person obtaining consent

______________________
Person obtaining consent signature

______________________
Today’s date
Study title: Characterization of balance impairments in individuals with chronic obstructive pulmonary disease

The investigation team includes the following:
- Dr. Dina Brooks, Research Associate, West Park (416 978 1739)
- Dr. Roger Goldstein, Respirologist, West Park (416 243 2179)
- Dr. Sunita Mathur, Assistant Professor, University of Toronto (416-978-7761)
- Dr. Kathryn Sibley, Post-doctoral fellow, Toronto Rehab (416 597-3422 ext. 3540)
- Marla Beauchamp, PhD student, West Park (416 243 3600 ext. 3665)

Introduction
The purpose of this study is to compare measures of balance control in people with COPD to those without COPD of the same age.

Process
If you agree to participate in this study, one of the investigators will collect information from your medical notes about your lung disease and exercise capacity. Specifically, we will record the results of your most recent breathing tests and walking tests that you did at West Park as well as the medications that you are taking.

For this study, you will be asked to attend two testing sessions. The first testing session will occur at one of two locations of your choice: West Park Healthcare Centre or the University of Toronto. The second session will occur at the Toronto Rehabilitation Institute. Each testing session will last about 2 hours. You will be asked to complete the following tasks under the supervision of an investigator:

1st testing session
- Clinical balance tests: This will involve performing a series of tasks designed to challenge your balance.
- Muscle strength testing: You will be asked to sit in a chair and push or pull your leg against a pad. We will record how much force you can push or pull during the test.
- Complete questionnaires asking information about your balance confidence, physical activity and fall history.

2nd testing session
- Balance control tests: You will stand on a special floor that measures the pressure you exert on the ground and you will stand and balance against a small weight attached to you by a harness. The weight will be released periodically requiring you to make a balance adjustment. You will wear a safety harness and will be spotted by a research assistant.
- Muscle Activity: We will record which muscles are used when you recover your balance and how much they turn on. The activity of muscles of your legs and arms will be measured using sticky disks that will be placed on your skin and attached to wires leading to the computer.

Eligibility: You will be considered eligible for this study if you meet the following criteria: diagnosis of COPD; forced expiratory volume in one second (FEV1)<80% predicted; smoking history greater than 10 pack years and ability to provide written informed consent. You will not be eligible to participate in this study if you have any known cognitive impairment, require mechanical ventilation for all or part of the day, are on tapering doses of oral
corticosteroids or xanthines, show evidence of a neurological or musculoskeletal condition that severely limits your mobility and postural control, or have significant, symptomatic cardiovascular disease.

**Discomforts and Risks**
You may feel generally tired from the testing sessions. If you have sensitive skin, you may be a little red underneath the sticky disks used to measure your muscle activity. The tests of balance used in this study are tests that are often used in rehabilitation programs in Canada. However, because we will be challenging your balance during these tests, there is a small risk of falling. To minimize this risk a registered physiotherapist or kinesiologist will be present during all testing sessions and we will be watching you closely so that we may provide any necessary assistance should you lose your balance. You will also be wearing a safety harness for some of the more challenging balance tests.

During the muscle strength test, you will be asked to push or your pull or leg as hard as possible. You may feel that your thigh and calf muscles are tired after the test and your leg muscles may feel sore the next day. These are normal responses to muscle testing. The tiredness will recover in a few hours after the test and the muscle soreness (if any) will recover by 1 or 2 days after the test. We will also have you do a warm-up to stretch your legs before the muscle strength tests to reduce the chances that you may feel muscle soreness.

As part of your participation in this study we require that you inform Marla Beauchamp at 416-243-3600 ext. 3665 if you experience any symptom that concerns you either during the tests or during the day following the tests. Specifically, you must tell the researcher if you experience any dizziness, irregular heart beat, upset stomach, chest, neck or arm pain. In the unlikely event that you suffer a physical injury as a direct result of participating in the study, you will obtain medical care in the same manner as you would ordinarily obtain any other medical treatment.

**Benefits**
You will not directly benefit from participating in this study. However, we hope that the results of this study will help health care workers to identify which components of balance they should train to minimize the risk of falls in people with COPD.

**Data Storage and Confidentiality**
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and identifying personal information will not be used on any of the data collection forms. In addition to the researchers involved in this study, individuals from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be granted access to the information collected during this study.

**Voluntary Participation**
Your participation in this study is strictly voluntary. You are able to withdraw at any time before, during, or after the study. Should you wish to withdraw from this study please contact one of the members of the research team listed at the top of this form. If you should decline to participate, it will not affect your therapeutic relationship with the investigators/facility.

**Questions and Concerns**
If you have any questions or concerns, please contact Dr. Dina Brooks at 416-978 -1739 or Marla Beauchamp at 416-243-3600 Ext. 3665. This study has been approved by the Research Ethics Boards at West Park and Toronto Rehab. If you have any concerns regarding the ethics of the study, please contact Dr. Ron Heslegrave, Joint Research Ethics Board Chair, at Bridgepoint Health, 14 St. Matthews Rd., Toronto, ON, M4M 2B5 (416) 461-8252 Ext. 2343.
Consent
The researcher whose name appears below has explained the study to me. I have also read the information above that the researcher has given me. I understand the possible risks/discomforts, and I that my participation in this study is voluntary and that I can stop being a part of this study at any time for any reason without affecting my therapeutic relationship with the investigators/facility. I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I agree to be part of this study.

________________________
Participant’s Name

___________________________
Participant’s Signature

________________________
Name of Person Obtaining Consent

________________________
Signature of Person Obtaining consent

_________
Date
Participant Information and Consent Form (CONTROL)

Study title: Characterization of balance impairments in individuals with chronic obstructive pulmonary disease

The investigation team includes the following:
- Dr. Dina Brooks, Research Associate, West Park (416 978 1739)
- Dr. Roger Goldstein, Respirologist, West Park (416 243 2179)
- Dr. Sunita Mathur, Assistant Professor, University of Toronto (416-978-7761)
- Dr. Kathryn Sibley, Post-doctoral fellow, Toronto Rehab (416 597-3422 ext. 3540)
- Marla Beauchamp, PhD student, West Park (416 243 3600 ext. 3665)

Introduction
The purpose of this study is to compare measures of balance control in people with COPD to those without COPD of the same age.

Process
For this study, you will be asked to attend two testing sessions. The first testing session will occur at one of two locations of your choice: West Park Healthcare Centre or the University of Toronto. The second session will occur at the Toronto Rehabilitation Institute. Each testing session will last about 2 hours. You will be asked to complete the following tasks under the supervision of an investigator:

1st testing session
- Clinical balance tests: This will involve performing a series of tasks designed to challenge your balance.
- Muscle strength testing: You will be asked to sit in a chair and push or pull your leg against a pad. We will record how much force you can push or pull during the test.
- Complete questionnaires asking information about your balance confidence, physical activity and fall history.

2nd testing session
- Balance control tests: You will stand on a special floor that measures the pressure you exert on the ground and you will stand and balance against a small weight attached to you by a harness. The weight will be released periodically requiring you to make a balance adjustment. You will wear a safety harness and will be spotted by a research assistant.
- Muscle Activity: We will record which muscles are used when you recover your balance and how much they turn on. The activity of muscles of your legs and arms will be measured using sticky disks that will be placed on your skin and attached to wires leading to the computer.

Eligibility: You will be considered eligible for this study if you between the ages of 55 and 90 years of age, have the ability to walk independently, and have no known diagnosis of a lung condition or smoking history. You must also have the ability to provide written informed consent. You will not be eligible to participate in this study if you have any known cognitive impairment, require mechanical ventilation for all or part of the day, are on tapering doses of oral corticosteroids or xanthines, show evidence of a neurological or musculoskeletal condition that severely limits your mobility and postural control, or have significant, symptomatic cardiovascular disease.

Discomforts and Risks
You may feel generally tired from the testing sessions. If you have sensitive skin, you may be a little red underneath the sticky disks used to measure your muscle activity. The tests of balance used in this study are tests that are often used in rehabilitation programs in Canada. However, because we will be challenging your balance during these tests, there is a small risk of falling. To minimize this risk a registered physiotherapist or kinesiologist will be present during all testing sessions and we will be watching you closely so that we may provide any necessary assistance should you lose your balance. You will also be wearing a safety harness for some of the more challenging balance tests.

During the muscle strength test, you will be asked to push or your pull or leg as hard as possible. You may feel that your thigh and calf muscles are tired after the test and your leg muscles may feel sore the next day. These are normal responses to muscle testing. The tiredness will recover in a few hours after the test and the muscle soreness (if any) will recover by 1 or 2 days after the test. We will also have you do a warm-up to stretch your legs before the muscle strength tests to reduce the chances that you may feel muscle soreness.

As part of your participation in this study we require that you inform Marla Beauchamp at 416-243-3600 ext. 3665 if you experience any symptom that concerns you either during the tests or during the day following the tests. Specifically, you must tell the researcher if you experience any dizziness, irregular heart beat, upset stomach, chest, neck or arm pain. In the unlikely event that you suffer a physical injury as a direct result of participating in the study, you will obtain medical care in the same manner as you would ordinarily obtain any other medical treatment.

**Benefits**
You will not directly benefit from participating in this study. However, we hope that the results of this study will help health care workers to identify which components of balance they should train to minimize the risk of falls in people with COPD.

**Data Storage and Confidentiality**
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and identifying personal information will not be used on any of the data collection forms. In addition to the researchers involved in this study, individuals from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be granted access to the information collected during this study.

**Voluntary Participation**
Your participation in this study is strictly voluntary. You are able to withdraw at any time before, during, or after the study. Should you wish to withdraw from this study please contact one of the members of the research team listed at the top of this form. If you should decline to participate, it will not affect your therapeutic relationship with the investigators/facility.

**Questions and Concerns**
If you have any questions or concerns, please contact Dr. Dina Brooks at 416-978-1739 or Marla Beauchamp at 416-243-3600 Ext. 3665. This study has been approved by the Research Ethics Boards at West Park and Toronto Rehab. If you have any concerns regarding the ethics of the study, please contact Dr. Ron Heslegrave, Joint Research Ethics Board Chair, at Bridgepoint Health, 14 St. Matthews Rd., Toronto, ON, M4M 2B5 (416) 461-8252 Ext. 2343.
Consent
The researcher whose name appears below has explained the study to me. I have also read the information above that the researcher has given me. I understand the possible risks/discomforts, and I that my participation in this study is voluntary and that I can stop being a part of this study at any time for any reason without affecting my therapeutic relationship with the investigators/facility. I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I agree to be part of this study.

__________________________________________  ___________________________
Participant’s Name                            Participant’s Signature

__________________________________________  ____________________________  ____________
Name of Person Obtaining Consent              Signature of Person Obtaining consent  Date
Participant Information and Consent Form

Study title: A Randomized Controlled Trial of Balance Training in Individuals with COPD

The investigation team includes the following:
- Dr. Dina Brooks, Research Associate, West Park (416 978 1739)
- Dr. Roger Goldstein, Respirologist, West Park (416 243 2179)
- Marla Beauchamp, PhD Student, West Park (416 243 3600 ext. 3665)
- Tania Janaudis-Ferreira, Postdoctoral Research Fellow, West Park (416 243 3600 ext 2518)

Introduction
We are trying to develop a balance training program for patients with COPD who may be at risk of falling and to test the effects of this training program on measures of balance and fall risk.

Process
If you agree to participate in this study, one of the investigators will collect information from your medical notes about your lung disease and exercise capacity. Specifically, we will record the results of your most recent breathing tests and walking tests that you did at West Park as well as the medications that you are taking.

For this study, you will be asked to attend two 1.5-hour testing sessions. In addition, you may be asked to spend time (30 minutes) with an instructor 3 times a week, during your classes for pulmonary rehabilitation.

Testing sessions
The first testing session will take place in your first few days of respiratory rehabilitation. The second testing session will take place on completion of the pulmonary rehabilitation program. Each testing session will last about 1.5 hours. You will be asked to complete the following tasks under the supervision of an investigator:

- Clinical balance tests: This will involve performing a series of tasks designed to challenge your balance.
- Chair stand test: You will be asked sit down and stand up from a chair as many times as you can in 30 seconds.
- Complete questionnaires asking information about your balance confidence, health, and fall history.

Training program
You will be assigned to either “training group A” or “training group B”. Both groups will participate in the regular West Park Pulmonary Rehabilitation Program which includes both lower limb training and educational sessions. The only difference between the groups will be the type of balance exercises/activity training we will ask you to do. We expect one of these types of exercises/activity trainings to be more effective than the other for training balance but we do not know for sure and this is what the study will tell us. You will know which group you were allocated to at the end of the study. An investigator will show you exercises that the other group was doing and write a home program for you based on these exercises if you would like.
Depending on which group you are assigned to, you may be asked to do a part of your exercise training with one of our study team members. These training sessions will last approximately 30 minutes and will be given by a physiotherapist three times per week in a different location than your regular West Park exercise sessions.

**Discomforts and Risks**
You may feel generally tired from the testing and training sessions. The balance tests and training methods used in this study are commonly used in rehabilitation programs in Canada. However, because we will be challenging your balance during the testing and training sessions, there is a small risk of falling. To minimize this risk a registered physiotherapist will be present during all testing and training sessions and we will be watching you closely so that we may provide any necessary assistance should you lose your balance.

As part of your participation in this study we require that you inform Marla Beauchamp at 416-243-3600 ext. 3665 if you experience any symptom that concerns you either during the tests or during the day following the tests. Specifically, you must tell the researcher if you experience any dizziness, irregular heartbeat, upset stomach, chest, neck or arm pain. In the unlikely event that you suffer a physical injury as a direct result of participating in the study, you will obtain medical care in the same manner as you would ordinarily obtain any other medical treatment.

**Benefits**
You may not directly benefit from participating in this study. However, we hope that the results of this study will help health care workers to identify if balance training can be used to minimize the risk of falls in people with COPD.

**Data Storage and Confidentiality**
All information collected during this study will be stored for 7 years in a safe, secure and locked location at West Park. At the end of 7 years, all information collected during this study will be destroyed (paper will be shredded and electronic documents will be deleted). We will take care to protect your confidentiality. Your name and identifying personal information will not be used on any of the data collection forms. In addition to the researchers involved in this study, individuals from regulatory authorities or the Research Ethics Board who are involved in monitoring and auditing of studies may be granted access to the information collected during this study.

**Voluntary Participation**
Your participation in this study is completely voluntary. You are able to withdraw at any time for any reason before, during, or after the study. Should you wish to withdraw from this study please contact one of the members of the research team listed at the top of this form. If you decide not to participate, it will not affect your therapeutic relationship with your doctor, the investigator or the facility.

**Questions and Concerns**
If you have any questions or concerns, please contact Dr. Dina Brooks at 416-978-1739 or Marla Beauchamp at 416-243-3600 Ext. 3665. This study has been approved by the Joint Research Ethics Board. If you have any concerns regarding the ethics of the study, please contact Dr. Ron Heslegrave, Joint Research Ethics Board Chair, at Bridgepoint Health, 14 St. Matthews Rd., Toronto, ON, M4M 2B5 (416) 461-8252 Ext. 2343.
Consent
The researcher whose name appears below has explained the study to me. I have also read the information above that the researcher has given me. I understand the possible risks/discomforts, and I that my participation in this study is voluntary and that I can stop being a part of this study at any time for any reason without affecting my therapeutic relationship with the investigators/facility. I have had the opportunity to ask questions about the study and any questions that I have asked have been answered to my satisfaction. I agree to be part of this study.

____________________  ______________________
Patient name          Patient signature

____________________  ______________________
Person obtaining consent  Person obtaining consent signature

____________________
Today’s date
## Appendix 3- Balance Intervention Exercises

<table>
<thead>
<tr>
<th>Stance exercises (static &amp; dynamic)</th>
<th>Transition exercises</th>
<th>Gait exercises</th>
<th>Functional strength exercises</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1. Narrow Stance</strong></td>
<td><strong>1. Sit to stand</strong></td>
<td></td>
<td><strong>1. Lower leg</strong></td>
</tr>
<tr>
<td>- Standing without support</td>
<td>- Chair with arms (5 reps)</td>
<td>- Tandem walk with light finger support</td>
<td></td>
</tr>
<tr>
<td>- Eyes closed (time 20sec)</td>
<td>- Fast speed chair with arms (time 30sec)</td>
<td>- Tandem walk no U/E support</td>
<td></td>
</tr>
<tr>
<td>- Reaching beyond BOS</td>
<td>- Chair with no arms (5 reps)</td>
<td>- Sideways walk</td>
<td></td>
</tr>
<tr>
<td>- Throw and catch ball</td>
<td>- Fast speed chair with no arms (time 30sec)</td>
<td>- Backwards walk</td>
<td></td>
</tr>
<tr>
<td>- Count backwards</td>
<td>- Low seat</td>
<td>- Tandem walk while spelling words</td>
<td></td>
</tr>
<tr>
<td>- Perturbations</td>
<td>- Sit to stand and pick up objects from floor</td>
<td>- Backwards walk while naming words starting with ‘W’</td>
<td></td>
</tr>
<tr>
<td><strong>2. Tandem stance</strong></td>
<td><strong>2. Sit on floor and stand up</strong></td>
<td></td>
<td>- Low-level obstacle course (noodles, foam, block)</td>
</tr>
<tr>
<td>- Tandem stance (time 30sec)</td>
<td>- With chair for descent and ascent</td>
<td>- High-level obstacle course (wobble board, Bosu ball, widely spaced noodles)</td>
<td></td>
</tr>
<tr>
<td>- Reaching beyond BOS</td>
<td>- No chair</td>
<td><strong>2. Walking in open space</strong></td>
<td></td>
</tr>
<tr>
<td>- Throw and catch ball</td>
<td>- Timed (safely and quickly)</td>
<td>- Kick a ball</td>
<td></td>
</tr>
<tr>
<td>- Spell backwards</td>
<td></td>
<td>- Fast walking (over 6m)</td>
<td></td>
</tr>
<tr>
<td>- Eyes closed (time 20sec)</td>
<td></td>
<td>- Change in speed</td>
<td></td>
</tr>
<tr>
<td>- Perturbations</td>
<td></td>
<td>- Quick direction change</td>
<td></td>
</tr>
<tr>
<td><strong>3. One-legged stance</strong></td>
<td><strong>3. Stairs</strong></td>
<td></td>
<td>- Walk &amp; look</td>
</tr>
<tr>
<td>- One-leg stand (time 30 sec)</td>
<td>- Tap 10x with arm support</td>
<td>- Walk &amp; count backwards</td>
<td></td>
</tr>
<tr>
<td>- Visual targets (turn &amp; look)</td>
<td>- Tap 10x any speed</td>
<td>- Walk &amp; recite months of the year</td>
<td></td>
</tr>
<tr>
<td>- Spell names with foot</td>
<td>- Tap 10x fast speed</td>
<td>- Walk over obstacles</td>
<td></td>
</tr>
<tr>
<td>- Throw and catch ball</td>
<td>- Tap and count backwards by 2s</td>
<td></td>
<td><strong>1. Upper leg</strong></td>
</tr>
<tr>
<td>- Leg out to the side</td>
<td>- Tap and arm lift</td>
<td></td>
<td>- Mini-squats 2 x 10 reps</td>
</tr>
<tr>
<td>- Eyes closed</td>
<td></td>
<td></td>
<td>- Squats (arm support) 2 x 10 reps</td>
</tr>
<tr>
<td><strong>4. Stand on uneven surfaces</strong></td>
<td><strong>3. Core strengthening on ball</strong></td>
<td></td>
<td>- Squats (no arm support) 10 reps</td>
</tr>
<tr>
<td>- Foam (20 sec)</td>
<td>- Sit on ball &amp; hold 1 min</td>
<td>- Step-ups (arm support) 2 x 10 reps</td>
<td></td>
</tr>
<tr>
<td>- Foam + eyes closed (20 sec)</td>
<td>- Sit and weight shift</td>
<td>- Side stepping with theraband 2 x 10 steps</td>
<td></td>
</tr>
<tr>
<td>- Foam + narrow stance (20 sec)</td>
<td>- Sit on ball &amp; tap toes</td>
<td></td>
<td><strong>2. Walking in parallel bars</strong></td>
</tr>
<tr>
<td>- Foam + one legged stance</td>
<td>- Sit on ball &amp; knee raise</td>
<td>- Kick a ball</td>
<td></td>
</tr>
<tr>
<td>- Foam + reaching</td>
<td>- Sit on ball &amp; arm lifts</td>
<td>- Fast walking (over 6m)</td>
<td></td>
</tr>
<tr>
<td>- Foam + catch ball</td>
<td>- Sit on ball &amp; move arms + legs</td>
<td>- Change in speed</td>
<td></td>
</tr>
<tr>
<td>- Wobble board (time max)</td>
<td></td>
<td>- Quick direction change</td>
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<tr>
<td>- Wobble board + “dance”</td>
<td></td>
<td>- Walk &amp; look</td>
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<tr>
<td>- Wobble board + count</td>
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<td>- Walk &amp; count backwards</td>
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<tr>
<td>- Bosu ball/disc (time max)</td>
<td></td>
<td>- Walk &amp; recite months of the year</td>
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<tr>
<td>- Bosu ball (catch ball)</td>
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<td>- Walk over obstacles</td>
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<tr>
<td>- Bosu ball + dual task</td>
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<td><strong>Functional strength exercises</strong></td>
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</tbody>
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1. Sit to stand
   - Chair with arms (5 reps)
   - Fast speed chair with arms (time 30sec)
   - Chair with no arms (5 reps)
   - Fast speed chair with no arms (time 30sec)
   - Low seat
   - Sit to stand and pick up objects from floor
   - Sit to stand & “stop”
   - Sit to stand & walk with head turns
   - Sit to stand carrying basket/ball

2. Sit on floor and stand up
   - With chair for descent and ascent
   - No chair for either descent or ascent
   - No chair
   - Timed (safely and quickly)

3. Stairs
   - Tap 10x with arm support
   - Tap 10x any speed
   - Tap 10x fast speed
   - Tap and count backwards by 2s
   - Tap and arm lift

1. Walking in parallel bars
   - Tandem walk with light finger support
   - Tandem walk no U/E support
   - Sideways walk
   - Backwards walk
   - Tandem walk while spelling words
   - Backwards walk while naming words starting with ‘W’
   - Low-level obstacle course (noodles, foam, block)
   - High-level obstacle course (wobble board, Bosu ball, widely spaced noodles)

2. Walking in open space
   - Kick a ball
   - Fast walking (over 6m)
   - Change in speed
   - Quick direction change
   - Walk & look
   - Walk & count backwards
   - Walk & recite months of the year
   - Walk over obstacles

1. Lower leg
   - Toe raises (arm support) 2 x 10 reps
   - Toe raises (no arm support) 10 reps, 3 sec holds
   - Heel raises (arm support) 2 x 10 reps
   - Heel raises (no arm support) 2 x 10 reps
   - Walk on toes
   - Walk on heels

2. Upper leg
   - Mini-squats 2 x 10 reps
   - Squats (arm support) 2 x 10 reps
   - Squats (no arm support) 10 reps
   - Step-ups (arm support) 2 x 10 reps
   - Step-ups (no arm support) 2 x 10 reps
   - Lateral step ups (arm support) 2 x 10 reps
   - Lateral step ups (no arm support) 2 x 10 reps

3. Core strengthening on ball
   - Sit on ball & hold 1 min
   - Sit and weight shift
   - Sit on ball & tap toes
   - Sit on ball & knee raise
   - Sit on ball & arm lifts
   - Sit on ball & move arms + legs