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Text word count: 2888

Abstract word count: 244

Running head: Balance MCID in COPD

Interpretability of Change Scores in Measures of Balance in People with COPD

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The authors have no conflicts of interest to declare.

Funding support: Marla Beauchamp is supported by a fellowship from the Canadian Institutes of Health Research, Roger Goldstein by the University of Toronto, National Sanitarium Association Chair in Respiratory Rehabilitation Research and Dina Brooks by a Canada Research Chair.

An abstract of this work was presented at the 2015 American Thoracic Society conference in Denver, Colorado.

ABSTRACT

Background: Balance deficits and an increased fall risk are well documented in individuals with COPD. Despite evidence that balance training can improve performance on clinical balance tests their Minimal Clinically Important Difference (MCID) is unknown. The aim of this study was to determine the MCID of the Berg Balance Scale (BBS), Balance Evaluation Systems Test (BESTest) and Activities-specific Balance Confidence Scale (ABC) in COPD patients undergoing pulmonary rehabilitation.

Methods: We performed a secondary analysis of data from two studies of balance training in COPD (n=55). The MCID for each balance measure was estimated using the following anchor and distribution-based approaches: 1) mean change scores on a patient-reported global change in balance scale; 2) optimal cut-point from receiver operating curves (ROC); and 3) the minimal detectable change with 95% confidence (MDC₉₅).

Results: Data from 55 patients with COPD (mean age 71.2 ± 7.1 ; mean FEV₁ 39.2 ± 15.8 percent predicted) were used in the analysis. The smallest estimate of MCID was from the ROC curve method. Anchor-based estimates of the MCID ranged from 3.5 to 7.1 for the BBS, 10.2 to 17.4 for the BESTest and 14.2 to 18.5 for the ABC scale; their MDC₉₅ values were 5.0, 13.1 and 18.9, respectively.

Conclusion: Among COPD patients undergoing pulmonary rehabilitation, a change of 5 to 7 points for the BBS, 13 to 17 points for the BESTest and 19 points for the ABC scale is required to be both perceptible to patients and beyond measurement error.

Abbreviations

ABC	Activities-Specific Balance Confidence Scale
BBS	Berg Balance Test
BESTest	Balance Evaluation Systems Test
COPD	Chronic Obstructive Pulmonary Disease
FEV1	Forced expiratory volume in one second
FVC	Forced vital capacity
GRC	Global rating of change scale
MCID	Minimal clinically important difference
MDC ₉₅	Minimal detectable change with 95% confidence
PR	Pulmonary rehabilitaion
ROC	Receiver Operating Characteristic Curve

INTRODUCTION

Poor balance is a key modifiable risk factor for falls in older adults.¹ Given the negative health sequelae and high economic burden of falls,² fall prevention is a major healthcare priority. Exercise with balance-specific training has been shown to be the only effective intervention for successfully reducing both the rate and risk of falling.³ Accordingly, there is a large body of evidence devoted to examining exercise interventions for improving balance in older adults and in clinical populations with established balance impairment.

People with COPD have well-documented deficits in balance,⁴⁻¹² and several recent studies have noted a high risk of falls in this population.¹³⁻¹⁵ In a study of more than 16,000 participants, the presence of COPD was the only chronic condition, out of the 13 examined, that predicted falls.¹⁵ Individuals with COPD have an estimated annual fall rate of 1.2 per person, a five-fold higher rate than that reported for older adults.¹⁴ We have previously shown that balance training incorporated into pulmonary rehabilitation (PR) can improve performance on measures of balance that are associated with fall risk.¹⁶ Therefore, it is important to establish the amount of improvement that can be considered important to patients and beyond measurement error. This information is critical for informing clinical practice and development of fall prevention strategies in this population.

A recent systematic review identified the Balance Evaluation Systems Test (BESTest), the Berg Balance Scale (BBS) and the Activities-Specific Balance Confidence (ABC) scale as recommended tools for assessing balance in patients with COPD, based on their breadth of content and validity.¹⁷ However, this review highlighted that there was insufficient research

examining their responsiveness in COPD. The aim of this study was to determine the Minimal Clinically Important Difference (MCID) of the BBS, BESTest and ABC scale in patients with COPD enrolled in PR. Given the inherent strengths and weaknesses of distribution and anchor-based methods for determining responsiveness,¹⁸ we used a combination of techniques to determine a range of MCID values that can be applied in specific clinical contexts.

METHODS

We performed a secondary analysis of data from 55 subjects who participated in either a randomized controlled trial of balance training¹⁶ (n=36) (NCT01424098) or a study of knowledge translation of balance training into PR (n=19) (NCT02080442).¹⁹ Both studies were conducted at the same centre and used identical procedures for screening and assessing patients. Details of the balance training, study methods and outcomes used have been previously published.¹⁶ Briefly, the studies both involved individuals with COPD, enrolled in PR, who met one or more of three criteria: 1) a self-reported problem with their balance; 2) a history of one or more falls in the last 5 years; or 3) a report of a recent trip or loss of balance that resulted in a near fall. Those with co-morbid conditions that might affect communication, balance or safety were excluded. Patients assigned to the intervention group in the RCT and those in the knowledge translation study underwent 30 minutes of balance training three times a week for 6 weeks in conjunction with PR. Individuals assigned to the control arm of the RCT received only PR. All the outcome measures were collected prior to and on completing rehabilitation by the same rater and all assessments were conducted by physiotherapists experienced in administering the balance tests. All subjects gave written informed consent and the studies were approved by

the West Park Healthcare Centre and Bridgepoint Health Joint Research Ethics Board (13-011-WP).

Balance measures

Berg Balance Scale (BBS): The 14-item BBS²⁰ is a commonly used measure of balance in older adults. Discrete physical tasks such as changes in body position, reaching, stair tapping and standing on one leg are evaluated on a scale from 0 (unable/unsafe) to 4 (independent/safe). Total scores on the BBS range from 0 to 56 with higher scores for better balance control. Evidence supports the BBS's construct validity¹⁷ and sensitivity to change²¹ following PR in individuals with COPD. Test-retest reliability and predictive validity for fall risk has been demonstrated in community-dwelling older adults.²²

The Balance Evaluation Systems Test (BESTest): The BESTest is a 36-item comprehensive balance measure that evaluates six underlying postural control systems: biomechanics, stability limits/verticality, anticipatory control during postural transitions, reactive control strategies, weighting of sensory information, and stability during gait.²³ Total scores range from 0 to 100% with higher scores indicating greater balance ability. Evidence supports the BESTest's construct validity in COPD^{5,17} and sensitivity to change, test-retest reliability and concurrent validity in adults with and without balance disorders.^{23,24}

The Activities-Specific Balance Confidence (ABC) scale: Patients are asked to rate their confidence in maintaining their balance during 16 specific activities requiring progressively increased balance control on an 11-point scale.²⁵ Examples of tasks include standing on a chair

and walking on an icy sidewalk. Overall scores range from 0 to 100% with higher scores indicating greater balance confidence. The ABC scale has good test-retest reliability and predicts falls in older adults residing in the community.^{22,25} In patients with COPD, the ABC scale has demonstrated construct validity as well as criterion validity for falls.^{4,17}

Global rating of change scale (GRC): The GRC was administered only at 6-weeks; participants were asked to rate the amount of change they experienced in their balance over the 6-week period on a 5-point Likert scale with the following options: much better; a little better; no change; a little worse; or much worse. We selected a 5-point GRC to facilitate discrimination between categories of change and to be consistent with the number of categories (5-7) previously recommended for such scales.²⁶

Analysis

To optimally determine increments of meaningful change, a combination of distribution- (i.e., statistical distributions of change and reliability) and anchor-based approaches (i.e., external criterion that reflects a patient's perspective) are recommended.^{18,27} The following methods were used to calculate meaningful change estimates for each balance measure:

- 1) The mean change scores on the balance measures were calculated for each answer on the GRC.
- 2) The Minimal Detectable Change with 95% confidence (MDC_{95}) refers to the smallest amount of change that falls outside of measurement error and was calculated as $1.96 * \sqrt{2} * SEM$.²⁷ The SEM is the standard error of measurement and was calculated as $S_b * \sqrt{(1-r)}$, where S_b is the standard deviation of our sample at baseline and r is the test-

retest reliability coefficient. As there are no reliability studies of the balance measures specifically in COPD, we used test-retest reliability coefficients derived from other clinical populations with similar baseline balance ability and age as our sample.^{24,25,28}

- 3) The optimal cut-point from a receiver operating characteristic curve (ROC) was used to determine the MCID using the balance measures as diagnostic tests for discriminating between improved and unchanged patients based on the GRC. We performed this analysis twice: 1) including those with any improvement (GRC: much better, little better) vs. those who were unchanged (GRC: no change) and 2) including those with a large improvement (GRC: much better) vs. those with small or no improvement (GRC: little better, no change). The data point closest to the upper left corner of the curve (i.e., cut-point that optimizes both sensitivity and specificity) was chosen as the optimal threshold for detection of a change, with the area under the curve (AUC) of the ROC reflecting the measure's accuracy. An AUC > 0.7 was considered sufficient for discrimination.²⁹

Given that those with lower starting scores on the balance tests have higher change potential than those with scores near the ceiling, we also conducted a sensitivity analysis to examine the effect of the baseline score on the MCID. Among those with a self-reported improvement on the GRC, we compared the change scores of patients with low starting balance scores (lowest tertile) with change scores of patients with higher baseline scores (highest tertile). Spearman correlation coefficients were computed to examine the association between GRC score and change in the balance measures. Data were analysed using SPSS 22.0 for Windows (SPSS Inc, Chicago, USA). A sample size of 50 or more was deemed adequate for determining the MCID based on recommended guidelines.²⁹

RESULTS

Data from 55 patients with COPD were used in the analysis. Their characteristics are summarized in Table 1. On average, patients were 71 years of age with a mean FEV1 of 39% predicted; 38% of the sample used supplemental oxygen.

After 6-weeks of usual or balance-enhanced PR, 28 patients (51%) rated themselves as “much better”, 18 (33%) as “a little better” and 9 (16%) as unchanged. The associations between change in the balance measures and the GRC scale were 0.5 for the BBS and BESTest (both $p < 0.001$) and 0.2 for the ABC ($p = 0.08$). At baseline, there were no floor or ceiling effects on any of the measures, however at 6 weeks 12 patients performed at the ceiling for the BBS (21.8%) and 3 for the ABC scale (5.5%). Table 2 shows the distribution of scores on the BBS, BESTest and ABC scale at baseline and after 6 weeks for patients who rated themselves as “much better”, “a little better” or “unchanged”. For all measures, an improvement corresponds to a positive change score.

The MCID values determined by each of the three methods for the balance measures are shown in Table 3. The magnitude of the MCID was dependent on the method used with the ROC curve analysis yielding the smallest values and the MDC_{95} and mean change score corresponding to “much better” on the GRC yielding the largest values. Therefore, a range of MCID values for each measure could be determined (Table 3). The AUCs generated from the ROC analyses for the BBS and BESTest showed adequate discrimination between those reporting a large improvement and those with small or no changes: $AUC = 0.74$ (95%CI 0.60-0.87) and $AUC = 0.76$

(95%CI 0.62-0.89), respectively (see Figure 1). Acceptable AUCs were also observed for discriminating between those with any improvement and unchanged patients for the BBS (AUC=0.80 (95%CI 0.66-0.94)) and BESTest (AUC=0.86 (95%CI 0.74-0.98)). The AUCs for the ABC scale were not significantly better than chance and therefore an MCID using ROC analysis is not presented for this scale.

Results of the sensitivity analysis are shown in Table 4. Among those with a self-reported improvement on the GRC, individuals with baseline balance scores in the lowest tertile showed higher mean change scores compared to those with starting scores in the highest tertile.

DISCUSSION

Balance deficits are increasingly recognized as an important functional limitation in individuals with COPD.⁴⁻¹¹ In fact, the recently updated American Thoracic Society (ATS)/European Respiratory Society (ERS) Statement on PR recommended expanding the scope of outcomes assessment in COPD to include balance.³⁰ To our knowledge, this is the first study to identify clinically important increments of change for measures of balance in people with COPD. We present a range of MCID values for three recommended balance measures that can be used to enhance the interpretability of balance assessment in this population.

The choice of MCID value hinges on its definition. When a global rating scale of self-reported change is used as an anchor, some authors define minimal as a “small” or “slight” change on the anchor whereas others use categories corresponding to “much” or a “good deal” of improvement.³¹ This highlights a critical issue in defining what constitutes a minimally

important improvement when using anchor-based approaches. Should the MCID be based on the magnitude of change or on its importance? Given this problem and the often cited limitation of using an un-validated patient reported scale as a gold-standard, we propose that the optimal MCID should be one that is both *perceptible* and *detectable*. Therefore, we favour also using a distribution-based approach, such as the MDC_{95} , as a complementary method for determining the MCID. The MDC_{95} corresponds to a threshold for improvement that can be considered true change beyond measurement error.²⁷ Triangulating the estimates from the anchor- and distribution-based methods in our study suggests that the MCID should be at least 5 points for the BBS, 13 points for the BESTest and 19 points for the ABC scale. Nonetheless, selection of the optimal MCID will depend on the specific clinical context. Based on the results of our sensitivity analysis, a smaller MCID value (i.e., a change that is perceptible to patients but not necessarily above measurement noise) might be chosen for individuals with high baseline balance scores. For those with relatively good balance, a “large” improvement may not be realistic and a small improvement could still be considered important.

Similar to other research,^{32,33} the ROC method yielded the smallest MCID estimates in this study. An advantage of the ROC method is that the cut-off point is based on both unchanged and improved patients and thus uses all possible data.³² However, use of this approach can result in small MCID estimates that may not be beyond measurement noise. This is particularly true if data are not normally distributed resulting in curves that are not smooth and potentially erratic cut-points,³³ as was the case for the ABC scale in this study. Another challenge is to decide whether any perceived improvement should be considered as the diagnostic standard or whether this should be restricted to only a large improvement. To address this issue we included the

ROC curve MCID estimates for both categories of improvement (Table 2). It is re-assuring that for the BBS and BESTest the MCID estimate based on the ROC for “much improved” aligned well with the MDC₉₅ and the mean change in balance corresponding to a rating of “a little better”.

Previous reports on responsiveness of the BBS, BESTest and ABC scales in other clinical populations have focused on distribution-based approaches such as the MDC₉₅. The values we report are generally within the range of those previously reported for older adults and individuals with neurological conditions (3-7 points for the BBS, 9-16 for the BESTest and 13 for the ABC).^{23,24,34,35} For the BBS, it is well accepted that the MDC₉₅ varies across the scale with higher values of change being required for lower baseline starting scores.³⁵ We note a similar trend when using the GRC, in which individuals with baseline balance in the lowest tertile required larger amounts of change to be perceptible (table 4). This trend was apparent for all three balance measures, but most pronounced for the BBS and ABC scale, possibly because of a ceiling effect which has been well documented for the ABC and BBS in the gerontology literature.^{35,36} Although the patients in this report did not score at the ceiling for any of the balance measure at baseline, 18 patients had initial scores ≥ 51 out of 56 on the BBS. In these individuals, the BBS is unlikely to be able to detect a change in balance, even if a real change has occurred. The BESTest is recommended in these situations. It also has the added advantage of being able to guide treatment planning as it is the only standardized balance test that comprehensively assesses all components of balance.³⁷

An important strength of our study is the use of a combination of distribution- and anchor-based approaches for determining the MCID. In addition, our GRC scale had strong face validity as we specifically asked patients to rate their change in *balance* over 6 weeks. A possible limitation to our methodology is recall bias, which has been identified as limiting the validity of a retrospective GRC when compared with a prospective global measure.³⁸ However the latter study was over a 6-month period and evaluated health-related quality of life, whereas ours was over 6 weeks and evaluated balance, a more tangible construct. Of note, the ABC scale is a measure of balance confidence and not balance performance, and while the two constructs are related, they cannot be considered equivalent. This is reflected by the lower association between change in the ABC score and the GRC. A minimum correlation between anchor and change in outcome measure of 0.3 to 0.35 has been recommended.¹⁸ Whereas an association of 0.5 was noted for the BBS and BESTest, the association for the ABC scale was only 0.2. Use of other clinical anchors such as falls and health care utilization as well as prospective measures³⁸ may help refine the estimation of the MCID for the balance measures. A limitation of our distribution-based approach is that the reliability coefficients used as part of the MDC_{95} calculation were taken from test-retest reliability studies in other clinical populations. However, given that the samples were of a similar age and balance ability as our subjects, and that analysis of preliminary pilot data from our sample yielded similar test-retest parameters (data not shown), this likely had a minimal effect on our MDC estimates. Another study limitation is that as no patients reported a decline in balance, we were only able to identify the MCID for improvement; it is possible that a different threshold of change would have been identified for deterioration. Finally, the MCID values derived from this study may not be generalizable to COPD patients with milder disease or those who are not clinically stable.

In summary, our findings indicate that for patients with moderate to severe COPD undergoing PR, a change of 5 to 7 points for the BBS, 13 to 17 points for the BESTest and 19 points for the ABC scale is required to be both perceptible to patients and beyond measurement error. These values can be used to interpret the outcomes of clinical interventions designed to improve balance and fall risk in individuals with COPD.

FUNDING

Marla Beauchamp is supported by a fellowship from the Canadian Institutes of Health Research, Roger Goldstein by the University of Toronto, National Sanitarium Association Chair in Respiratory Rehabilitation Research and Dina Brooks by a Canada Research Chair.

CONTRIBUTORS

All authors contributed to the design, interpretation of data and critical revision of manuscript. MKB and SLH contributed to the acquisition of data. MKB conceived the idea, performed the analysis and drafted the paper; she is the guarantor.

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Figure 1. Receiver operating characteristic curves (ROC) for a) the Berg Balance Scale (BBS) and b) the Balance Evaluation Systems Test (BESTest) for discriminating between those with a large perceived improvement and those with little or no change. The data point closest to the upper left corner of the curve, which maximizes both sensitivity and specificity, was chosen as the optimal threshold. The area under the curve (AUC) of the ROC reflects the measure's accuracy.

Table 1 Subject characteristics at baseline (n =55)

Characteristic	Mean \pm SD
Age	71.2 \pm 7.1
BMI	26.7 \pm 8.1
FEV ₁ % predicted	39.2 \pm 15.8
FEV ₁ /FVC % predicted	42.9 \pm 14.6
MRC dyspnea	3.6 \pm 1.2
No. of women, %	31, 56.4
No. on oxygen, %	21, 38.2
Patients 'much better' (n,%)	28, 50.9
Patients 'a little better' (n,%)	18, 32.7
Patients unchanged (n,%)	9, 16.4

Data are mean change \pm standard deviation unless otherwise indicated. BMI = body mass index;

FEV₁ = forced expiratory volume in one second; FVC = forced vital capacity; MRC = Medical

Research Council.

Table 2 Mean scores at baseline and after 6 weeks for the three balance measures arranged by global rating of change scale

	Measure	Baseline	6 weeks	Change	Percent change from baseline
BBS	Much better	46.5 ± 6.3	53.6 ± 2.6	7.1 ± 5.3	17.4 ± 17.1
	A little better	45.4 ± 6.3	50.2 ± 4.4	4.8 ± 6.1	12.5 ± 18.0
	Unchanged	49.7 ± 6.5	50.4 ± 5.4	0.8 ± 3.6	2.2 ± 7.7
BESTest	Much better	65.2 ± 13.0	82.6 ± 7.7	17.4 ± 8.3	30.9 ± 24.0
	A little better	62.8 ± 13.4	76.4 ± 12.0	12.6 ± 10.5	22.7 ± 22.6
	Unchanged	76.3 ± 12.4	80.8 ± 10.3	4.4 ± 5.4	6.7 ± 7.9
ABC scale	Much better	60.2 ± 24.5	78.8 ± 14.8	18.5 ± 21.9	62.8 ± 101.4
	A little better	64.1 ± 23.8	78.2 ± 14.4	14.2 ± 16.7	40.8 ± 77.7
	Unchanged	85.1 ± 12.2	89.1 ± 8.2	4.0 ± 5.4	5.7 ± 8.7

Data are mean change ± standard deviation unless otherwise indicated. BBS= Berg Balance Scale; BESTest = Balance Evaluation Systems Test; ABC = Activities-Specific Balance Confidence

Table 3 Minimal Clinically Important Difference (MCID) values for the three balance measures assessed using three different approaches: mean change, MDC₉₅ and ROC curve cut-off value

Measure	Approach	MCID	
BBS	MDC ₉₅	5.0	
	ROC curve	A little or much better	3.5
		Much better	4.5
	Mean change	A little better	4.8
		Much better	7.1
	Overall range		3.5-7.1
BESTest	MDC ₉₅	13.1	
	ROC curve	A little or much better	10.2
		Much better	11.1
	Mean change	A little better	12.6
		Much better	17.4
	Overall range		10.2-17.4
ABC scale	MDC ₉₅	18.9	
	ROC curve	N/A*	
	Mean change	A little better	14.2
		Much better	18.5
	Overall range		14.2-18.9

Data are mean change \pm standard deviation unless otherwise indicated. MDC₉₅= minimal detectable change with 95% confidence; ROC = receiver operating characteristic curve; BBS= Berg Balance Scale; BESTest = Balance Evaluation Systems Test; ABC = Activities-Specific Balance Confidence.

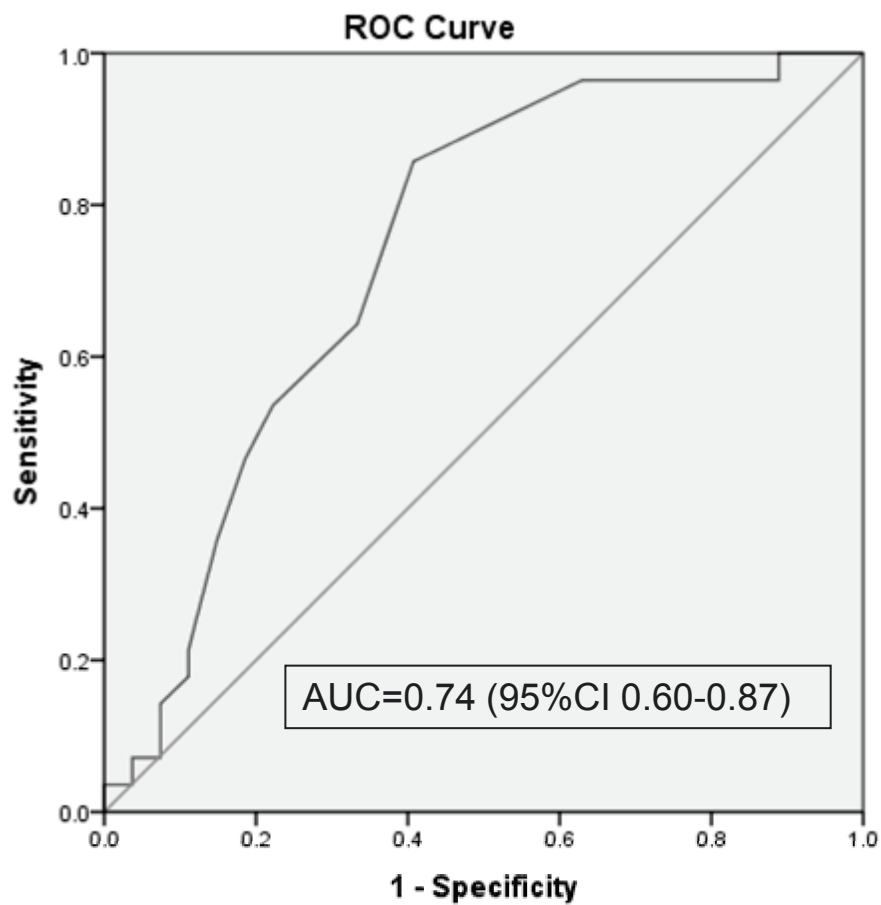
*Area under the curve was not significant.

Table 4. Influence of baseline balance score on the Minimal Clinically Important Difference based on the global rating of change scale

Measure	Baseline score	Mean change \pm SD for improved patients, (n)
BBS	Low	9.7 \pm 7.1, (18)
	High	2.2 \pm 2.7, (12)
BESTest	Low	21.4 \pm 10.2, (17)
	High	9.4 \pm 4.8, (10)
ABC scale	Low	32.5 \pm 20.4, (19)
	High	1.8 \pm 4.2, (11)

Notes: Data are presented for change scores based on lowest and highest tertiles of baseline scores. BBS= Berg Balance Scale; BESTest = Balance Evaluation Systems Test; ABC = Activities-Specific Balance Confidence.

a)



b)

