<u>Original article:</u> Reliability of Diaphragmatic Mobility Assessment Using a Real Time Ultrasound Among Non-Specific Low Back Pain.

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Abstract

Background and Objective: Ultrasound measurement of Diaphragmatic Mobility (DM) has been shown to be a reliable measurement tool among healthy subjects. However, the measures of reliability are needed prior to clinical use of this device among Non-Specific Low Back Pain (NS-LBP). Therefore, the aim of the study was to investigate the relative and absolute reliability of DM using Real Time Ultrasound (RTUS) among subjects with NS-LBP. **Materials and Methods:** Nine subjects with NS-LBP (23.33 ± 1.58) years old were recruited. A qualified examiner performed measurement of DM using RTUS by placing transducer on the right subcostal region in semi-fowler's position with 30 degree elevation of the trunk. The test-retest measures were re-assessed with 24 hour interval between sessions. **Results:** There was no systematic errors between the test-retest measures (p>0.05). Intra rater reliability showed ICC value of 0.92, which indicates an excellent reliability. The SEMs of the measurement was 2.56 mm and the MDC of 7.09mm. **Conclusion:** The RTUS for assessing DM provides an excellent intra-rater reliability which may be used as an assessment technique for clinical evaluation of DM in adults with NS-LBP. The SEMs and MDC reported may also allow for accurate interpretation of DM assessments in NS-LBP.

Keywords: diaphragm; low back pain; ultrasound

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Introduction

Non-specific low back pain (NS-LBP) is one of the major health problems with a prevalence of about 23% and this causes 11-12% of the population being disabled by LBP¹. One of the dysfunction which associates with LBP is respiratory dysfunction²⁻⁴. An earlier study which examined the function of diaphragm during postural limb activities in patients with LBP and healthy controls reported that those subjects who encountered chronic LBP appear to have

abnormal position and steeper slope of diaphragm². In this context, it has been postulated that alteration in mobility of diaphragm also may predispose to NS-LBP as because of postural instability. In order to evaluate the diaphragmatic mobility (DM), inclusions of reliable and quantifiable measurement tool is necessary to confirm the involvement of respiratory compromise among NS-LBP.

In relation to that, real time ultrasound (RTUS) is one of the modality of ultrasonography in which

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specific structures and functions of the diaphragm can be assessed. This equipment has been used as an outcome measure to measure diaphragmatic muscle shape, size and movement among healthy and various pathologic population such as hemiplegia and Chronic Obstructive Pulmonary Disease (COPD) subjects^{5,6}. In addition, RTUS has been introduced as an alternative to radiographic measurement for measuring diaphragm muscle shape, size and movement⁷. The RTUS equipment has been considered as a valid and one of the important outcome measure in the field of rehabilitation to evaluate muscle morphology and function among people with neuro musculoskeletal disorder such as low back pain⁸. Even though many studies have suggested involvement of respiratory component in NS-LBP^{9,10}, the DM component are understudied in the low back pain disorders with respect to RTUS.

In order to include RTUS as an outcome measure in LBP related trial, it is necessary to establish the reliability of the measurements. Reliability measures of RTUS for assessing DM has been established for healthy young adults¹¹. However, the measures of reliability measures are needed for clinical population. At present, to our knowledge there is no information for the reliability measures of the RTUS in assessing DM among NS-LBP. Therefore, the purpose of this study was to investigate the relative and absolute reliability of DM using RTUS which could be used to evaluate pathology and assess effects of treatment interventions among subjects with NS-LBP related clinical trials.

Materials and Methods

Study design and subjects

This study was a test-retest reliability and the testing was carried out at the Department of Medical Imaging, Faculty of Health Science of a public university. A total sample of 9 subjects was required to establish the significant α =0.05 and β =0.20, when one-way random effects model is used for estimating reliability as described by an earlier statistical study designs¹².

The selection criteria for the study were as follows: Inclusion criteria included, male and female participants aged between 18-55 years, diagnosed as NS-LBP, characterized by mechanical pain (pain that worsens with movement and improves with rest) for a period of at least 6 months between the last ribs and gluteal sulcus^{13,14}, symptoms of LBP at least three episodes for the last six months¹⁵, intensity of low back pain in the range of 2/10 - 7/10 by the Numerical Rating Scales (NRS), ratio of forced expiratory volume with forced vital capacity (FEV1%) > $80\%^{16}$. Exclusion criteria included, participants who had chronic respiratory disease such as bronchial asthma, Chronic Obstructive Pulmonary Disease (COPD) and pregnancy¹⁵, previous history of any surgeries to the lumbo-sacral spine¹⁵, numbness or neural signs on their leg(s), smokers who have been smoking one pack or less than 15 cigarettes per day and exsmokers who burned at least 100 cigarettes in their life time¹⁷.

The study protocol was approved by the institutional, research ethics committee. Prior to the data collection, written informed consent and health evaluation form was obtained from each individual participant.

Pulmonary Function Test

Parameters such as FEV1, FVC, and FEV1% were examined to ascertain that all the included subjects did not have any obstruction or restriction in the airways using spirometer (Pony FxCosmed, Italy). Details such as age, height and weight using SECA weight and height scale (Vogel & Halke, Hamburg, Germany). The test was carried as recommended in the earlier guidelines^{16,18}. Followed by the dynamic lung volume test ascertaining that the subjects did not have any abnormalities in the expiratory functional indices and other indices of the lung, the subjects were subjected to undergo evaluation of DM.

Evaluation of DM

B-Mode real time ultrasound device (HD 3; Philips Ultrasound, Bothell, USA) with 3.5 MHz convex transducer was used to detect DM. A qualified person who is trained from medical imaging department with three years of experience performed the test. Participants were set in semi-fowler's position with the head end elevated to 30 degree. Then the transducer was placed over the right subcostal region with the striking angle of the ultrasound to the craniocaudal axis to detect left portal vein branch. Baseline values for each position were marked on the image using the cursor and the subjects were required to perform required breathing to mark the second point on the image. The distance between these two points corresponded to right hemi diaphragmatic mobility in millimeters and this method of assessment has been validated and used in previous studies^{7,19}. Measurement were carried out for three times and the highest value was taken for the each session. A time period of 24 hours was given between two session of assessment to assess the reliability of the measurements.

Statistical analysis

The data were analyzed with the SPSS program

for windows, version 21.0. Distribution of DM are presented as mean \pm standard deviation. The average of test days and the mean differences from test session 1 to test session 2 were presented. DM demonstrated a normal distribution based on Kolmogorov-Smirov test with p<0.05. Since, the data of DM was normally distributed, the parametric test was opted. Paired t-test were used to test whether there was a systematic difference between the test measures. Relative reliability is the degree to which the test's ability to differentiate between the participants. In order to assess the relative reliability of DM, intra-class correlation coefficient [ICC (3, 1)] was opted with the corresponding 95% confidence interval (95% CI). Absolute reliability is the degree to which the test's ability to differentiate on different occasions. In order to assess the absolute reliability, coefficient of variation (CV), standard error of measurements (SEMs), minimal detectable change (MDC) were calculated. The CV, SEMs, MDC were calculated manually as described by earlier methods²⁰.

Table 1: Demographic characteristics of participants in the study

| n=9 23.33 ± 1.58 |
|---------------------|
| 23.33 ± 1.58 |
| - |
| 158.44 ± 9.36 |
| 59 ± 15.09 |
| 23.61 ± 6.31 |
| 1.11 ± 1.45 |
| 4.00 ± 1.32 |
| 103 ± 9.02 |
| 5 2 1 4 |

| | Test Mean ± SD | Retest Mean ± SD | Difference test - retest | Paired t-test (p-value) | ICC (CI 95%) | CV (%) | SEMs (mm) | MDC (mm) |
|------------|-------------------|---------------------|-----------------------------|----------------------------|----------------------------|-----------------|--------------|----------|
| DM (mm) | 42.76 ± 8.04 | 40.63 ± 7.22 | 2.73 ± 4.09 | .080 | 0.923 (0.657- 0.983) | 18.80- 17.77 | 2.56 | 7.09 |

<u>Results</u>

Descriptive statistics are presented in Table 1. The results of descriptive statistics on expiratory flow parameters revealed that none of the subjects had obstructive pattern of disease. The reliability of DM is presented in Table 2. Paired t-test revealed that there was no systematic difference between the test – retest measures with p>0.05. Relative reliability measure of ICC value was 0.92, which revealed it was > 0.8 and indicates it has excellent reliability²¹. Absolute reliability measures of SEM showed it has 2.56 mm and for MDC it was 7.09 mm, when assessing subjects for DM using real time ultrasound. **Discussion**

The present study aimed to determine absolute and relative reliability of DM using RTUS among NS-LBP. The findings showed DM assessment using RTUS among NS-LBP can be performed in a clinical setting with small measurement variation of one percent. The percentage change of DM can be considered to be "real changes" in NS-LBP. The difference in test-retest variation, when using the highest value of three consecutive measurement, was insignificant. This indicates that there was no difference between measurements on two occasion. Reliable DM measurement assessments make it possible to objectively determine whether changes in DM have occurred over time. Reliable DM assessment can also provide a screening tool for the detection of respiratory impairment which has been shown to be a predisposing factor for NS-LBP².

The present study is, to our knowledge, the first study investigating the test-retest measurement variation of DM among NS-LBP. In recent years, the component of DM on healthy and among pathological state such as LBP and Chronic obstructive pulmonary disease was initially studied. DM on NS-LBP has not been described previously in the literature and the present study shows that reliable measurements of this procedure can be obtained. However, the clinical relevance of DM and its possible implications on NS-LBP need to be investigated in future studies.

Direct comparison of the absolute reproducibility of DM to our knowledge, have not been investigated. Studies on the reproducibility of DM have shown relative reliability, with ICC value of 0.86 among healthy adults¹¹. This values can be compared indirectly with the present study results of ICC value of 0.92 and SEM value of 2.56 which could be considered acceptable for DM measurement using RTUS. This

indicates there were excellent reproducibility between the studies²¹. Therefore, it can be inferred that RTUS could be used as a modality for assessing DM. Even though, the ICC value was high in the present study, the CI interval was wide. The change in pain intensity, awareness of the study subjects are probably some of reasons which could have altered the values when reading were taken on two different days.

Coefficient of variation is a measurement of variability which can be used to measure the designated data measured on interval or ratio scale²⁰. It is quite evident from the present study that the dispersion is lower in the second variable than the first coefficient of variation values (18.80-17.77). Hence, it can be proposed that the DM values are more sensitive in detecting changes. From the clinical point of view, the MDC values suggest 7.09 mm changes are needed for DM as a result of changes in any sort of intervention measures. However, the results of the study need to be interpreted with caution as the study is preliminary in the field. The study has a limitation with only nine subjects as the study sample. Hence, future studies are to be carried out with larger sample size to standardize MDC values as well as to calculate mean change score and receiver operating characteristics curves for DM using RTUS.

Conclusion

The use of RTUS for assessing DM in clinical settings can be reliable instrument for the study of NS-LBP. The position of subject and the method of assessment provide reliable method to measure DM.

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