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Original Research Article

Reliability and validity of low cost pressure gauge manometer for measurement of respiratory muscle strength in healthy children: a cross-sectional study

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ABSTRACT

Background: Assessing respiratory muscle strength is an important aspect for clinical practice as well as in research. Multiple factors such as health status of an individual, level of physical fitness and postsurgical recovery of an individual have an influence on respiratory biomechanics. Respiratory muscle strength is determined by measuring maximal inspiratory pressure and maximal expiratory pressure. There is a need for a cost effective, portable, easy to build device specifically to estimate respiratory muscle strength. There is insufficient literature regarding the resources used to determine the respiratory muscle strength testing in children, hence this study aims to establish the reliability and validity of low cost pressure gauge manometer which could be a useful tool in measuring respiratory muscle strength in children.
Methods: A capsule sensing pressure gauge constructed according to the American thoracic society guidelines with a calibration of pressure between −200 cmH2O to +200 cmH2O. It was used to measure the respiratory muscle strength. The study was conducted on 300 healthy children.
Results: SPSS software was used for statistical analysis. Reliability of 0.92 and 0.97 was obtained for MIP and MEP respectively by test retest method. Construct validity index showed a validity score of 0.8 for MIP and MEP.
Conclusions: The results indicate that the low cost pressure gauge manometer can be used as a reliable and valid device to measure respiratory muscle strength in children.

Keywords: Capsule sensing pressure gauge, Children, Maximal inspiratory pressure, Maximal expiratory pressure, Pressure gauge manometer, Respiratory muscle strength

INTRODUCTION

The major role of muscles is to develop force and to shorten by contracting. In the thorax, force is generally estimated as pressure and shortening as lung volume change or displacement of structures of the thoracic cage. Therefore, the function of respiratory muscles can be quantified as measures of pressures, volumes, and its changes in accordance with time.[1]

Similar to assessing other aspects of the body, assessment of respiratory biomechanics and function is crucial in clinical practice, especially in cases with and neuromuscular conditions (NMDs) and respiratory disorders aiding in patient phenotyping, assessment of effectiveness of ongoing treatments and during follow-ups. The American Thoracic Society (ATS) and the European Respiratory Society (ERS) had published a statement on respiratory muscle testing in 2002 suggesting various methods to test respiratory muscle strength.[2]

Fields including respiratory biomechanics, respiratory muscle neurophysiology, and respiratory muscle imaging has advanced since the last two decades not only in healthy individuals but also in pediatrics and critically ill cases in the intensive care unit (ICU). The present focus is on assessment of respiratory muscles, its biomechanics during exercise and stressors involving the evaluation of the response of respiratory muscle to increased ventilatory demand.[2] According to literature, methods of assessment of strength of respiratory muscles be divided into invasive and noninvasive. The invasive methods include esophageal and gastric balloons which are used to measure esophageal, gastric, and transdiaphragmatic pressure. They are considered more dependable, but they involve delicate, lengthy, and unwelcome procedures. The noninvasive procedures include measurement of mouth or nasal pressure, do not cause discomfort, are generally preferred and are extensively applied and accepted.[3] Barometric pressure is the measured as the difference in pressures at a given point. This pressure represents the pressure in space. Gravitational force and shear stress cause differences in pressure in normal subjects. In the abdomen these changes in pressure are due to the effect of gravitational force. The pressure generated is 0.2 cmH2O cm-1 height and is related to lung viscosity.[4] Maximal inspiratory pressure (MIP) and minimal expiratory pressure (MEP) are methods of measuring maximal mouth pressures in the mouth. They are easy, accessible, and are noninvasive indicators of respiratory muscle strength.[5] They are easy methods to estimate global respiratory muscle strength in a clinical setting. These tests are voluntary, hence they require full subject cooperation. PImax is generally measured at residual volume and PEmax at total lung capacity(TLC). They record the maximum value of the best of three maneuvers that vary by less than 10%.[2] The cost of these devices are significantly lesser in comparison to whole-body plethysmograph, but they are still not so affordable for low- and middle income countries (LMIC).[6] The device being used in this study is constructed as per ATS guidelines. The gauge used in this study is a capsule-sensing pressure gauge that measures maximal mouth pressures (inspirations and expiratory pressure), which is established as the standardized method for assessment of respiratory muscle strength.

In recent days, awareness of respiratory muscle weakness as an influencing factor in recovery of an individual is rising. In a recent study, lowering of oral corticosteroid showed positive return of respiratory muscle strength and reduced dyspnea in cases with corticosteroid convinced myopathy after inspiratory muscle training post the assessment of MIP-MEP device.[7] Assessment of MIP is beneficial in assessing the progress of weaning off patients who are on mechanical ventilators and in prognosticating cardiac transplantation surgery in cases with congestive heart failure.

Evaluating respiratory muscles can be used in diagnostics and prognostics of various pediatric conditions. It can be used to estimate the deleterious effects, treatment progress and prognosis in neuromuscular and respiratory conditions. The relationship between decreased respiratory muscle strength and lung functions has been observed in patients with intermittent complications of respiratory system like infections and failure.

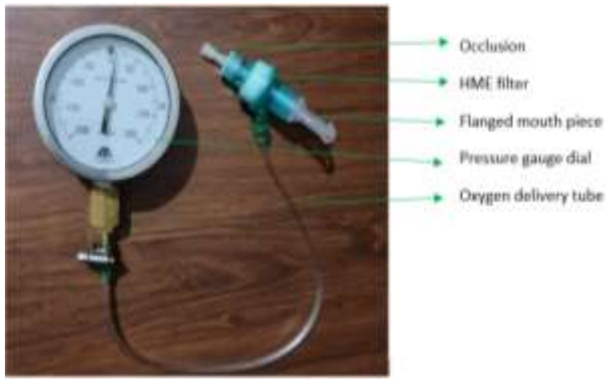

Figure 1: Capsule sensing low cost pressure gauge manometer used to measure maximal inspiratory and expiratory pressures in cmH2O.

This leads to a compromise in the ventilatory capacity, resulting in the onset of more severe morbidities. Hence, to estimate the impact of various clinical conditions and their effect on the lung functions, assessing respiratory muscle strength can be a helpful tool.[8] Whole- body plethysmography is a traditional method to assess MIP/MEP and is highly expensive. The availability of the device to test the respiratory mouth pressures is also very scarce in India. There's a need for a low cost, easily accessible, constructible and portable device specifically to measure MIP and MEP values.

The aim of this study was to produce a dependable and valid standardized device to measure the respiratory muscle strength which is readily available. The device isn't battery operated nor has the need for an electrical source, hence it can be used anywhere without an energy source making it further therapist or user friendly. Since the device conducts non-invasive tests, it doesn’t require a laboratory setup and can be done anywhere at any time. There's a lack of research to determine the respiratory muscle strength testing in children. There has been no study done on children using a pressure gauge manometer, hence this study aims to establish the reliability and validity of a low cost pressure gauge manometer in measuring respiratory muscle strength in healthy children.

METHODS

Study design

A sample of 300 healthy children (145 boys, 155 girls) were included for reliability and validity of the pressure gauge manometer. The sample size was calculated using Winpepi software. Convenient sampling method was used to collect the desired samples. The study was conducted between March 2023 to April 2023 in GG International school, Pune.

Inclusion criteria

The children included in the study were of both genders, had a mean (±SD) age of 10±5 years and body mass index of 5th percentile to less than the 85th percentile.

Exclusion criteria

Children with respiratory tract infection since two weeks; neurological and musculoskeletal conditions involving the respiratory system; congenital or acquired diseases of the heart and lungs as they influence the functioning of the respiratory system.

The anthropometric measurements of all participants were documented. The children seated on a chair with their back supported. Maximal inspiratory and expiratory pressure was measured using the capsule sensing pressure gauge according to American Thoracic Society (ATS) guidelines.[9]

Capsule sensing pressure gauge (CSPG)

It is constructed using a capsule sensing pressure gauge, HME (heat and moisture exchange) filter, flanged mouthpiece and oxygen tube (18 inches). The capsule-sensing pressure gauge is a tool that measures mouth pressure (a standard for assessment of respiratory muscle strength). It is a lightweight, portable, handheld, noninvasive, non-battery powered, cost effective device with HME filter attached to a flexible tube and a pressure gauge manometer with a dial that shows the test results in cmH2O.

The pressure measured by this devices ranges between −200 cmH2O to +200 cmH2O. One end of the HME filter is attached to a flanged rigid mouthpiece and the other end is occluded. A small leak (2 mm) is introduced between the occlusion and the mouthpiece to prevent glottis closure.[1] The mouthpiece and HME filter are of low cost and are disposable. An added advantage of HME filter is that it avoids potential bacterial and cross-contamination and hence can also be used in hospitalized patients.

Method of measurement of maximal inspiratory and expiratory pressure

During the measurement of both maximal inspiratory and expiratory pressures, the participants held the pressure gauge manometer with both the hands and sealed their lips firmly around the flanged mouthpiece. Their nose was clipped using a nasal clip to prevent leakage of air through their nose. For maximal inspiratory pressure the participants were asked to exhale as much as possible and then inhale maximally for more than 1 second. For measurement of maximal expiratory pressure, participants were asked to inhale as much as possible and exhale into the device for more than 1 second.

The subjects performed three efforts for both MIP and MEP, with at least 1second hold. An interval of 1 min was given between each effort. The best of each of three inspiratory efforts and expiratory efforts was used for analysis. To assess the reliability, each subject was assessed two times, one day apart during the same time. The validity of the device was assessed by three individual researchers who were blinded to each other and the primary investigator. They each performed MIP and MEP measurements on 10 different subjects. The data collected was then analyzed.

Statistical analysis

The data was statistically analysed using the SPSS software, (SPSS Inc., Chicago, IL, USA). The $p<0.05$ was set as the level of significance for all statistical tests. The inter-item correlation was calculated to assess the reliability. The criteria range for reliability were as follows: <0.50, poor; 0.50-0.75, moderate; >0.75, good.[10] 95% confidence interval was set to determine the amount of error in the measurement. The validity of the device was measured using the content validity index (CVI). CVI of 0.8 or higher is stated as an acceptance value.[11]

RESULTS

The study included 300 children (Boys-145; Girls-155) of ages ranging between 5 and 15 years. The mean and standard deviations of age, BMI, MIP and MEP are presented in (Table 1).

The reliability of maximal inspiratory pressure (MIP) and maximal expiratory pressure using test-retest method is summarized in (Table 2-3). The inter-item correlation plot of MIP and MEP respectively is depicted in (Figure 2-3). The content validity index (CVI) of MIP measurements of three individual researchers, with a validity of 0.8 is depicted in (Table 4). The CVI values of MEP of three individual researchers, with a validity of 0.8 is shown in (Table 5).

Table 1: Mean and standard deviations of age, BMI, MIP and MEP measurements.

Gender	Age (years)	BMI±SD (kg/m^2)	MIP±SD (cmH2O)	MEP±SD (cmH2O)
Boy	10±5	17.2±2.7	56.9±25.7	59.7±26.7
Girl	10±5	17.0±2.9	51.2±19.7	54.8±18.9

Table 2: Reliability scores of MIP using test-rest method.

Parameters	Values
Common variance	545.674
True variance	537.538
Error variance	8.135
Common inter-item correlation	0.985
Reliability of MIP	0.992

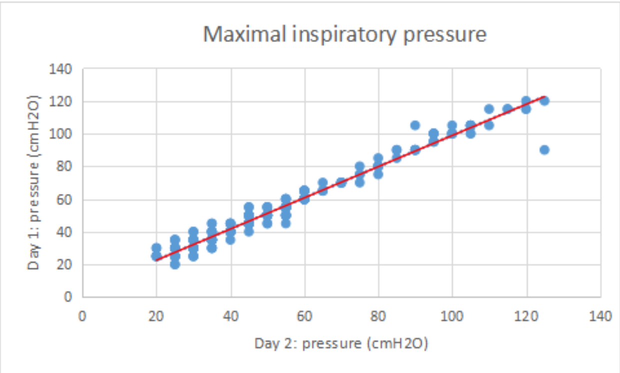

Figure 2: Pot depicting inter-item reliability for MIP of best of 3 readings on 1st day (reading I) and 2nd day (reading II).

Table 3: Reliability scores of MEP using test-rest method.

Parameters	Values
Common variance	543.924
True variance	540.256
Error variance	3.667
Common inter-item correlation	0.993
Reliability of MEP	0.997

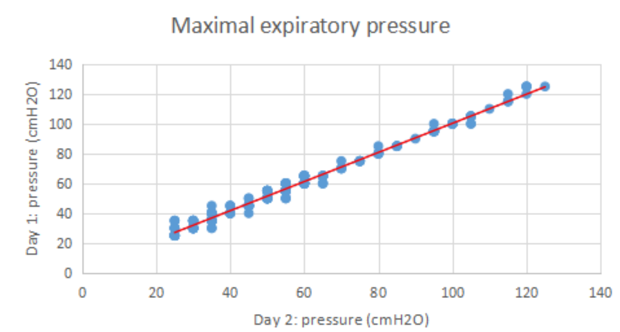

Figure 3: Pot depicting inter-item reliability for MEP of best of 3 readings on 1st day (reading I) and 2nd day (reading II).

DISCUSSION

The present study aimed at constructing a reliable and valid device to measure the strength of respiratory muscles in healthy children aged between 5-15 years. It is a low cost, portable, reliable device to measure respiratory muscle strength can be made using ATS guidelines. It showed a reliability of 0.992 for maximal inspiratory pressure and 0.997 for maximal expiratory pressure. The validity scores obtained for MIP and MEP were 0.8 and 0.8 respectively. The reliability and validity scores obtained are >0.8 which suggests that the low cost pressure gauge manometer device is a highly reliable and valid tool for assessing respiratory muscle strength with high accuracy.

Table 4: CVI values for MIP.

Parameters	N	CVI
Researcher 1	10	1
Researcher 2	10	0.7
Researcher 3	10	0.8
Interpretation		0.8

Table 5: CVI values for MEP.

Parameters	N	CVI
Researcher 1	10	0.9
Researcher 2	10	0.8
Researcher 3	10	0.7
Interpretation		0.8

The procedure followed to measure the maximal inspiratory and expiratory pressure in this study is according to the joint statement published by American thoracic society and European Respiratory Society in the year 2002. Dimitriadis et al published a study on the test/retest reliability of MicroRPM portable manometer's measurements of MIP and maximum expiratory pressure of 15 subjects. They were measured in both sitting and standing for three sessions one week apart.[7] ICCs for MIP and maximum expiratory pressure in the sitting position were 0.86 to 0.90, and were 0.78 to 0.83 for the standing postion.[3] We found that the mean of MIP and MEP for boys was 56.9±25.7 cmH2O and 59.7±26.7 cmH2O respectively and MIP and MEP for girls was 51.2±19.7 cmH2Oand 54.8±18.9 cm H2O. These measures are consistent with the range which was published in a study conducted by Saloni et al in children.[12] Having a reliable and valid device is important as it ensures that the measures from the device are precise and free from errors or biases. This is important for making appropriate evaluations based on the results obtained from the device. This can lead to improved decision-making and ultimately better outcomes for individuals or populations.

A flanged mouthpiece piece was used in this study as authors Herrero et al in their study conducted in 2018 concluded that MEP values obtained with a plastic flanged mouthpiece were much higher those obtained with the scuba type mouthpiece.[13] To our knowledge, there is lack of availability of low cost, easily affordable, portable device which can be used to measure respiratory muscle strength. Overall, having a reliable and valid device is important for ensuring accurate and consistent measurement, confidence in results, efficient use of resources, and improved outcomes. Future scope of this study is that further studies can investigate reduced respiratory muscle strength using the reference values in this study. Studies are also needed for estimation of reference values in children with neuromuscular and musculoskeletal conditions which affect the respiratory system. Studies can also be conducted in different geographical regions to accumulate precise data to plan and execute outcome-based therapeutic strategies.

CONCLUSION

The pressure gauge manometer described in this study is a portable, reliable and reproducible device for assessment and treatment in patients with respiratory muscle weakness. It is cost effective and non-battery operated, which is an advantage for typical clinical setups. Implementation of this device may lead to improved patient outcomes and treatment strategies pertaining to known and unknown causes of respiratory muscle weakness.

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