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Concurrent Validity of a Low-Cost Manometer for Objective Assessments of Respiratory Muscle Strength

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Abstract

Objective(s): This study examined the agreement in maximal expiratory (MEP) and inspiratory (MIP) pressure readings between two digital manometers: (1) the MicroRPM – the gold standard manometer for respiratory muscle strength testing; and (2) the LDM – a low-cost, commercially available, alternative manometer.

Methods: Positive (MEP) and negative (MIP) pressures were simultaneously applied to the MicroRPM and LDM using a 3-liter syringe within a controlled laboratory setting. Pressure readings were compared, and agreement was analyzed using Lin's concordance correlation (ρ_c). Agreement was interpreted as 'poor' if < 0.90, 'moderate' if 0.90 – < 0.95, 'substantial' if 0.95 – < 0.99, and 'excellent' if ≥ 0.99. Twenty percent of the pressure trials were repeated by a second researcher to examine test-retest reliability.

Results: A total of 150 trials were completed, ranging from −167 to +208 cmH_2O. There was a median absolute difference of 0.3 cmH_2O in pressure readings between the MicroRPM the LDM. Lin's concordance correlation revealed 'excellent' agreement between the LDM and MicroRPM devices, with test-retest reliability assessment revealing 'substantial-to-excellent' agreement between the LDM and MicroRPM devices, with a concordance correlation coefficient of ρ_c = 0.999 (95% CI: 0.999 – 0.999).

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Authorship Contributions

All authors met the minimum requirement criteria for authorship recommended by the International Committee of Medical Journal Editors (ICMJE). The below authorship contributions were characterized using the Contributor Roles Taxonomy (CRediT).

Conclusions: There was a median difference of 1.0% in MEP and MIP pressure readings consistently observed between the LDM and MicroRPM. Despite these relatively small differences, excellent agreement between the two manometers was present. These data suggest the LDM may be a valid, lower cost alternative to the MicroRPM for objectively assessing respiratory strength in clinical practice, however additional research is needed in healthy adults and in patient populations.

Lay summary:

Findings from this study suggest that the low-cost Leaton Digital Manometer has the potential to be a valid substitute for the MicroRPM Respiratory Pressure Manometer for measurement of respiratory muscle strength during clinical assessments of cough and swallowing.

Keywords

cough; swallowing; MicroRPM; LDM; Respiratory; Strength

Introduction

Respiratory muscle strength is important for breathing [1,2], swallowing [3,4], and coughing [5,6]. When impaired, reductions in respiratory strength can contribute to compromised airway protection, including impairments in both cough and swallowing[7,8]. Conversely, improvements in respiratory strength are associated with subsequent improvements in swallowing[9-11] and cough [12-14] in people with dysphagia and dystussia. Because of this, it is important for clinicians to objectively assess respiratory strength during routine clinical assessments of cough and swallowing in people with dysphagia and dystussia.

Manometers are pressure reading devices used to objectively measure positive and negative pressures. One manometer developed specifically for maximal expiratory (MEP) and inspiratory (MIP) respiratory pressure testing is the MicroRPM Respiratory Pressure Meter (‘MicroRPM’; Manufacturer: MD Spiro; Figure 1). The MicroRPM consists of an ‘On/Off’ switch, a front panel display, and a 22 mm port to which respiratory bacteria filters and one-way valves can be placed. MEP and MIP are obtained by exhaling or inhaling forcefully into or out of the manometer via the attached respiratory filter. From there, the maximal positive (expiratory) or negative (inspiratory) pressure reading is displayed. The MicroRPM displays pressures in units of cmH_2O, with an operating range of ± 300 cmH_2O, an accuracy of ± 3%, and a resolution of 1 cmH_2O.

Clinicians can use the MicroRPM to objectively assess maximal respiratory pressures (i.e., respiratory strength) in patients with known or suspected cough and swallowing impairments. From there, clinicians can: (1) compare a patient’s MEP and MIP to normative reference values; (2) create a personalized respiratory muscle strength training treatment plan by setting training targets to a percentage of the patient’s objective MEP or MIP; and (3) track changes in respiratory strength over time following a course of cough and swallowing therapy and/or passive patient monitoring. However, one potential limitation of the MicroRPM is its cost, priced at approximately $1500 [15]. For speech-language pathologists, equipment costs have been identified as one of the primary barriers for using

manometers to objectively assess the strength of other important muscles for cough and swallowing function (i.e., orofacial muscles) [16]. Financial burden may explain why 95% of speech-language pathologists assess muscle strength in clinical practice, but only 13% use objective manometers[17].

The MicroRPM is a gold-standard device for assessing respiratory pressures. Because of this, several studies have examined agreement (concurrent validity) in respiratory pressure readings between the MicroRPM and alternative manometers. These studies revealed substantial to near-perfect agreement between the gold-standard and alternative manometers during testing with human participants [18-21]. Importantly, near-perfect agreement was seen even in manometers designed for general (as opposed to respiratory-specific) pressure testing purposes [19]. These studies were important in demonstrating that alternative manometers could be used as a potential substitute to the MicroRPM for respiratory strength testing. However, an important consideration for clinicians in the United States is that the manometers researched in these studies are not commercially available within the United States. Additionally, while the alternative manometers are notably cheaper than the gold standard MicroRPM, they cost greater than $200.

To reduce financial burden and increase the feasibility for objectively assessing respiratory strength in clinical practice, there is a need to identify low-cost alternatives to the MicroRPM that are commercially available within the United States. Many low-cost manometers, sometimes referred to as ‘pressure gauges’, are commercially available within the United States through a variety of online shopping platforms. One such manometer is the Leaton Digital Manometer (‘LDM’; Manufacturer: Leaton; Figure 2) [22]. The LDM consists of an LCD screen which can display pressures in 12 different units, along with a (+) and (−) tube connecting ports. The LDM has an operating range of ± 210.8 cmH_2O, an accuracy of ± 0.3%, and a resolution of 0.1 cmH_2O.

There are several important differences between the LDM (and similar commercially available manometers) and the MicroRPM. First, the pressure testing range of the LDM is 30% smaller than that of the MicroRPM (± 210.8 cmH_2O vs. ± 300 cmH_2O). Despite this, the pressure testing range of the LDM encapsulates the higher range of pressures observed for healthy adults (± 190 cmH_2O) [1,23,24]. This would suggest that the LDM has a testing range suitable for patient populations, whereby respiratory muscle strength is typically reduced when compared healthy adults. Second, the accuracy and resolution of the LDM are 10x greater than that of the MicroRPM, per technical specifications within each device’s operating manual. Lastly, the LDM is approximately 97% cheaper than the MicroRPM, costing between $39-$42 depending on the online distributor.

No published research has compared simultaneous pressure readings between the MicroRPM and the LDM. If the LDM and the MicroRPM exhibit a high level of agreement, then clinicians could consider using the LDM as a cheaper alternative to the MicroRPM, thereby improving clinician and patient access to objective respiratory strength measurements. Therefore, the aim of this study was to examine the concurrent validity between the MicroRPM (the current gold standard manometer) and the LDM (a low-cost alternative manometer) within a controlled laboratory setting. Based on previous

research comparing the MicroRPM to alternative manometers, we hypothesized that that a near-perfect relationship between the two devices would be present.

Materials and Methods

Equipment

The MicroRPM (MD Spiro) and the LDM (Leaton) manometers were simultaneously coupled to a 3-Liter calibration syringe (Hans Rudolph, Inc.) via a tee-connector. The MicroRPM was coupled to the tee-connector via a respiratory bacteria filter (Manufacturer: AirLife; Product #: 001851). The (+) tube connecting port of the LDM was coupled to the tee-connector using soft silicone tubing (4 mm ID), a 6 mm OD x 22 mm OD adaptor (Manufacturer: Qosina; Product #: 52206), and a respiratory bacteria filter. Notably, the default tubing supplied with the LDM has an inner diameter of 3 mm which did not fit around the Qosina adaptor. Therefore, LDM tubing was replaced for silicon tubing with a 4 mm inner diameter so that it could be coupled with the Qosina adaptor. The simultaneous testing setup is depicted in Figure 3.

Procedures

Pressures ($n = 150$) were manually applied to the MicroRPM and LDM simultaneously using a 3-liter calibration syringe. Negative pressures ($n = 65$), which were intended to represent MIP, were generated by pulling the calibration syringe out at varying velocities. Positive pressures ($n = 85$), which were intended to represent MEP, were generated by pushing the calibration syringe in at varying velocities. A testing range of −167 cmH_2O to +208 cmH_2O, using the MicroRPM as the reference, was selected a priori for this experiment. This pressure testing range was deemed appropriate for this study since it represents 1-2 standard deviations above the mean for healthy adult normative reference values [1,23,24].

The order with which pressures were tested was randomized. Each device was set to its ‘peak’ function, so that the maximum pressures applied to the manometers were accurately displayed. Trials whereby too much pressure was inadvertently applied were discarded and re-trialed. Once a trial was complete, the manometers were ‘reset’ back to 0 so that a new peak pressure could be recorded.

Statistical Analysis

All data were statistically analyzed using R version 4.2.3 [25]. Data and R code were made openly available in the Open Science Framework repository at https://osf.io/bth35/ for data transparency and open science use. Lin’s concordance correlations (ρ_c) [26] were used to calculate level of agreement between the LDM and MicroRPM across all three experiments, with ρ_c interpreted as ‘poor’ if < 0.90, ‘moderate’ if 0.90 – 0.949, ‘substantial’ if 0.95 – 0.998, and ‘excellent’ if ≥ 0.999 [27]. Bland-Altman plots were also used as a supplement to Lin’s concordance correlations to further aide in assessment of concurrent agreement. Twenty percent of the trials were repeated for analysis by a second rater, with Lin’s concordance correlation repeated for analysis, to examine test-retest reliability. The second rater was blinded to the results from primary rater.

Results

Across the total sample (n = 150), there was a median absolute difference of 0.3 cmH_2O in pressure readings between the MicroRPM the LDM (Table 1; Figure 4). Lin's concordance correlation revealed excellent agreement between the LDM and MicroRPM devices, with a concordance correlation coefficient of ρ_c = 0.999 (95% CI: 0.999 – 0.999), a scale shift of ω = 1.001, a location shift of υ < −0.001, and a correction bias of C.b = 0.999. Additionally, Bland-Altman plots revealed 95.4% of the data points were in agreement with each other.

Test Reliability

Across the test-retest reliability sample (n = 28), there was a median absolute difference of 0.2 cmH_2O in pressure readings between the MicroRPM the LDM (Table 1). Lin's concordance correlation revealed substantial to excellent agreement between the LDM and MicroRPM devices, with a concordance correlation coefficient of ρ_c = 0.999 (95% CI: 0.999 – 0.999), a scale shift of ω = 0.996, a location shift of υ < −0.001, and a correction bias of C.b = 0.999.

Discussion

Manometers are important for facilitating valid, reliable, and objective measurements of maximal respiratory pressures during clinical assessments of voice, speech, cough, and swallowing. By comparing a person's maximal respiratory pressure to normative reference values, clinicians can improve the diagnostic accuracy of identifying if a patient's respiratory strength is 'normal' or 'weak'. These data assist clinicians in determining if a patient's respiratory strength may be a contributing factor to their presenting symptoms. This, in turn, helps clinicians identify patients who might benefit from a course of expiratory muscle strength training (EMST) and/or inspiratory muscle strength training (IMST). Given their relatively high measurement resolution, digital manometers are also sensitive at detecting relatively small differences in respiratory pressures. This makes manometers valuable for tracking changes over time in respiratory strength, either as a result of clinical monitoring (e.g., with a person with a degenerative disease), or during/after a course of EMST and IMST. Because manometers provide immediate feedback regarding how much pressure was generated by a patient upon exertion, it may be possible to also use manometers to facilitate EMST and IMST in lieu of other handheld devices.

In the present study, excellent agreement was observed in pressure readings between the LDM and MicroRPM. This suggests a high level of concurrent validity was present for the LDM when compared to the current gold standard respiratory manometer. Specifically, there was a median *absolute* difference of 0.3 cmH_2O in pressure readings between the LDM and MicroRPM. Furthermore, the median *relative* difference in pressure readings between the LDM and MicroRPM was approximately 0 cmH_2O. This demonstrates that differences in LDM pressure readings were never consistently higher or lower than the MicroRPM. Instead, the small differences in pressure readings between the LDM and MicroRPM were random across the entire pressure testing range.

Results from the present study are consistent with findings from previous research using similar simultaneous assessment study designs. Kim & Lee [18] compared simultaneous pressure readings between the MicroRPM and the 'Spirokit' in young healthy volunteers. The Spirokit (TR Ltd., Daejeon, Korea; 2020), which is not available within the United States, is a novel device manufactured and distributed in South Korea used for pulmonary function testing and respiratory pressure testing. This study by Kim & Lee found an average difference of 0.9-1.4 cmH_2O between the MicroRPM and the Spirokit, with correlation coefficients between the two manometers that were >0.99.

Similarly, Torres-Castro and colleagues [19] compared simultaneous pressure readings between the MicroRPM and a 'non-clinical,' low-cost, commercially available digital manometer in healthy young adults [19]. MIP testing ranged from −40 cmH_2O to −160 cmH_2O, whilst MEP testing ranged from +54 cmH_2O to +244 cmH_2O. That study found an average relative difference of 0.3-0.7 cmH_2O with correlation coefficients that were >0.99. Torres-Castro and colleagues concluded that the 'non-clinical' digital manometer can accurately measure maximal respiratory pressures and may be a valid, reliable, and clinically feasible method for respiratory pressure measurements. However, one of the limitations of the Torres-Castro study was that lower pressures, which may likely be observed in patient populations with compromised respiratory strength, were not tested. Specifically, pressures from 0 to −40 cmH_2O were not tested for MIP, and pressures from 0 to 54 cmH_2O were not tested for MEP. Our study addressed this limitation by including MIPs ranging from 0 to −167 cmH_2O, and by including MEPs ranging from 0 to +208 cmH_2O. Including this full range of pressures, we found a median absolute difference of 0.3 cmH_2O, with correlation coefficients >0.99. These findings are similar to those reported by both Kim & Lee and Torres-Castro and colleagues.

One limitation of the present study is that pressures were manually applied to the two manometers in a controlled laboratory setting – pressures were not obtained with adult volunteers. Therefore, future work should examine differences in pressure readings with the LDM during 'real-world' respiratory pressure testing conditions with healthy adult volunteers and in patient populations. A second limitation is that the simultaneous pressure readings between the LDM and MicroRPM were observed and recorded by the same researcher, introducing the potential for measurement bias. However, results from the test-retest reliability assessment, which was completed by a second researcher who was blinded to the findings from the primary study sample, demonstrated nearly identical results as those observed from the primary study sample. This suggests the potential measurement bias did not influence study findings. Nonetheless, future research should consider having different researchers record data for each manometer separately to increase the blinding of study data. A third limitation of this study is that it did not determine what a clinically meaningful difference is in pressure reading differences. Most often, the disagreement between the MicroRPM and LDM was <1.0 cmH_2O. It is unknown if this represents a clinically meaningful difference when comparing to normative data, monitoring change in people with degenerative condition, or tracking changes over time in response to treatment. Therefore, future work should identify clinically meaningful margins of error.

Conclusions

This study revealed excellent agreement in MEP and MIP pressure readings between the gold standard MicroRPM and the low-cost alternative device within a controlled laboratory setting. These results suggests that the lower-cost LDM may be a valid substitute to measure respiratory pressures in clinical practice, thereby improving access to objective assessments of MEP and MIP for clinical cough and swallowing evaluations. Future research should expand on the present findings by assessing the validity of the LDM, and similar manometric devices, in healthy adults and in patient populations.

Financial Disclosures/Conflicts of Interest

The authors have no relevant financial disclosure or conflicts of interest.

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Figure 1:
The MicroRPM handheld manometer, with the on/off ‘MIP/MEP’ switch, an LCD panel, and a 22 mm connection port

Figure 2:
The Leaton digital manometer, with an on/off power switch, an LCD panel displaying one of 12 units of measurement (including cmH_2O), (+) and (−) connection ports, and silicone tubing

Figure 3:
Simultaneous testing setup, with the LDM, silicone tube, oxygen tubing, adaptor, and respiratory filter (bottom), the MicroRPM and respiratory filter (top), and the tee-connector and 3-liter calibration syringe (middle)

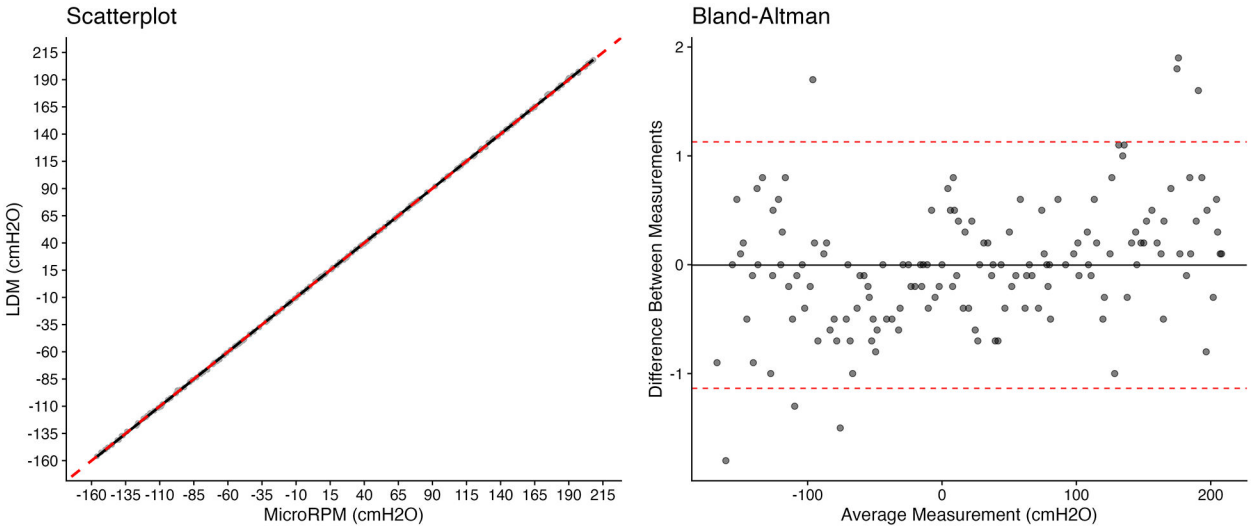

Figure 4:

Relationship between MicroRPM and LDM pressure readings. The left graph is a scatter plot, with the red dashed line representing data points with perfect agreement between MicroRPM and LDM, and the black solid line representing the line of best fit. The right graph is a Bland-Altman plot of differences between the two testing methods, with the black solid line representing the average difference between the matched trials, and the red dashed lines representing 1.96 standard deviations below and above the average difference.

Table 1:

Descriptive statistics characterizing differences in pressure readings between the LDM and MicroRPM during the original testing (top) and the test-retest reliability testing (bottom)

Original Testing	**Overall (N=150)**
Relative Difference (LDM - MicroRPM)	
Mean (SD)	−0.00333 (0.577)
Median [Q1, Q3]	0 [−0.400, 0.300]
Min, Max	−1.80, 1.90
Absolute Difference	
Mean (SD)	0.419 (0.396)
Median [Q1, Q3]	0.300 [0.100, 0.600]
Min, Max	0, 1.90
Test-Retest Reliability Testing	**Overall (N=28)**
Relative Difference (LDM - MicroRPM)	
Mean (SD)	−0.00357 (0.347)
Median [Q1, Q3]	0 [−0.225, 0.200]
Min, Max	−0.800, 0.700
Absolute Difference	
Mean (SD)	0.261 (0.223)
Median [Q1, Q3]	0.200 [0.0750, 0.400]
Min, Max	0, 0.800