Reliability and Diagnostic Accuracy of a New Vaginal Dynamometer to Measure Pelvic Floor Muscle Strength

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Aims: Assess the intrarater and interrater reliabilities and diagnostic accuracy of a new vaginal dynamometer to measure pelvic floor muscle (PFM) strength in incontinent and continent women.

Methods: A test-retest reliability study including 152 female patients. Exclusion criteria: history of urge urinary incontinence, prolapse of pelvic organ, pregnancy, previous urogynecological surgery, severe vaginal atrophy, or neurological conditions. The examination comprised digital assessment using the modified Oxford scale (MOS) and dynamometry measurements with a new prototype hand-held dynamometer. The MOS score ranges from 0 to 5: 0, no contraction; 1, flicker; 2, weak; 3, moderate; 4, good; 5, strong. Examinations were performed by a physiatrist, a physiotherapist and a mid- wife. The rest period between each rater measurement was 5 minutes. Assessment of intrarater and interrater reliability was calculated with the intraclass correlation coefficient.

Results: One hundred twenty-two incontinent women and 30 continent women were included. Scores between 0 and 2 in MOS were recorded in 72% of incontinent women versus 20% in continent patients ($P < 0.001$). Intrarater reliability of the dynamometer was 0.942 (95% confidence interval [CI], 0.920–0.958) and the interrater reliability was 0.937 (95% CI, 0.913–0.954). The analysis of variance analysis showed significant differences in PFM strength across digital assessment categories. The post-hoc analysis showed statistical differences between adjacent categories of MOS 1–2 and 2–3. The diagnostic accuracy showed an area under the curve of 0.82 (95% C,: 0.75–0.89), 0.87 (95% CI, 0.81–0.92), and 0.83 (95% CI, 0.77–0.90) for the physiatrist, midwife, and physiotherapist, respectively. Conclusions: The results obtained show a good reliability and validity of this new vaginal dynamometer to quantify PFM strength.

Key Words: urinary incontinence, rehabilitation, pelvic floor muscle strength, dynamometer

INTRODUCTION

Urinary incontinence (UI) is defined as any involuntary urine leakage.[1] The most frequent type of UI is stress UI (SUI), which is defined as involuntary leakage upon effort or physical exertion, sneezing, or coughing.[2] Urinary incontinence is age-related and represents a significant health problem with a prevalence of 14% to 69%. Urinary incontinence affects over 50% of geriatric pa- tients.[3] It represents a major health problem and has a much higher prevalence than other common conditions such as hypertension, depression or diabetes mellitus. It has a social and emotional impact on suffers as it affects their social an personal relations,[4] limits their physical activity,[5] and often negatively affects sufferers' quality of life.[6]

Several factors may cause or promote SUI, including deficiency in the sphincter function,[1] pelvic floor muscle (PFM),[2,3] connective tissues,[6] or neural structures.[4] In women with SUI with level 1 evidence, encouraging results in the prevention of urine loss have been obtained with physical therapy including strength training of the PFM and the introduction of training motor control strategies.[5,7,8] The International Continence Society recommend physical therapy as the treatment of choice for women whose main problem is SUI.[8,9] Physical therapy has proved useful to support pelvic organs (urethra, uterus, and bladder) and prevent genital prolapse and other functional disorders of the pelvic floor such as incontinence.[10]

Vaginal palpation and manometry are currently the standard instruments used for testing PFM strength. Despite its demonstrated subjectivity and low test-retest and interrated reliability,[11] vaginal palpation using the modified Oxford grading scale[12] is presently the gold standard. Vaginal manometry[13] always has to be performed at the same anatomical level and cannot be considered an accurate method to measure intravaginal pressure, as measurements of abdominal pressures can alter PFM response.[14] Furthermore, it is difficult to measure intravaginal pressure when different measurement units, size and shape of instrument[15] are used. The urethra appears to be the optimal location to measure the pressure but it is difficult to fulfill the necessary conditions and uncomfortable for the women. Furthermore, vaginal manometry measures pressure rather than strength. Although several authors have suggested assessing PFM strength with prototype vaginal dynamometers, none are currently commercially available.[16–20] Other methods of assessing PFM function include electromyography (EMG), ultra- sound and dynamic magnetic resonance imaging, despite their limited clinical utility due to poor validation or reliability, limited accessibility, and high cost.[21–24]

Stress UI may also be associated with bladder neck hyper- mobility, possibly caused by PFM weakness.[25] Pelvic floor muscle strengthening exercises, such as those first described by Kegel in 1948, have commonly been used to treat SUI.[26]

Intensive PFM training has been shown to increase muscle size and stiffness and to stabilize the bladder neck when intraabdominal pressure is increased.[7] Numerous randomized controlled trials have demonstrated the effectiveness of this treatment according to the international practice guidelines.[27]

The recently established inpatient and outpatient multidisciplinary pelvic floor units require reliable data to assess PFM function for the initial assessment of patients consulting for incontinence and evaluate the outcome after treatment and rehabilitation.

To provide an objective assessment of the results of rehabilitation treatment, a prototype dynamometric speculum to measure PFM strength was recently designed by our team of researcher and biochemists.[28] A study previously published by our team showed the intrarater reliability and diagnostic accuracy of this new device for measuring PFM strength in incontinent women. As this study did not include continent women, the reliability of the dynamometer in women with higher modified Oxford scale (MOS) score could not be established. Likewise, the dynamometer reliability between the different professionals involved was not assessed. The aim of this study was to assess the intrratera and interrater reliabilities and diagnostic accuracy of a new vaginal dynamometer to measure PFM strength in incontinent and continent women.

MATERIALS AND METHODS

The PFM strength was measured by a new prototype dynamometer (Spanish patent application number P201130449) comprising a speculum in which an inductive displacement sensor is attached to a spring of known stiffness constant. The characteristics and operating mechanism of the dynamometer have previously been described in detail.[28] The measurements obtained show the actual force exerted by the patient on the PFM in newtons (N).

Study Design

This was a test-retest study.

Participants

Screening for inclusion was performed on all patients attended by a pelvic floor rehabilitation specialist in our Primary Care Centre. One hundred and twenty-two consecutive women with UI and 30 continent women older than 18 years were recruited between November and December 2014. Continent women were recruited among primary care professionals and physiotherapist students. The exclusion criteria were: history of urge UI or pelvic organ prolapse, current pregnancy, previous urogynecological surgery, severe vaginal atrophy, neurological conditions, or cognitive impairment.

Procedures

All participants filled in a two-part questionnaire. The first part of the questionnaire collected demographic and clinical characteristics: age, body mass index (BMI), age at menarche, menopause, age at menopause, if they were nulliparous or had previously given birth, type of delivery (vaginal of by caesarean section), and weight of baby at birth. The second part consists of the collection of scores obtained on the International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF), a clinical instrument used to assess the presence or absence of UI, developed by the ICS and translated and validated for the Spanish-speaking population.[29]

All clinical evaluations were conducted by the same three raters, a physiatrist, a physiotherapist, and a midwife who work in the Pelvic Floor Unit. Clinical evaluation was carried out with the participants in the lithotomy position. Three measurements of the PFM strength during contraction of pelvic floor were recorded using digital palpation quantified by the MOS. The MOS assesses patient's capacity to contract the PFM, as perceived by the specialist per- forming the palpation. Patients were asked to contract concentrically in a cranioventral direction and digital palpation and visual inspection revealed that all the patients correctly followed the instructions. The MOS score ranges from 0 to 5: 0, no contraction; 1, flicker; 2, weak; 3, moderate; 4, good; 5, strong. Examinations were conducted by the physiatrist, the physiotherapist and the midwife. The degree of agreement was substantial in the group of incontinent women and moderate in the group of continent women. Detailed results of the interrater reliability of the digital palpation of PFM by the MOS have been published by our team.[30]

Four consecutive measurements of the strength of contration of pelvic floor were subsequently taken on each participant using our vaginal dynamometric speculum (2 were taken by the same physiatrist, 1 by the physiotherapist and one by the midwife). The rest period between each rater measurement was 5 minutes. Participants were instructed by the specialist on how to contract PFM. The speculum branches were thoroughly disinfected and covered with a female condom before the assessment. Two values were determined for each of the four measurement: the baseline value of the passive force exerted after opening the device for 5 seconds, and the maximal voluntary strength registered by the de- vice in 10 seconds. The speculum was fully inserted during each measurement and the magnitude of force exerted was recorded. For each of the four measurements, contraction strength was calculated as maximum contraction strength minus baseline strength. The PFM strength was recorded in N. Raters were blinded to the urinary continence or incontinence status of the women and were masked to previous rater's MOS score and dynamometer measurement.

The study protocol was approved by an independent Clinical Research Ethics Committee. All patients provided written informed consent prior to recruitment.

Statistical Analysis

The estimated sample size for an expected interrater reliability (ICC) of 0.90, with a confidence level of 95%, a precision of 0.03 and with 3 raters was 113 women. Assuming an expected dropout rate of 10%, a total recruitment of 126 subjects was planned.

Continuous variables were expressed as means, standard de- viations (SD), minimum and maximum value, and categorical variables as the number and percentage.

The mean dynamometric value was computed for each cate- gory of the modified Oxford grading scale and compared using a one-way analysis of variance (ANOVA). The differences between pairs of assessment categories were compared using the Scheffe post hoc procedure.

The ICC for two-way mixed effect model and for absolute agreement[31] was calculated to assess the intrarater ICC and interrater ICC reliability of the dynamometer measures. Intrarater reliability was computed with the two measurements taken by the physiatrist and interrater was computed with the second measurement taken by the physiatrist and those taken by the physiotherapist and the midwife. The Bland and Altman plot was also used. The diagnostic accuracy of dynamometric speculum measurement with respect to the gold standard (MOS) conducted by the physiatrist was deter- mined by calculating the receiver operating characteristic (ROC) curve graph and the area under the curve (AUC). The ROC and AUC were computed for the second measurement of the dynamo- metric speculum taken by the physiatrist and those taken by the physiotherapist and the midwife. Vaginal palpation was measured with the MOS, and the categories were grouped from 0 to 2 and from 3 to 5. Statistical significance was set at the 2-sided 0.05 level. Statistical analysis was performed using IBM® SPSS® Statistics for Windows v.22 (IBM Corporation, Armonk, NY, USA) and Stata® v.14 Statacorp LP, College Station, Texas, USA).

RESULTS

One hundred twenty-two incontinent women and 30 continent women were included with a mean age of 55.6 years (SD = 10.3) and 36.4 (SD = 9.6), respectively ($P < 0.001$). Table 1 shows demo- graphic and clinical characteristics according to the presence of UI. A total of 36.1% of incontinent women were overweight and 30.3% obese (BMI > 30) compared with 13.3% overweight and no obese in the continent group ($P < 0.001$); 93.4% of incontinent women had a vaginal delivery versus 50% in continent women ($P < 0.001$); 54.9% were menopausal in the incontinent group versus 6.7% in the continent group ($P < 0.001$). Mean ICIQ-SF score in incontinent women was 11.2 (SD = 4.5).

Scores between 0 and 2 in MOS were recorded in 72.2% of incontinent women versus 20% in continent ones ($P < 0.001$).

Pelvic floor muscle strength measurements obtained with the dynamometric speculum for each category of the modified Oxford grading scale and according to the rater are shown in Table 2. The ANOVA analysis was significant for all raters, indicating differ- ences in PFM strength across digital assessment categories. Post hoc analysis showed no significant differences between adjacent assessment categories such as 0 to 1 and 3 to 4. Statistical differences were found between adjacent categories 1 to 2 and 2 tp 3 for each one of the raters.

Intrarater reliability according to ICC was 0.942 (95% confidence interval [CI], 0.920–0.958). The Bland and Altman plot (Fig. 1) indicates that the mean difference between the two measurements of PFM strength was −0.03 N (SD = 0.16). Intrarater disagreements were distributed similarly in the lowest and highest strength values and with little random variability between measurements. Interrater reliability according to ICC was 0.937 (95% CI, 0.913–0.954). Interrater disagreements were distributed similarly in the lowest and highest strength values (Fig. 2).

The results for the diagnostic accuracy of the dynamometer with regard to digital palpation and according to the rater are showed in Figure 3. The areas under the ROC curve were 0.85 (95% CI, 0.75–0.89), 0.87 (95% CI, 0.81–0.92), and 0.83 (95% CI, 0.77–0.90) for the physiatrist, midwife, and physiotherapist, respectively.

TABLE 1. Baseline Characteristics

	N = 152
Age (y)	51.8 (SD, 12.7)
BMI (kg/m^2)	26.6 (SD, 4.9)
Underweight (<18.5)	2 (1.3)
Normal (18.5–24.9)	65 (42.8)
Overweight (25.0–29.9)	48 (31.6)
Obese (≥30)	37 (24.3)
Age at menarche (y)	12.9 (SD, 1.7)
Menopause	69 (45.4)
Age at menopause (y)	48.8 (SD, 5.5)
Nulliparous	17 (11.2)
Vaginal delivery	129 (95.6)
Caesarean delivery	13 (8.6)
Birth weight (g)*	3561 (SD, 546)
MOS	
0	9 (5.9)
1	31 (20.4)
2	54 (35.5)
3	45 (29.6)
4	13 (8.6)
5	0 (0.0)
ICIQ-SF	8.8 (SD 6.1)
Dynamometry measurements	
Physiatrist 1st measurement (N)	0.58 (0.35)
Physiatrist 2nd measurement (N)	0.61 (0.36)
Midwife (N)	0.70 (0.37)
Physiotherapist (N)	0.63 (0.38)

Mean (SD) for continuous variables; number (%) for categorical variables.

*Maximum birth weight, 118 and 16 newborns in incontinent and continent women respectively.

Dynamometry measurement: contraction strength − baseline strength.

DISCUSSION

The aim of the present study was to evaluate the intrareliability and interreliability and diagnostic accuracy of a new dynamometric speculum for measuring PFM strength, based on a mechanicalinductive displacement sensor attached to a standard vaginal speculum. The results obtained show high intrarater and interrater reliability and good diagnostic accuracy in women using the MOS as a reference method.

The most common method used to evaluate the capacity of contraction of the pelvic floor is digital examination assessed with the modified Oxford grading scale. Yet, the capacity of this method to detect the true difference in strength and detect changes over time or to evaluate the response to rehabilitation is poor due to the high level of rater subjectivity and the low test-retest reliability and interrater reproducibility.[32] The results of our previous study[30] suggested that MOS had a higher interrater reliability for its use in clinical practice in incontinent women than in continent women who presented MOS scores between 3 and 5. The development of new specific dynamometers[28] is essential to obtain accurate and reliable measurements of PFM strength especially when performed by more than one examiner.

In 2003, an instrument based on a non-standard speculum comprising two aluminium branches was described by Dumoulin et al.[16] In 2015, Martinho et al.[19] assessed the intrarater and interrater reliability using a cylindrical shape dynamometer. The sample included was small and only comprised young women with no dys- function of the pelvic floor. In spite of these and other attempts to modify standard or newly designed speculums as instruments to measure PFM strength, none have been commercialized to date and have only been used only in research.[16–20]

Navarro-Brazález et al.[33] performed a comparative study of the measurement devices used to assess PFM. They evaluated the reliability of vaginal palpation, vaginal manometry, vaginal dyna- mometry and surface (transperineal) EMG. Nevertheless, the dynamometer used (Pelvimetre Phenix, Montpellier, France) is a device that measures muscle tone at rest and during contraction with a tone test and contractility test. This study, carried out only in women with pelvic floor dysfunction, concludes that manome- try and dynamometry are more reliable than vaginal palpation to assess PFM strength in patients with pelvic floor disorders, especially when different raters are involved.

We consider that the same measuring units and devices should grading scale and according to the rater are shown in Table 2. The ANOVA analysis was significant for all raters, indicating differences in PFM strength across digital assessment categories. Post hoc analysis showed no significant differences between adjacent assessment categories such as 0 to 1 and 3 to 4. Statistical differences were found between adjacent categories 1 to 2 and 2 tp 3 for each one of the raters.

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for the physiatrist, midwife, and physiotherapist, respectively.
be used to unify evaluation criteria. This is why we use a dynamometer that allows us to measure muscular strength expressed in New- tons, which is a validated reference value.

The dynamometric speculum described in this study presents several advantages over traditional measurement instruments. In addition to obtaining accurate measurements, this device stands out for its simplicity of use and the fact that it can be used by different healthcare professionals.

Several authors have demonstrated that 45% of women who attend a gynecology clinic for any reason other than UI are unable to contract PFM on demand.[34] This dynamometer would facilitate a reliable, regular exploration of the functional state of the pelvic floor during routine gynecological visit and allow patients to start preventive treatments to improve PFM from initial phases and avoid the appearance of UI, genital prolapse or fecal incontinence. The results obtained show a good intrarater and interreliability and validity of this new vaginal dynamometer to quantify PFM strength both in incontinent and continent women.

The limitations of this study include aspects related to the study design and aspects inherents to the prototype of the dynamometer. None of the 30 continent women included in the study had a score of 5 on the MOS. This may be due to the small number of continent women included in the study that, by chance, did not include any women with a score of 5 on the MOS. Our team is presently working on the definitive design of the dynamometer to be commercialized. It will include a disposable part to be introduced in the vagina, so no female condom will be required. The marketed device will be effective at measuring PFM strength, easy to use and cost effective, and designed to be used both in daily practice and clinical research. We cannot rule out a possible effect of intraabdominal pressure in the measurement of pelvic muscle strength using the vaginal dynamometer. Nevertheless, we can affirm that a very strong abdominal muscle interference would be re- quired to cause a displacement of the branches of the speculum. The instrumented speculum designed by Ashton-Miller et al. to minimize the effect of intraabdominal pressure on the measurement of PFM strength is useful in clinical research but its use in the daily clinical practice requires some training of health professionals.

Future studies should focus on the diagnostic reliability of the dynamometer with other instruments currently used, such as 3D/4D ultrasound and magnetic resonance, although these are more complex and require specialized staff and are more expensive as they offer a more complete study of the anatomical and functional state of the pelvic floor.

TABLE 2. PFM Strength Measurement With the Dynamometric Speculum With Respect to Scores on the MOS and According the Rater

	n	Mean	SD	Minimum	Maximum	*P*
No contraction (0)						
Physiatrist 1st measurement (N)	9	0.25	0.19	0.00	0.52	
Physiatrist 2nd measurement (N)	9	0.24	0.19	0.00	0.61	
Midwife (N)	7	0.37	0.38	0.00	1.18	
Physiotherapist (N)	12	0.48	0.56	0.00	2.05	
Very weak contraction (1)						
Physiatrist 1st measurement (N)	31	0.26	0.20	0.00	0.74	1.000
Physiatrist 2nd measurement (N)	31	0.31	0.24	0.00	0.94	0.986
Midwife (N)	45	0.36	0.25	0.00	0.95	1.000
Physiotherapist (N)	37	0.35	0.29	0.00	1.12	0.810
Weak contraction (2)						
Physiatrist 1st measurement (N)	54	0.57	0.26	0.16	1.14	<0.001
Physiatrist 2nd measurement (N)	54	0.57	0.28	0.00	1.14	0.002
Midwife (N)	44	0.70	0.26	0.19	1.24	<0.001
Physiotherapist (N)	46	0.61	0.30	0.02	1.27	0.009
Moderate contraction: maintenance of pressure (3)						
Physiatrist 1st measurement (N)	45	0.78	0.31	0.13	1.34	0.007
Physiatrist 2nd measurement (N)	45	0.84	0.29	0.18	1.44	<0.001
Midwife (N)	41	0.95	0.26	0.41	1.45	0.001
Physiotherapist (N)	44	0.81	0.31	0.26	1.40	0.060
Good contraction: maintenance of tension with resistance (4)						
Physiatrist 1st measurement (N)	13	0.93	0.33	0.24	1.45	0.559
Physiatrist 2nd measurement (N)	13	0.91	0.34	0.29	1.44	0.967
Midwife (N)	15	1.12	0.22	0.67	1.46	0.367
Physiotherapist (N)	13	1.03	0.24	0.56	1.38	0.370

For each rater, post hoc *P* values for the Scheffe test between adjacent Oxford scale categories (0 vs 1; 1 vs 2; 2 vs 3 and 3 vs 4) are shown.
Measurement: contraction strength − baseline strength.
SD, standard deviation; N, Newtons.

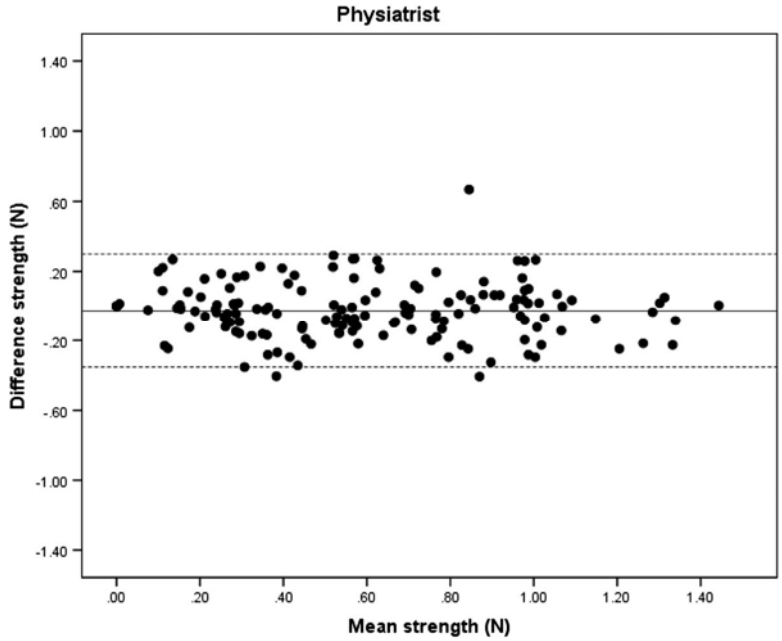

FIGURE 1. Intrarater reliability according Bland and Altman plot.

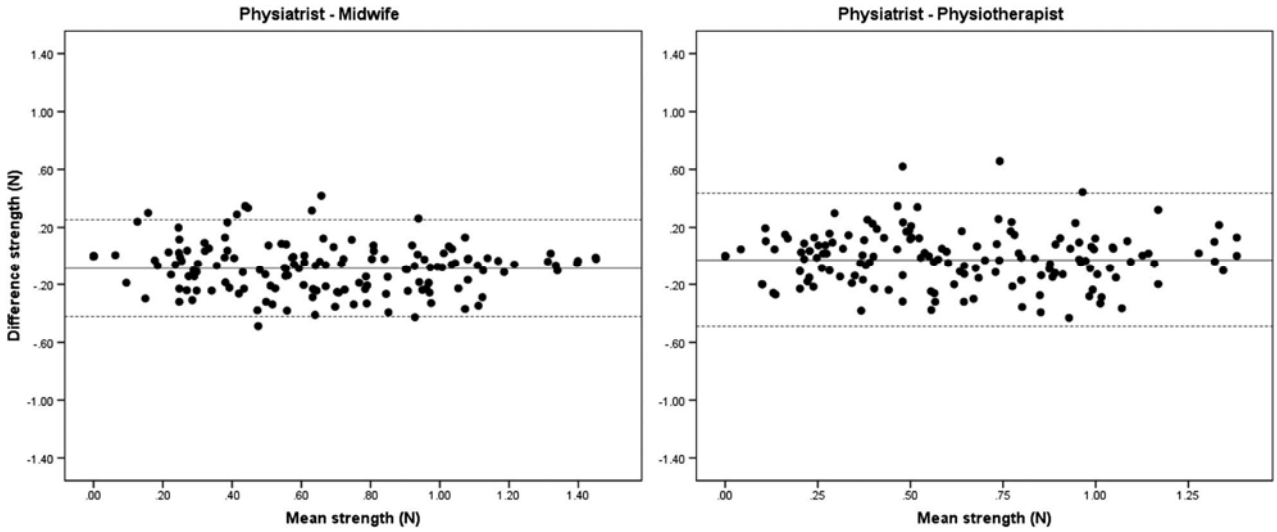

FIGURE 2. Interrater reliability according Bland and Altman plot.

CONCLUSIONS

The dynamometric speculum presented in this study shows good test-retest reliability and diagnostic accuracy. This novel instrument offers considerable advantages over those currently available and has proved to provide an objective clinical evaluation and an accurate measurement of PFM strength. It minimizes subjectivity bias rater and allows close monitoring of the outcome of pelvic floor rehabilitation. Further studies comparing this instrument with other currently available should be conducted.

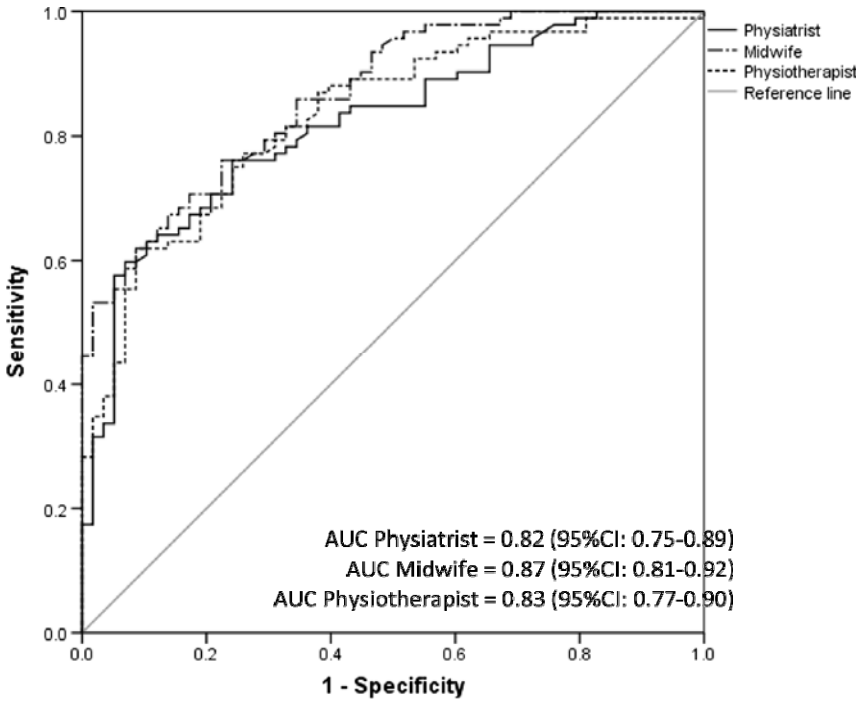

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FIGURE 3. Diagnostic accuracy of the dynamometer with regard to the gold standard (digital manual examination evaluated using the modified Oxford Grading Scale).

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