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Examining Laboratory Accuracy and Precision of 'Cervical Dilatometer' in Measuring Cervical Dilatation

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Abstract

Objective: To assess laboratory accuracy and precision of 'cervical dilatometer' in measuring cervical dilatation. **Methods:** Seven midwives in two groups of experimental phases were asked to measure cervix dilatation blindly in artificial simulators ranging from 40 to 100 mm by means of the device. Results were recorded and then after using a simple calculation, dilatations were reported. For the accuracy and precision of the instrument ICC (Inter-Class Correlation) between simulators and examiners reports, ICC between observers, Pearson's Correlation and Standard Error, all with 95% confidence interval, were used. Ninety-five examinations in 37 simulators were performed, none of the cases excluded. **Results:** According to the statistical analyses there were positive correlations between the instrument reports and simulators real sizes in either phases (ICC=0.968 in phase 1 and 0.834 in phase 2). Reliability of the instrument using Cronbach's Alpha was 0.995, inter-observer agreement due to ICC and Pearson's correlation was 0.995 and 0.697 in phase 1 and phase 2 respectively. **Conclusion:** Cervical Dilatometer qualifies accuracy, precision and reliability requirements to be used as a cervimetry instrument in laboratory phase. Further research is needed to determine those elements in clinical set-up.

Keywords: Accuracy, Cervical Dilatation, Device, Precision

1. Background

Monitoring labor progress is an important aspect of maternity care that may help health providers to predict potential problems and perform proper interventions when needed[1] . Diagnosis of prolonged labor is one of the most important goals of labor monitoring because of its unfavorable outcomes including infection, hospital expenses and maternal emotional discomfort[2,3]. On the other hand over-diagnosis of this problem can lead to unnecessary interventions which are not free of side effects[4]. Determining cervical dilatation is the gold standard for assessing labor progress and World Health Organization supports using Partographs mostly based on this index[5-11]. Digital Vaginal Examination (DVE) is the current way of determining cervical dilatation during labor[2,2-14]. But there are evidences against its accuracy and precision, especially inter-observer agreement, because of its interrupted and subjective nature[5,13-17]. Also numerous DVEs may increase the infection risk in mother and fetus, so reducing the number of DVEs during labor has been suggested[11,15] For this purpose several attempts have been made to use more objective ways of determining cervical dilatation by means of 'Cervimeteres'[12,18-22] Researchers classify cervimetres in 4 general categories including mechanical, electromechanical, electromagnetic and

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ultrasound methods[6,23] Mechanical instruments were the first invented ones that despite their acceptable and even high precision (e.g. 0.5 mm for Friedman's) are not used in clinic because of the risk of maternal tissue damage and discomfort[19] Other types of cervimeters are not used either, because of unknown or unpredictable risks of their technologies to fetus and economic issues[6,16]. Recently introduced ultrasound-based methods seem to justify their expensiveness by high accuracy, precision and less maternal discomfort, but unfortunately economic reasons still make it difficult to be afforded in less-developed countries and finding simpler methods are more favored[11,18] Cervical Dilatometer is a newly invented mechanical cervimeter[20] and researchers hope it may increase the inter-observer agreement and reduce the number of DVEs by making them more objective.

2. Methods

This experimental study was performed in two phases with participation 5 midwives in the first phase (3 with MSc degree and 2 with BS in midwifery and average clinical experience of 28.8 months) and 2 (with MSc degree and no clinical experience) in the second phase, as co-researcher examiners (not samples), all of the processes were done in the Faculty of Nursing and Midwifery of Tehran University of Medical Sciences campus. According to results of a pilot study before the main experiment, minimum correlation between real quantities and observed ones (measured by the device), was about 90 percent, thus with a 99% confidence and a power of 95% for having at least 70% correlation between this method and real quantities, a sample size of 30 observations was calculated (formulae 1 and 2).

Formula 1:

$$\frac{\left(Z_{1-\frac{a}{2}} + Z_{1-b}\right)^2}{2\left(c(r)\right)^2} + 3$$

Formula 2:

$$c(r) = \frac{1}{2} log \frac{1+r}{1-r}$$

R=0.7

N=26.6≈27 + 10%= 30

There were seven simulators in the first phase of the research, ranging from 40 to 100 mm in cervix model size, each examiner was asked to put the rings of the device on her fingers exactly at their middle length and perform the DVE on the simulator and count the narrow and thick lines of the thread which is stretched out of the container and one the researchers wrote every report separately for each examiner, the examiners and the recorder researcher were both blinded to the real sizes because cervix simulators were hidden in boxes simulating the vaginal canal and different sizes were in random row and written reports all needed to be multiplied by 2 and then participant's examiner fingers diameter should be added to the number (as Thales' part to whole rule in which thread and real cervix diameter are parallel lines in two triangles that thread's triangle is half of the bigger triangle in size with examiner fingers as sides of them) (Figure 1).

Real Dilatation= (Length of the thread out of the container * 2) + diameter of index and middle finger

The device was made of hard plastic (5 identical prototypes were built) that consists of two rings which should be placed on index and middle finger exactly at middle of their length while no scaled thread was out of the container (that was placed on one of the rings at palmar face of the fingers). Inside the container there was a small spool holding the scaled thread that could come out of the container from a tiny hole on it.

Thirty-five examinations performed in the first phase with seven simulators and 60 measurements in phase 2 with 30 simulators ranging from 40 to 100 mm, either of two phases were similar in method. For accuracy and precision of the instrument ICC between simulators and reports, ICC between observers, Pearson's Correlation and Standard Error, all with 95% IC, were used via SPSS-19 software.

3. Results

In the first phase ICC for agreement between simulator real quantities and reports was 0.968 (maximum accuracy at 50 mm and minimum at 80 mm with ICC of 0.994 and 0.913 respectively) and ICC between observers (for inter-observer agreement as reliability) was 0.995 (ranging from 0.984 to 0.999), all of tests with 95% IC.

In the second phase Pearson's Correlation for determining the agreement between examiner 1 reports and the real quantities (simulator), examiner 2 and the real quantities and between two examiners were 0.882, 0.815 and 0.697 respectively with 99% IC (Table 1 and

Figure 2 and 3). Reliability of the device using Chronbach's Alpha was 0.995; Total accuracy of the device using ICC was 0.834. Standard Error of the device by examiner 1 was 1.79 and 1.89 for the examiner 2 (Table 2).

Table 1. Pearson Correlations for 2nd Phase

	Simulator	P value
Examiner 1	0.882	<0.001
Examiner 2	0.815	<0.001
Inter-observer	0.697	<0.001

Table 2. Descriptive Statistics of 2nd Phase

	Mean Standard Error	Standard Deviation	P value
Examiner 1	1.79719	9.84360	<0.001
Examiner 2	1.89717	10.39125	<0.001

Cervical Dilatometer's precision according to the average errors (derivations from exact quantities) is 13.9 mm (ranging from 1.5 mm for 52 mm model to 31.5 mm in 94 mm model). Generally most precise measurements were at 40 to 52 mm dilatations in which mean error for examiner 1 was 3.2 mm and 3.7 mm for examiner 2, which gives average derivation of 3.5 mm in this dilatation range. The least precise measurements were recorded in 86 to 100 mm range that were 26.1 and 25.3 mm for examiner 1 and 2 respectively (average error= 25.75 mm).

4. Discussion

Agreement between simulator real quantities and reports was somewhat similar to Kordi et al.'s findings by means of 'Purple Line' method[24]. Cervical Dilatometer's precision according to the average errors (13.9 mm) was similar to Zador et al's ultrasonic method[25]. It is noteworthy that despite less-precise measurements in 86 to 100 mm range, the examiner in the clinical set-up has little doubt about her examination because at this points fetal presenting part fills the vaginal canal mostly and at full-dilatation no cervix tissue is palpable; so high errors of the device may not decrease the quality of care and clinical decision-makings. Similarly, according to Huhn et al and Nizard et al clinical examiners errors in determining dilatation increase as dilatation proceeds and less precise determinations belong to dilatations more than 8 cm (error= 12.5±8.7 mm)[2,13].

Friedman's cervimetery device was one of the most precise ones among mechanical cervimeters but unfortunately because of physical discomforts, it is not used in clinical set-up[19], although ultrasound devices despite their ergonomic design and high accuracy and precision[15] are still expensive for some hospitals especially in developing countries[6,16,17,21-23], but 'Cervical Dilatometer' can be mass-produced at lower prices and potentially, because of its non-contacting design, may not hurt maternal tissues as it has a very small size and doesn't technically touch cervix or fetus[20].

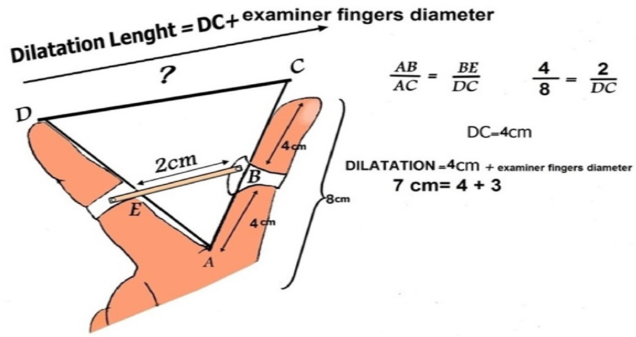

Figure 1. Determining cervical dilation by means of "Thales' part to whole rule" using Cervical Dilatometer.

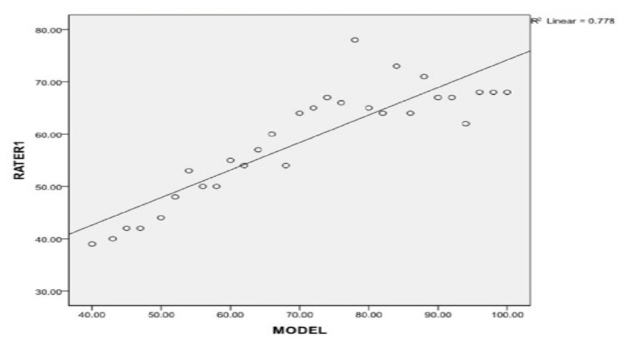

Figure 2. Linear regression of agreement between examiner 1 and real quantities.

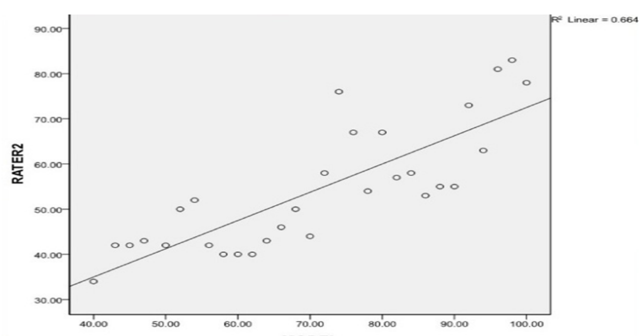

Figure 3. Linear regression of agreement between examiner 2 and real quantities.

5. Conclusions

According to the present study 'Cervical Dilatometer' qualifies acceptable accuracy, precision and reliability requirements to be used as a cervimetry instrument in laboratory phase and for educational purposes as well. Further research for determining those elements in clinical set-up is needed.

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