

## Accuracy of Ultrasound Methods Versus Other Methods for Detecting of Cervical Dilatation during Labor, a Protocol for Systematic Review

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### Abstract

**Background:** Fear of vaginal examination during labor is one of the major reasons for employing a surgical procedure to manage childbirth when it not medically justified. Women who request cesarean section dislike vaginal examination during labor because they find it painful, distressing, and embarrassing. Given that clinician could offer an alternate accurate method of monitoring the cervical dilation during birth, hence replacing the frequent vaginal examination, women may choose vaginal delivery rather than caesarean section. Current systematic review aims at identifying a ultrasound compared to other methods for detection of cervical dilation.

**Method:** This is a protocol for a systematic review of published and unpublished papers related to accuracy of cervical dilation using ultrasound compared to other methods for detection of cervical dilation. We will search MEDLINE, EMBASE, CINAHL, PSYCINFO and the Cochrane Library for studies published from inception till 2019. We will check reference lists of included studies for further studies. Two authors will independently screen the titles and abstracts identified from the search using Covidence; any discrepancies will be resolved by discussion and consensus. Full-text papers will be obtained and relevant reviews will be selected against inclusion criteria. Eligible studies are those that study sensitivity and specificity of ultrasound to identify cervical dilatation during labor compared to other method of diagnosis of cervical dilation. Quality of papers will be assessed using Quality Assessment of Diagnostic Test Accuracy Studies-2. Data from high quality eligible studies will be extracted using a data extraction form and analyzed using Revman.

**Results:** The proposed systematic review will provide findings useful for identifying the accuracy of ultrasound method compared to other methods for measuring cervical dilation.

**Conclusion:** This systematic review will be very helpful in clinical practice and of immense importance in the management of delivery.

**Keywords:** Ultrasound Methods; Cervical Dilatation; Labor

### Background

Measuring cervical dilatation is considered as the most important indicator of labour progress [1-3]. Failure in labour progress is one of the causes of caesarean section because almost 40% of women who have undergone a caesarean section have been diagnosed with

failure of cervical dilatation [4]. Cervical dilatation is often used as a parameter to study uterine activity, oxytocin use and transition from latent to active phase of labour. Cervical dilatation is also an essential element of pre-induction scoring process (Bishop Score) [5] as well as partogram, a universal method for monitoring the progress of labour. Therefore, errors in cervical dilatation assessment may compromise the favourable results of the partogram [6].

The methods used to measure cervical dilatation are classified into three categories: a) historical methods consistent of digital examination, use of mechanical devices, electromagnetic devices, and electronic sensor systems, b) manual examination, c) ultrasonic machines [7].

**Historical methods:** The most common method of measuring cervical dilatation in the past was digital examination that was used several times during vaginal delivery by clinicians [6]. Digital examination yielded accurate results in only 50% of cases. This method showed a 1-cm error (higher or lower than actual value) in 40% of cases, and a  $\geq 2$ -cm error in the remaining 10% of cases [6]. Digital examination is therefore considered an imprecise measure of the labour progress, particularly when performed by different examiners [8].

Apart from digital examination, more than eleven mechanical devices have been historically introduced for measuring cervical dilatation. Two main prototypes of these devices are callipers, including "light and heavy weight callipers" and "string-type callipers" [9]. Fireman invented the later caliper [10]. This instrument has two clips that are connected to the cervix which extend when the cervix is dilating. The distance of the extension is then measured using a ruler attached to the device [7]. Callipers invented by Siener, Glass and Noack also worked in the same manner [11]. String-type calliper has two cervical forceps that are attached to the cervix at 3 and 9 o'clock. Changes in dilatation lead to changes in length of the strings, which are then mechanically or electrically transmitted to a kymograph [9,12]. The disadvantage of the mechanical devices is the difficulty in placement of devices on the cervix [7].

Another method used in the past was electromagnetic technique that involves the use of two small induction coils attached to opposing cervical rims. When one of the coils is connected to a signal generator, it sends an electric current, thereby establishing a magnetic field which is then detected by the other coil and results are recorded [9]. The accuracy of this technique is low [7]. The electronic sensor system transmits information wirelessly to a transponder worn like a mobile phone or a personal digital assistant [7,9]. The information can be transferred to a remote point, enabling intervention by the medical personnel as necessary [7]. However, more researches are needed for using this system as its fetomaternal side effects are unclear.

**Manual examination:** The accuracy of vaginal examination is unclear and sometimes there is no compliance between midwives' and obstetrician's examinations. Results of Muliira's study showed that clinicians differed in dilatation measurements by 2 cm or more in 11% of cases [3]. It is known that inconsistent findings between examiners may cause distress in women and loss of confidence in their care providers [3,13].

Attitudes of women towards manual examination are very important. In 1986, Murphy found that the manual examination during labour is slightly uncomfortable for almost half the number of women (47%) and is very uncomfortable for 11% of women [14]. These results were confirmed by Khalil, who found that 70.5% of women expressed their dissatisfaction towards vaginal examination [15]. Moreover, Muliira reported that 68% of women feel discomfort during vaginal examination, and 82% of the women even found it painful or intolerable. Many women disliked vaginal examination because they find it embarrassing, painful and uncomfortable. Unfortunately, at times, examiners have responded to this negative reaction by invasive and semi-sterile vaginal examination, which increased the risk of infection in the mother and her baby [3]. The General Medical Council has received many complaints about improper or aggressive behaviour during vaginal examinations [16].

**Ultrasound measurements:** Abdominal, vaginal, trans-labial, and trans-perineal 2-dimensional (2D) and 3D ultrasounds have been used to visualise cervical dilatation during labour. The first usage of ultrasonic technology for measuring cervical dilatation was reported

in 1991. Ultrasonic device comprises of two ultrasound transducers is attached to opposing rims of the cervix. An ultrasonic signal generated by one transducer is then received by the opposing one. The obtained data are analysed off-line by a computer. The precision of this technique has been shown to be fairly good in labour [9,11].

In a non-imaging computerised ultrasound technology, sensors are placed on the cervix. Then, the dilatation of the cervix is calculated from transducers that are placed on the abdomen and send ultrasonic waves [17,18]. The assessment of cervical dilatation in this method is prone to inaccuracy due to maternal position, uterine contractions, and misplacement of transducer on the cervix [19].

Trans-perineal 2D ultrasound is a technique used to assess cervical dilatation during labour in most women and provides the measurement of the cervix from 1 cm to almost full dilatation. For both trans-labial and trans-perineal methods, the probe must be placed longitudinally in the medial sagittal position between both labia major, below the symphysis pubis [20]. A study showed that 70.5% of women believed that trans-labial ultrasound is better than manual examination as compared to only 4% who believed the opposite [15].

3D ultrasonography has been described for intrapartum measurement of cervical dilatation. The researchers suggest that 3D ultrasound could play a role as an imaging modality in selected cases. This technique is complicated and operator dependent and it is not suited for acute assessment of a woman on the delivery unit [19].

Trans-labial 3D ultrasonography has been suggested as an accurate and reproducible method for the assessment of cervical dilatation during labour. It can be used in selected cases, wherein there is a need to reduce repeated digital vaginal examinations, and in cases, wherein an accurate measurement of cervical dilatation is needed. Furthermore, it is useful in pelvic examination training, management of premature rupture of membranes, arrest of dilatation and when woman's preferences or sensitivities preclude repeated manual examinations [21].

In conclusion, the evidence shows that ultrasound is the most commonly used imaging technology for measuring cervical dilatation [19]. Whether any particular ultrasound modality is superior to the others is unclear. It is also not clear how accurate ultrasound measurements is compared to vaginal examination. Till now no systematic review attempted to test the accuracy of ultrasound methods compared with vaginal examination. This review attempts to verify the sensitivity and specificity of ultrasound methods compared with other methods in relation to cervical dilation.

### **Index test(s)**

There is a need for objective, repeatable and accurate measurements of cervical dilatation [13]. The accuracy of cervical dilatation measurement is very important. The estimation and accuracy test of each system are important for both clinical practice and research purposes [7].

Digital examination has always been the 'gold standard' method to evaluate cervical ripening and dilatation before and during labour. However, this view is being challenged because digital examination is a subjective evaluation [19] with several limitations. First, it varies from one examiner to another; second, the result is not reproducible even when the examination is performed by the same clinician, and it only allows the examination intermittently, thus the variation of cervical change cannot really be measured [7]. Thirdly, it is influenced by the actual cervical dilatation, cervical tissue compliance and the examiner's technique [21]. Therefore, digital examination can be inaccurate, inconsistent and insensitive [11].

Mechanical and electromagnetic devices have been designed to improve accuracy of the cervical dilatation measurement but none of them introduced significant advancement in the labour management [22]. Most of these devices are not automated and require staying in bed and hospitalization [7]. Also, the accuracy of these systems is low. The electronic sensor system is an advanced, continuous and real-time monitoring device with a good accuracy and possible movement of mother during labour [9]. However, these methods should be assessed for reproducibility and acceptability in blinded studies.

Diagnostic ultrasound is a sophisticated electronic technology, which utilises pulses of high frequency sound to produce an image. Through the ultrasonic methods, intrapartum trans-labial/perineal 2D/3D ultrasound could play an important role in the accurate diagnosis of cervical dilatation. These method may be used for repeated pelvic examinations and viability of foetus, placenta position, etc. But

it is not clear if ultrasound can replace digital vaginal examination in the management of routine low-risk labour. It should be noted that there is overlap in the use of these diagnostic tests from one trimester to another.

### **Clinical pathway**

The vaginal examinations have become a routine intervention in labour for assessing labour progress. Impaired labour progress can be a sign of labour dystocia, which is associated with maternal and foetal morbidity and mortality, particularly in the countries where appropriate interventions are not easily accessible [23].

Monitoring cervical dilatation starts in women in labour with a live singleton foetus in cephalic presentation and gestational age > 37 weeks. The women lie in supine position with flexed hips and knees. They should have ruptured membranes and an empty bladder. Digital examinations are performed before using the other examination devices by the midwife or obstetrician [13]. The full components of the vaginal examination can be summed up as follows: the position of the cervical os (posterior to anterior); consistency of the cervix (from hard to soft or 'ripe'); effacement of the cervix (from thick to thin); dilatation of the cervical os (from 0 to 10 cm, nominally) [23]. Cervical dilatation can be reported according to each device. Measuring cervical dilatation continues until full dilatation is indicated.

### **Alternative tests(s)**

Digital examination is not highly sensitive for identifying cervical dilatation. Repeated digital cervical examinations may be time consuming for the clinician, poorly reproducible and uncomfortable for the patient. Thus, continued efforts are made to design a suitable device for clinical use. Although many instruments have been developed to measure cervical dilatation during labour, the ideal device has not yet been successfully introduced for clinical obstetrics [10].

### **Rationale**

For a long period, errors in cervical dilatation assessment were considered of no importance, and only in the recent decade this issue received much attention [6]. The pattern of labour progress in contemporary populations differs significantly from what was observed in the 1950s by Friedman [3]. It seems that the rate of cervical dilatation is slower in women with different parities compared with that described by Friedman. A recent review concluded that the active phase of labour does not begin until the cervix is dilated 5 cm in multiparas and even further in primiparas [3]. Besides, there is no evidence-based information on which to make recommendations for the timing and frequency of vaginal examinations in labour [16]. If the assessment of cervical dilatation is performed every 4 hours, the possibility of drawing incorrect conclusions is 11%, and considering the length of time that women remain in labour, the rate of error increases to 33%. If the interval for cervical dilatation assessment is shortened, the percentage of possible inaccuracy in measurement of cervical dilatation rises further [6]. All of these issues plus inaccuracies in cervical dilatation measurement could be the causes of inconsistencies in clinical decisions, delaying of interventions or performing unnecessary interventions. Given the large number of deliveries and performed interventions, even a small fraction of mistakes can lead to a large number of mistreated labours [19]. Therefore, the necessity of using a more accurate method of cervical assessment with lowest rate of errors is essential.

Using ultrasound during labour has been explored in the last decade, from simple uses such as determination of foetal presentation and identifying the foetal heartbeat to advanced diagnosis like prediction of the mode of delivery, foetal station and assessment of cervical dilatation [19]. The maximum error of ultrasonic measurements is 3 mm in the range of 2 to 10 cm [7]. Therefore, an ultrasound cervical dilatation score was developed to assess the quality of cervical measurement. In this method, score zero to 3 was introduced, when 3 indicates that cervical dilatation is visible in more than 75% of the cervical circumference and zero indicates that the cervical dilatation is visible in less than 25% of the cervical circumference [19]. The preference of using 2D or 3D ultrasound still remains unanswered. The technical difficulties of using trans-perineal and trans-labial ultrasound are related to poor visualisation of the cervix during labour. Poor visualisation can happen due to the poor echogenicity, relatively small thickness of cervix after progress of effacement, inadequate reso-

lution and because of the descending of foetus into the birth canal. However, trans-labial 2D has the potential to measure the progress of labour entirely, without discomfort of conventional vaginal examination. In this method, the anterior-posterior diameter of cervix is a basis of measurement, as this is clearer than the transverse diameter. The reason for this is that the axial ultrasound resolution is greater than lateral ultrasound resolution.

### **Primary Objectives**

Measuring cervical diameter by ultrasound is more accurate than digital measurement of cervix during labour. Therefore, the ultrasound method is our index test and our primary objectives are as follows:

1. To determine the diagnostic accuracy of the ultrasonic method compared to manual examination for detection of cervical dilatation during labour.
2. To determine the diagnostic accuracy of the ultrasonic method compared to mechanical method for detection of cervical dilatation during labour.
3. To determine the diagnostic accuracy of the ultrasonic method compared to electromagnetic method for detection of cervical dilatation during labour.
4. To determine the diagnostic accuracy of the ultrasonic method compared to electronic sensor method for detection of cervical dilatation during labour.

### **Secondary objectives**

1. To assess the sensitivity and specificity of available diagnostic methods in various parities for diagnosis of cervical dilatation during labour.
2. To assess the sensitivity and specificity of available diagnostic methods in intact membranes versus ruptured membranes for diagnosis of cervical dilatation during labour.
3. To assess the sensitivity and specificity of available diagnostic methods in the diagnosis of cervical dilatation in latent phase (0 - 4 cm), maximum slope phase (5 - 8 cm) and deceleration/full dilatation phase (8 - 10 cm) [21].
4. To assess the sensitivity and specificity of available diagnostic methods in different effacement and station of foetus head.
5. To assess the sensitivity and specificity of available diagnostic methods in different severity of pain (mild, moderate, severe) during labour.

### **Methods**

Criteria for considering studies for this review.

#### **Types of studies**

We will review published, peer-reviewed studies with cross-sectional and diagnostic case-control study designs evaluating the accuracy of available methods for cervical measurement during labour. We will evaluate each of the measurement method alone or in combination with other methods (when they have been used in a diagnostic algorithm). No language barrier will be imposed on this review. All studies performed in any healthcare setting will be included.

Articles that have the following characteristics will be included:

1. Use at least one measuring device for cervical dilatation during labour.
2. Reporting any method for the diagnosis of cervical changes.
3. Reporting any technique for monitoring the progress of child birth.
4. Using manual vaginal examination.

The following studies will be excluded:

1. Narrative or systematic reviews.
2. Studies that included inappropriate comparisons.
3. Studies that do not include the data on the reference standard.
4. Studies that evaluate specific technical aspects of an index test or focus primarily on an inter-observer variability, rather than assess diagnostic accuracy.
5. Studies that do not report data in sufficient detail to construct  $2 \times 2$  tables or if this information will not be available from the primary investigators.

### Participants

Pregnancies with ultrasound measurements at any stage of pregnancy will be included. The pregnancies will include any type of placenta attachment, any type of conception, and any maternal age and body mass index. Pregnancies that include inappropriate comparisons that are likely to distort an assessment of the diagnostic value of antenatal ultrasound will be excluded (e.g. pregnancies that include twins or other multiple pregnancies such as triplets or quadruplets). Only participants that had both the index test and reference standard reported will be included.

### Results and Discussion

#### Index tests

The measurements are considered eligible if performed by using transabdominal or transvaginal ultrasound machines of any brand based on 2D or 3D ultrasound methods. The data on experience of the operators and inter-/intra-observable variability will be collected and incorporated in the quality assessment tool. Studies that do not report data in sufficient detail to construct  $2 \times 2$  tables, and where this information is not available from the primary investigators, will be excluded.

Ultrasound diagnostic accuracy will be calculated using the anterior-posterior diameter for the measurement of cervical dilatation in comparison with other methods of cervical dilatation methods.

#### Target conditions

The target condition is singleton pregnancy with measurement of cervical dilatation during labour. It occurs when a woman enters the labour phase. For this review, studies that investigated any devices for measurement of cervical dilatation during labour or vaginal examination will be taken into consideration.

#### Reference standards

The reference standard is the vaginal examination or digital measurements of cervical dilatation during labour. We will include studies that document the method of measurement during labour. We will document the methods used to optimise accuracy of cervical dilatation, for example, whether ultrasound and digital measurement show the same result to ensure accuracy and comparability. Measurements will be considered if performed in the hospital (labour ward, nursery or new born intensive care unit) by trained medical personnel (doctor, nurse, midwife, paramedic). We will include only the measurements performed within duration of labour. Where available, the data on scale calibration will be recorded and incorporated in the QUADAS-2 quality assessment tool. The measurements including length of cervix, cervical dilation will not be used in this review.

### **Search methods for identification of studies**

A comprehensive search of multiple sources for eligible studies will be adopted, which will minimise the risk of reporting bias. However, publication bias generally arises when studies have a greater chance of being published if their results are positive. Therefore, we are planning to search unpublished and published study databases and conference proceedings, and evaluate identified sources.

The search strategy will be developed by a librarian following the recommendations in the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy (de Vet 2008). The searches will not be limited to particular language or publication date restrictions. The search strategy will incorporate words in the title, abstract, text words across the record and the subject headings.

### **Electronic searches**

We will search the following electronic databases from inception to present.

- Cochrane Central Register of Controlled Trials (CENTRAL) via Cochrane Library
- MEDLINE via Ovid (from 1946 to current)
- Embase via Ovid (from 1980 to current)
- CINAHL (from 1982 to current)
- ISI Web of Science Core Collection (from 1900 to current)
- Trip Database (from 1997 to current)
- PubMed Systematic Reviews subset (from 1946 to current)
- DARE and NHS EED via the University of York (1994)
- HTA (2003) and Prospero via the University of York (2011)

### **Searching other resources**

Additional searches will include:

1. A hand search of Australasian Journal of Ultrasound in Medicine (2009); Canadian Journal of Medical Sonography (2013), the reference lists of all the included studies and the seminal reviews from the field; and
2. Communication with at least 5 experts in the field asking them to review our reference list and identify any studies that may be missing.

### **Data collection and analysis**

Data extraction and handling, assessment of methodological quality and statistical analyses will be performed based on the recommendations of the Diagnostic Test Accuracy (DTA) group and their internet-based tutorials (<http://methods.cochrane.org/sdt/dta-author-training-online-learning>).

### **Selection of studies**

One review author will scan the titles of studies identified by our search to remove any clearly irrelevant articles and further, will scan the titles and abstracts of the remaining studies to select potentially-relevant articles. Two review authors will independently review full-text versions of the articles selected by title and abstract and assess their eligibility for inclusion. Any disagreements will be resolved by discussion and, if necessary, with a third review author, who is an expert in the field and in methodological aspects of Cochrane systematic reviews.

When we identify the reports that update previous publications of the same study population at different recruitment points, the earlier records will be classified as excluded. The most complete data set that superseded previous publications will be used, in order to avoid double counting participants or studies.

Missing data will be retrieved by contacting the authors of identified studies directly, in order to clarify the study eligibility. When potentially-relevant studies are found in languages other than English, a translation will be arranged where possible.

For excluded studies, we will document the reasons for exclusion with details of which criteria were not met. The characteristics of included and excluded studies and studies awaiting classification will be presented under ‘Characteristics of included studies’, ‘Characteristics of excluded studies’ and ‘Characteristics of studies awaiting classification’, respectively.

A single failed eligibility criterion is sufficient for a study to be excluded from the review.

**Data extraction and management**

We will use a structured, piloted data-extraction form to extract data from included studies. Two review authors will independently extract study characteristics. Disagreements will be solved by discussion. If disagreement persists, a third review author will resolve the issue. We will extract information on: author, year of publication, journal; study design; timing of data collection (prospective, retrospective); study population (age, parity, gestational age); type of index test and reference standard and data on index and reference test operators. The reported number of true positives (TP), false negatives (FN), true negatives (TN) and false positives (FP) will be used to construct a two-by-two (2 x 2) table for each index test. If these values were not reported, we attempted to reconstruct the 2 x 2 tables from the summary estimates presented in the article. Data will be extracted into Review Manager (Revman 2014) software, which is used to graphically display the quality assessment, the diagnostic estimates data and the descriptive analyses.

**Assessment of methodological quality**

We will use the Quality Assessment of Diagnostic Test Accuracy Studies-2 (QUADAS-2) to assess the methodological quality of included studies. The QUADAS-2 tool will be applied in four phases: summarizes the review question, tailor the tool and produce review-specific guidance, construct a flow diagram for the primary study, and judge bias and applicability. Each paper will be judged as having a ‘low’, ‘high’ or ‘unclear’ risk for each of four domains, and concerns about applicability will be assessed in three domains. The review-specific QUADAS-2 tool and explanatory document are presented in appendix 1. Two review authors will independently pilot the review-specific tool to rate three of the included studies. The tool will be utilized if a high level of agreement is achieved at the pilot stage. Two review authors will independently apply the QUADAS-2 tool to the full text of each study. Disagreements will be resolved by discussion, or if needed, by a third review author. Revman software will also be used to construct methodological quality summary graphs.

<b>Domain 1 - Patient selection</b>	
Description	Describe methods of patient selection; describe included patients (previous testing, presentation, intended use of index test, and setting)
Type of bias assessed	Selection bias, spectrum bias
Review question	Pregnancies with ultrasound measurements at any stage of pregnancy. The pregnancies will include any type of placentation, any type of conception, any BMI, any maternal age and any maternal condition.
Information collected	Study objectives, study population, selection (inclusion/exclusion criteria), study design, clinical presentation, age, number of enrolled and number of available for analysis, setting, place and period of the study
<b>Signaling question 1</b>	<b>Did the study avoid inappropriate exclusions?</b>
Yes	If all the study participants with alive pregnancies were included

No	If the study selected patients based on particular clinical features. This section should include something indicated that the population was pre-selected and hence may not reflect the accurate findings applied to general population. Example: only participants with or without specific medical conditions; participants selected based on BMI; only participants attending certain number of previous ultrasound examinations; only participants selected on the basis of other antenatal tests
Unclear	If the study did not provide a clear definition of the selection (inclusion/exclusion) criteria and 'no' judgment was not applicable
<b>Signaling question 2</b>	<b>Was a consecutive or random sample of patients enrolled?</b>
Yes	If a consecutive sample or a random sample of the eligible patients was included in the study
No	If a non-consecutive sample or non-random sample of the eligible patients was included in the study
Unclear	If this information was unclear
<b>Signaling question 3</b>	<b>Was a case-control design avoided?</b>
Yes	If the study had a single set of inclusion criteria, defined by the clinical presentation (i.e. only participants with alive pregnancy)
No	If the study had more than one set of inclusion criteria in respect to clinical presentation (i.e. participants with alive twin pregnancy and participants with multiple pregnancies or additional group of participants used as historical cohort)
Unclear	If it was unclear whether a case-control design was avoided or not
<b>Risk of bias</b>	<b>Could the selection of patients have introduced bias?</b>
High	If 'no' classification for any of the above 3 questions
Low	If 'yes' classification for all the above 3 questions
Unclear	If 'unclear' classification for any of the above questions and 'high' risk judgment was not applicable
<b>Concerns about applicability</b>	<b>Are there concerns that the included patients do not match the review question?</b>
High	If the study population differed from the population defined in the review question in terms of demographic features and co-morbidity
Low	If the study includes only clinically-relevant population that would have undergone the index test in real practice
Unclear	If this information was unclear; Only studies with sufficient information on study population will be included, therefore none of the included studies are anticipated to be classified as 'unclear'
Description	Describe the index test, how it was conducted and interpreted
Type of bias assessed	Test review bias, clinical review bias, inter-observer variation bias
Review question	Any type of ultrasound method and any type measurements for assessment of cervical dilatation
Information collected	Index test name, description of positive case definition by index test as reported, examiners (number, level of expertise, blinding), inter-observer variability, conflict of interests
<b>Signaling question 1</b>	<b>Were the index test results interpreted without knowledge of the results of the reference standard?</b>
Yes	If the operators interpreting the index test were unaware of the results of reference standard. All the index tests are expected to be performed and interpreted before execution of the reference standard, therefore none of the included studies are anticipated to be classified as 'Yes' in response to this question

No	If the operators interpreting the index test were not blinded to the results of reference standard
Unclear	If this information was unclear
<b>Signaling question 2</b>	<b>Did the study provide a clear pre- specified definition of what was considered to be a ‘positive’ result of index test?</b>
Yes	If study provided clear definition of positive findings, which was defined before execution/interpretation of index test
No	If definition of the positive result was not provided or if study described the findings derived from the index test and not defined prior to its execution
Unclear	If it was unclear whether the criteria were pre-specified or not
<b>Signaling question 3</b>	<b>Was the level of expertise of the index test operator provided?</b>
Yes	If test was performed/interpreted either by single operator or interpreted after collegial discussion of the case
No	If test was performed/interpreted independently by several operators
Unclear	If this information was unclear
<b>Signaling question 4</b>	<b>Were the same clinical data available when the index test results were interpreted as would be available when the test is used in practice?</b>
Yes	If operators performing/interpreting the test were aware of suspected birth weight discordance and/or of the clinical history, but were not aware of the results of other imaging tests or of previous diagnosis of birth weight discordance, including the results of previous ultrasounds
No	If operators performing/interpreting the test were not blinded to the results of other imaging tests or tests raising suspicion for birth weight discordance
Unclear	If this information was unclear
<b>Risk of bias</b>	<b>Could the conduct or interpretation of the index test have introduced bias?</b>
High	If ‘no’ classification for any of the above 4 questions
Low	If ‘yes’ classification for all the above 4 questions
Unclear	If ‘unclear’ classification at least for one question and ‘high’ risk judgment was not applicable
<b>Concerns about applicability</b>	<b>Are there concerns that the index test, its conduct, or interpretation differ from the review question?</b>
High	We plan not to consider the studies where index tests other than ultrasound measurements were included or where index test looked at other target conditions not specified in the review (for example studies aimed at identifying maternal diseases), therefore none of the included studies is expected to be classified as ‘high concern’
Low	We will consider all types of ultrasound methods as eligible, therefore all the included studies are expected to be classified as ‘low concern’
Unclear	Only studies with sufficient information on index will be included, therefore none of the included studies will be classified as ‘unclear’
<b>Domain 3 - Reference standard</b>	
Description	Describe the reference standard, how it was conducted and interpreted
Type of bias assessed	Verification bias, bias in estimation of diagnostic accuracy due to inadequate reference standard
Review Question	Target condition - birth weight discordance
Information collected	Target condition, prevalence of target condition in the sample, reference standard, description of positive case definition by reference test as reported, examiners (number, level of expertise, blinding)

<b>Signaling question 1</b>	<b>Is the reference standard likely to correctly classify the target condition?</b>
Yes	If the study reported at least one of the following: calibration of scales, electronic scales, timing of weighing in relation to delivery, or drying of neonate before weighing
No	If the reference standard did not classify the target condition correctly; considering the inclusion criteria, none of the studies are expected to be classified as 'no' for this item
Unclear	If information on execution of the reference standard, its interpretation or operators was unclear
<b>Signaling question 2</b>	<b>Were the reference standard results interpreted without knowledge of the results of the index tests?</b>
Yes	If operators performing the reference test were unaware of the results of index test
No	If operators performing the reference test were aware of the results of index test
Unclear	If this information was unclear
<b>Risk of bias</b>	<b>Could the reference standard, its conduct, or its interpretation have introduced bias?</b>
High	If 'no' classification for any of the above 2 questions
Low	If 'yes' classification for all the above 2 questions
Unclear	If 'unclear' classification for any of the above 2 questions and 'high risk' judgment was not applicable
<b>Concerns about applicability</b>	<b>Are there concerns that the target condition as defined by the reference standard does not match the question?</b>
High	We plan to exclude the studies where participants did not have ultrasound measurement, therefore none of the included studies are expected to be classified as 'high concern'
Low	Considering the inclusion criteria, all the studies are expected to be classified as 'low concern'
Unclear	Only studies where scales to assess cervical dilatation as a reference test will be included; therefore none of the included studies is expected to be classified as 'unclear concern'
<b>Domain 4 - Flow and timing</b>	
Description	Describe any patients who did not receive the index tests or reference standard or who were excluded from the 2 x 2 table, describe the interval and any interventions between index tests and the reference standard
Type of bias assessed	Disease progression bias, bias of diagnostic performance due to missing data
Review Question	Cervical dilation is measured during labour
Information collected	Time interval between index test and reference standard, withdrawals (overall number of reported and if were explained)
<b>Signaling question 1</b>	<b>Was there an appropriate interval between index test and reference standard?</b>
Yes	If time interval was reported and was within the period of labour
No	We plan to exclude all the studies where the time interval was longer than duration of labour, therefore none of the included studies is anticipated to be classified as 'no' for this item
Unclear	If time interval was not stated clearly, but authors description allowed the reader to assume that the interval was reasonably short
<b>Signaling question 2</b>	<b>Did all patients receive the same reference standard?</b>
Yes	If all participants underwent cervical dilation assessment and there are sufficient data to record dilatation; considering the inclusion criteria, all of the studies are expected to be classified as 'yes' for this item

No	If all participants did not undergo cervical dilatation assessment or if only a subset of participants had this assessment, but the information on this population was not available in isolation
Unclear	If this information was unclear
<b>Signaling question 3</b>	<b>Were all patients included in the analysis?</b>
Yes	If all the patients were included in the analysis or if the patients were excluded prior to execution of index test or if the withdrawals were less than 2% of the enrolled population (arbitrary selected cut off)
No	If any patients were excluded from the analysis because of uninterpretable results, inability to undergo either index test or reference standard or unclear reasons
Unclear	None of the studies expected to be classified as 'unclear' for this item
<b>Risk of bias</b>	<b>Could the patient flow have introduced bias?</b>
High	If 'no' classification for any of the above 3 questions
Low	If 'yes' classification for all the above 3 questions
Unclear	If 'unclear' classification for any of the above 3 questions and 'high risk' judgment was not applicable

**Appendix 1:** QUADAS-2 risk of bias assessment tool. Methodological items and applicability judgments.

We will consider studies as having low methodological quality when classified at high or unclear risk of bias or at high concern regarding applicability in at least one domain. The assessment of methodological quality will be undertaken for each domain but a summary score to estimate the overall quality of studies will not be calculated.

**Statistical analysis and data synthesis**

The unit of analysis in studies will be women in labour, as cervical dilatation is a single calculated measure using various methods. We will extract the absolute counts of true positive (TP), false positive (FP), false negative (FN) and true negative (TN) from each study. TP is defined as ultrasound positive for cervical dilatation score greater than zero, when the cervical dilatation is visible in less than 25% of the cervical circumference [19], confirmed by digital examination. FP is defined as ultrasound positive for cervical dilatation, as mentioned above, without the diagnosis of cervical dilatation by digital examination. FN is a negative ultrasound with the diagnosis of cervical dilatation confirmed by digital examination. Finally, TN is a negative ultrasound without diagnosis of cervical dilatation by digital examination.

We will then use the counts TP, FP, FN and TN to construct two by two tables to estimate sensitivity and specificity with 95% confidence intervals for each study. Extracted data will be recorded in data extraction forms. Two authors will extract the counts separately and discuss disagreements before engaging a third author to resolve any disagreements. We will then transfer the data into Revman to produce plots and estimates. We will present individual study results graphically by plotting the estimates of sensitivity and specificity in forest plots. We will use random-effects modelling to obtain summary estimates of the pairs of sensitivity and specificity. Additionally, we will draw receiver operator characteristic (ROC) curves using sensitivity and specificity estimates. Our main analysis will be a multivariate model with covariates indicating the measurement methods (digital, mechanical, electromagnetic, electronic sensor system, 2D and 3D ultrasound), parity (discrete variable), gestational age (continuous variable), the type of the comparison, labour phases (latent, maximum slope and deceleration), severity of pain (mild, moderate and severe), effacement and station of foetus. Multivariate models will be performed with generalised mixed logistic module in SPSS statistical software, version 21 (SPSS Inc., NC, USA). P-values less than 0.05 will be considered significant.

### **Investigations of heterogeneity**

Heterogeneity will be investigated for the diagnostic tests if there are sufficient numbers of studies (> 5). We will check the heterogeneity through following steps. Firstly, the heterogeneity will be checked through visual examination of ROC plots and the forest plots by grouping the generated estimate according to all the items listed as potential sources of heterogeneity. Factors like type of ultrasound, year of publication, geographic areas (high income versus LMIC), consecutive enrolment, blindness of the operators to clinical data, modifications applied to the widely accepted method of imaging techniques (e.g. bowel preparation), number of index test operators, missing data and quality of studies based on QUADAS 2 tool will be considered in heterogeneity. Secondly, we will perform meta-regression analysis to investigate potential sources of heterogeneity, conditional to access to the adequate data for analysis. Meta-regression will take into account the specific sources of clinical heterogeneity such as parity (nulliparous versus multiparous), status of the membranes (rapture versus intact), satisfaction (maternal versus obstetrician), complications (neonatal versus maternal), techniques (old versus novel) and cost (cheap versus expensive).

Methodological sources of heterogeneity will also be investigated using meta-regression analysis. These will be listed as verification bias, incorporation bias, diagnostic review bias, and clinical review bias.

### **Sensitivity analyses**

We plan to conduct two sensitivity analyses to restrict the analysis to studies that

1. Used 2D ultrasound as the reference standard in all measuring cervical dilatations.
2. Used old techniques compared with novel techniques only as the reference standard.

### **Assessment of reporting bias**

We are not planning to use funnel plots to evaluate the impact of publication bias or other biases associated with small studies, because according to Leeflang, *et al.* the tests commonly used in interventional systematic reviews for publication bias are not useful for diagnostic testing reviews [2]. Deeks, *et al.* verified that the use of an asymmetric effective sample size plot to detect publication bias lacks power in situations where sample variability is present [1]. We will attempt to use unpublished data to minimize reporting bias.

### **Conclusion**

This systematic review will be very helpful in clinical practice and of immense importance in the management of delivery.

### **Ethical Approval and Consent to Participate**

This systematic review did not need ethical approval as there is no primary data collection.

### **Consent for Publication**

All authors have given their consent to the publication.

### **Availability of Supporting Data**

Systematic reviews are based on data extracted from other papers. These data are typically included in Tables of “included studies”.

### **Competing Interests**

None.

### **Funding**

None.

### Authors' Contributions

All three authors designed the study. P.S. searched the articles, P.S and P.A will conduct the screening, data will be analyzed by S.J. All three authors wrote the manuscript.

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