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Pulmonary ultrasound can be used to exclude pulmonary pathology in pregnancy: a prospective controlled study.

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November 2, 2020

Abstract

Objective: To evaluate and validate the specificity of pulmonary ultrasound as a diagnostic tool for pleural effusion, pneumonia and pulmonary oedema in healthy pregnant women compared to non-pregnant healthy women. Design: Single-centre, prospective, observational controlled study. Setting: Large teaching hospital in the Netherlands. Population: All women underwent pulmonary ultrasound evaluation. We included 127 pregnant and 124 non pregnant women. Methods: Pulmonary ultrasound was performed in both pregnant and non-pregnant women. Presence and/of symptoms of pulmonary or cardiovascular pathology and [?]20 weeks of pregnancy were among the exclusion criteria. Pulmonary ultrasound was performed by following the BLUE-protocol. Main outcome measures: The following items were assessed: A-lines, B-lines, comet tails, pleural effusion, sub pleural consolidation and hepatization. Presence of three or more B-lines, pleural effusion and/or sub pleural consolidation was interpreted as a false positive outcome after review of an expert. Results: We included 251 patients, who underwent pulmonary ultrasound evaluation. None of the participants showed pleural effusion, sub pleural consolidation or hepatization. One participant showed presence of >3 B-lines. One ultrasound showed a spine sign. Thus, two of the pulmonary ultrasounds was considered false positive. Conclusions: In this study no differences in specificity of pulmonary ultrasound were found in healthy pregnant women compared to healthy non-pregnant women. This suggests translatability of pulmonary ultrasound studies to the pregnant population for the evaluation of respiratory complaints.

TITLE PAGE

Pulmonary ultrasound can be used to exclude pulmonary pathology in pregnancy: a prospective controlled study.

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Shortened Running Title : Pulmonary ultrasound in healthy pregnant woman.

ABSTRACT

Objective *:* To evaluate and validate the specificity of pulmonary ultrasound as a diagnostic tool for pleural effusion, pneumonia and pulmonary oedema in healthy pregnant women compared to non-pregnant healthy women.

Design : Single-centre, prospective, observational controlled study.

Setting: Large teaching hospital in the Netherlands.

Population: All women underwent pulmonary ultrasound evaluation. We included 127 pregnant and 124 non pregnant women.

Methods: Pulmonary ultrasound was performed in both pregnant and non-pregnant women. Presence and/of symptoms of pulmonary or cardiovascular pathology and [?]20 weeks of pregnancy were among the exclusion criteria. Pulmonary ultrasound was performed by following the BLUE-protocol.

Main outcome measures: The following items were assessed: A-lines, B-lines, comet tails, pleural effusion, sub pleural consolidation and hepatization. Presence of three or more B-lines, pleural effusion and/or sub pleural consolidation was interpreted as a false positive outcome after review of an expert.

Results *:* We included 251 patients, who underwent pulmonary ultrasound evaluation. None of the participants showed pleural effusion, sub pleural consolidation or hepatization. One participant showed presence of >3 B-lines. One ultrasound showed a spine sign. Thus, two of the pulmonary ultrasounds was considered false positive.

Conclusions *:* In this study no differences in specificity of pulmonary ultrasound were found in healthy pregnant women compared to healthy non-pregnant women. This suggests translatability of pulmonary ultrasound studies to the pregnant population for the evaluation of respiratory complaints.

Funding: No involvement from funding sources or financial support.

Keywords: Ultrasound, pulmonary ultrasound, pregnancy, pulmonary embolism, pulmonary oedema, ultrasound, ultrasonography, lung diseases.

Tweetable abstract

Pulmonary complaints and pregnant? Avoid radiation and use pulmonary ultrasound.

MAIN TEXT

Introduction

Significant anatomic and physiologic adaptations involving the respiratory and cardiac systems occur during pregnancy and are necessary because of the increased metabolic demands of both the mother and the foetus. The prominent respiratory changes include mechanical alterations to the chest wall and diaphragm to accommodate the enlarging uterus, a reduction in functional residual capacity (FRC) and an increase in minute ventilation. The major cardiovascular changes include increased plasma blood volume, increased cardiac output, and a reduction in systemic vascular resistance. It can be challenging for physicians to distinguish the common physiologic dyspnoea from breathlessness caused by cardiopulmonary pathology. This while community acquired pneumonia is a common cause for hospital admission in pregnant women

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and acute respiratory failure (ARF) in pregnancy is one of the most common and potentially lethal causes for pregnant women to be admitted in the intensive care unit.

The current diagnostic tools for the diagnosis of cardiac and pulmonary pathology such as pneumonia, pulmonary oedema, pneumothorax and pleural effusion are all based on radiation, with inherent risks to both mother and foetus. An upcoming alternative, pulmonary ultrasound, is radiation-free and highly sensitive and specific for these pathologies and applicable at the bedside. Diagnostic accuracy for detecting pulmonary oedema is even better compared to chest radiography and thoracic computed tomography. Pulmonary ultrasound has not been evaluated in the pregnant population study yet. This while especially these patients would benefit from reduction of radiation.

While sensitivity of pulmonary ultrasound will probably not be affected by pregnancy, specificity may, because of possible occurrence of clinically non-significant mild pulmonary oedema during (late) pregnancy, combined with the high sensitivity of pulmonary ultrasound. This could possibly result in a high rate of false positive outcomes. However, when specificity does not differ from the non-pregnant population, pulmonary ultrasound can safely be used instead of X-ray to exclude common pulmonary pathology and pulmonary manifestations of cardiac disease in pregnant women as it already does in the non-pregnant population.

The objective of this study is to evaluate the specificity of pulmonary ultrasound for pleural effusion, pneumonia and pulmonary oedema in pregnant women compared to non-pregnant women.

Methods

This prospective observational controlled study was conducted in pregnant women who were seen at the outpatient obstetric clinic of the Medical Centre Leeuwarden and in non-pregnant women who were recruited as a non-pregnant control group. The study was conducted in a four-month period (March 2020-June 2020). Written informed consent was obtained from all participants.

Study population

Patients were divided in two groups, pregnant and non-pregnant. Inclusion criteria for the pregnancy group were as follows: [?]18 years of age, ability to read and sign informed consent, gestational age [?]20 weeks (because increased aorto-caval pressure is not likely and therefore false positive pulmonary ultrasound results are not plausible), and no history or clinical signs of acute or chronic respiratory or cardiac disease.

Non pregnant participants were recruited all over the hospital (students, doctors, nurses and other staff members). Inclusion criteria for the control group were: fertile women, [?]18 years of age, at least one previous menstruation and no history or clinical signs of acute or chronic respiratory or cardiac diseases.

Exclusion criteria for both groups were as follows: <18 years of age, known or suspected cardiovascular or pulmonary disease, clinical signs of acute/chronic respiratory or cardiovascular diseases, not being able to sign or understand informed consent form and non-consent.

Extra exclusion criteria for the pregnant group were: pregnancy <20 weeks, (pre-)eclampsia or HELLP and illness requiring current hospitalization of the patient.

Extra exclusion criteria for the control group were: a possible pregnancy or post-partum period (up to 6 months post-partum) and clinical signs of climacterium (e.g. hot flashes, decrease of regularity of menstruation).

Pregnancy was defined by a (reported) positive pregnancy test and confirmation by clinician or midwife on ultrasound. Non-pregnancy was defined by not being pregnant as stated by the woman (this was not controlled by pregnancy testing because early pregnancy is not suspected to bias outcome due to absence of increased aorto-caval pressure). Absence of cardiovascular or pulmonary disease were defined as without known pulmonary disease as stated by the clinician after reviewing medical history and pulmonary complaints. Thus, the clinicians' point of view was regarded as the golden standard for absence of cardiovascular pulmonary disease. X-ray was not used as the golden standard, mainly because of ethical considerations (unnecessary

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radiation during pregnancy) and because of the known lower sensitivity and specificity of pulmonary X-ray compared to ultrasound.

Study procedures

Baseline criteria were age, height, weight, gestational age, medical history, smoking (current and one year ago), use of alcohol (current and one year ago), use of medication (current use for all patients and for pregnant women the use of medication before pregnancy) and presence of peripheral oedema.

Pulmonary ultrasound in the pregnant population was two researchers (I.A. and L.V.). Both researchers were trained by two pulmonary ultrasound experts (H.L. and J.D.). If more than one pregnant woman presented at the same time at the outpatient obstetric clinic only one could be included because of logistic and ethical committee considerations in this study (pulmonary ultrasound had to be made right after the consultation at the physician to minimalize waiting time for the participant).

For the pulmonary ultrasound a curved-linear or phased array probe (type C6-2) visualizes deep structures of the lung. Images were viewed at a depth of 17 cm, with the included patients and volunteers and in supine or semi-recumbent position. The basic pulmonary ultrasound in emergency (BLUE) protocol was used to visualize four points of the hemi thorax. The ultrasound device used to obtain all of the ultrasound images in this study is the Toshiba type Xario 100. The PVU-375BY probe (abdominal probe) was used for this study.

Three images per hemi thorax were saved during this study for all included women. Afterwards the images were reviewed for the presence of A-lines, B-lines, pleural effusion, spine sign, sub pleural consolidation and hepatization.

All obtained pulmonary ultrasound images were interpreted by two researchers (I.A. and L.V.) and randomly double checked by two pulmonary ultrasound experts (H.L. and J.D.). In case of discrepancy between researchers, experts (H.L. and J.D.) reviewed the images and their consensus was leading.

Images were reviewed for presence of A-lines, comet tails, number B-lines (maximum number of B-lines in one intercostal space), presence of pleural effusion, spine sign, subpleural consolidation and hepatization by following the BLUE protocol.

Statistical analysis

Continuous data are presented as median with interquartile range (IQR) whereas nominal data are presented as absolute numbers and percentages. Normality of data was tested with the Kolmogorov-Smirnov test with Lilliefors' correction. The Chi-square test was used for comparison of nominal variables and the independent t -test and Mann Whitney test were used when appropriate for comparison of continuous variables across two groups. For all tests a p [?]0.05 was considered statistically significant. All tests are two-tailed. Statistical analysis was performed using IBM SPSS Statistics Premium' V 24 for Windows (IBM Corp. released 2011. IBM SPSS Statistics for Windows, version 22.0. Armonk, NY: IBM Corp.).

Endpoints

Primary endpoint: Bilateral presence of [?]3 B-lines at any anatomical point during pulmonary ultrasound (indicating pulmonary oedema).

Secondary endpoints: Bilateral A-lines at all anatomical points on pulmonary ultrasound images (indicating no pleural effusion, consolidation and/or interstitial syndrome), unilateral or bilateral presence of spine sign on pulmonary ultrasound images (indicating pleural effusion), presence of hepatization sign on pulmonary ultrasound images (indicating pneumonia), unilateral or bilateral presence of subpleural consolidations pulmonary ultrasound images (indicating pneumonia or pulmonary embolism).

Other study parameters in this study were the reason for obstetric outpatient clinic visit for the pregnant woman, age, weight, height, gestational age, medical history, smoking (current and one year ago), use of

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alcohol (current and one year ago), use of medication (current use for all patients and for pregnant women the use of medication before pregnancy) and presence of peripheral oedema.

Sample size calculation

This study was designed as a non-inferiority study using the likelihood test with a 90% confidence interval as normally accepted in non-inferiority settings. Sample sizes of 122 in group one and 122 in group two achieved 80% power to detect a non-inferiority margin difference between the group proportions of -0.10. The reference group proportion was 0.90. The treatment group proportion was assumed to be 0.80 under the null hypothesis of inferiority. The power was computed for the case when the actual treatment group proportion is 0.90. The statistic test used is the one-sided Score test (Farrington & Manning). The significance level of the test was targeted at 0.05.

Results

Patients were included from March 2, 2020 until June 19, 2020. During this, inclusion of participants was stopped for six weeks because of ethical considerations and implications regarding the outbreak of the Covid-19 pandemic in the Netherlands. In total 127 pregnant participants and 124 non pregnant participants were included in this study. For exclusion see figure 1.

Baseline characteristics

Baseline characteristics of the study population are demonstrated in table 1. Parameters only collected in the pregnant study population are described in table 2. Pregnant women were averagely older compared to non-pregnant women. The Body Mass Index (BMI), bodyweight and systolic blood pressure were also significant higher in the pregnant study group.

Primary outcomes

Outcomes of the reviewed pulmonary ultrasound images are showed in table 3. Presence of [?]3 B-lines in one of the six obtained ultrasound images was observed in one pregnant woman (38 weeks of gestation) and in none of the non-pregnant women.

The specificity of pulmonary ultrasound findings suggestive for pulmonary oedema is 0.99 in the pregnant population versus 1.0 in the non-pregnant population. For ultrasounds findings suggestive of pneumonia, the specificity is 1.0 in both the pregnant and non-pregnant group. The specificity of pulmonary ultrasound for pleural effusion is 0.99 in the pregnant population versus 1.0 in the non-pregnant population.

Secondary outcomes

All of the pulmonary ultrasounds in both pregnant and non-pregnant women showed bilateral A-lines and comet tails. No hepatization sign and/or subpleural consolidations were seen on the pulmonary ultrasound images. One pregnant woman (35 weeks of gestation) showed a spine sign on pulmonary ultrasound (figure 2). This concerns another pregnant participant than the participant that showed [?]3 B-lines on ultrasound (figure 3).

Discussion

Main findings

In this study designed to study specificity of pulmonary ultrasound in pregnant patients, no significant difference in pulmonary ultrasound outcomes were found in pregnant women compared to non-pregnant women. The found specificity for pulmonary ultrasound in the pregnant population was 0.99 for pulmonary oedema, 1.0 for pneumonia and 0.99 for pleural effusion. This is comparable to current literature and suggests translatability of upcoming studies regarding the evaluation of pulmonary ultrasound in pregnant patients presenting with clinical signs or symptoms of cardiac or pulmonary pathology. We therefore tend to assume that pulmonary ultrasound studies in the non-pregnant population may possibly be well translatable to the pregnant population.

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Notably, the 2 false positive ultrasounds did occur in the pregnant population. These were stated false-positive because the women did not experience any complaints and were not suffering from pulmonary and/or cardiovascular diseases as stated by the physician. One of the false positive cases showed a spine sign on pulmonary ultrasound, which suggests pleural effusion. The other false positive case showed more than three B-lines in only one of six regions, which could be observed with pulmonary oedema. However, this patient showed 3 B-lines on only one view of the six stored images of the pulmonary ultrasound evaluation, which does not account for clinical pulmonary oedema as stated by current ultrasound guidelines. Hence, study outcomes in these women may even be reviewed as negative.

Strengths and limitations

Major strength of this study is the prospective controlled study design and the use of validated ultrasound protocols (BLUE-protocol).

Our study has some limitations as well. We included pregnant women with at least 20 weeks of gestation, which may have been too early to detect pregnancy related false positives. This study was temporarily paused because of ethical considerations and implications during the commencement of the Covid-19 pandemic in the Netherlands. After we continued the study, the risk of finding pulmonary characteristics of Covid-19 was not ruled out. However, true positive pulmonary abnormalities like consolidations, possibly suggestive for Covid-19 infection, were not observed.

Interpretation [in light of other evidence]

We found two studies about pulmonary ultrasound in a healthy pregnant population. One observational study demonstrated the efficacy and the feasibility of pulmonary ultrasound as a diagnostic tool during late pregnancy (36-38 weeks of gestation), and found 25% of the women to have 1 or 2 B-lines in at least 3 regions and 2 participants to show 2 positive regions also. However, following current ultrasound guidelines these findings are insufficient to account for abnormalities. Another study showed three or more B-lines during labour in 67% of the participants (24 women). Hence, study outcomes in these women may even be reviewed as negative. Our study is to our knowledge the largest study regarding this topic, and the only study comparing ultrasound images of pregnant women to the images of non-pregnant women. Furthermore, we did not only study late pregnancy.

Interestingly, Krawczyk et al. included women in labour and showed a (false) positive pulmonary ultrasound in 67%. Both patients with false positive outcomes in our study were in late pregnancy. Therefore, pulmonary ultrasound may debatably be less reliable in these patients with respiratory deterioration in late pregnancy.

A case series described 16 pregnant women affected by respiratory pathologies, which were detected, managed and followed up during therapies with the aid of chest ultrasonography. They found promising sensitivity. Another study demonstrated the use of pulmonary ultrasound in 20 women with severe pre-eclampsia compared to healthy parturients, and found 25% of the women with preeclampsia to have B-lines on ultrasound compared with none of the healthy participants. Although the control group in this study is small, results are comparable to ours. While these two studies are mainly focussed on sensitivity, our study adds information regarding specificity.

Regarding future research, the study could be repeated evaluating possible differences in pulmonary ultrasound outcomes during different stages of pregnancy and labour. Furthermore, both healthy women as well as women with known pulmonary and cardiac pathology or presenting with typical complaints, to evaluate both specificity and sensitivity.

Conclusion

In this study no significant differences in specificity of pulmonary ultrasound were found in healthy pregnant compared to non-pregnant women. This suggests translatability of pulmonary ultrasound studies to the pregnant population during the evaluation of respiratory complaints. However, women in late pregnancy may be more susceptible for false positive outcomes.

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Disclosure of Interests

All authors report no conflict of interests.

Contribution to Authorship

I.S. Antonescu: Substantial contributions to the conception or design of the work, the acquisition, analysis, interpretation of data for the work and drafting the work and final approval of the version to be published including agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

L.J. de Vries: Substantial contributions to the conception or design of the work, the acquisition of data for the work and drafting the work and final approval of the version to be published including agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

J. Datema: Substantial contributions to the conception or design of the work, revising the work critically for important intellectual content, final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

H. Lameijer: Substantial contributions to the conception or design of the work interpretation of data for the work, drafting the work or revising it critically for important intellectual content, final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

J. Stekelenburg: Substantial contributions to the conception or design of the work, revising the work critically for important intellectual content and final approval of the version to be published and agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

Details of Ethical Approval

This study was approved by the ethics committee of the Medical Centre Leeuwarden on 7 February 2020 (RTPO-nWMO405).

Funding

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List of figures and tables

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Figure 3. Pulmonary ultrasound image of the false positive participant with 3 B-lines

Table 1. Baseline characteristics of the study population

Table 2. Baseline characteristics of pregnant women

Table 3. Outcomes of pulmonary ultrasound

TABLES

Table 1

Baseline characteristics of the study population.

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Characteristic	**Total (n=251)**	**Pregnant (n=127)**	**Non-pregnant (n=1**
Woman, *n (%)*	251 (100%)	127 (51%)	124 (49%)
Age, *years (median [IQR])*	29 [21-37]	31 [23-39]	26 [19-33]
Length, cm (mean ±SD)	172 [165-179]	171 [164-178]	172 [163-181]
Weight, *kg (median [IQR])*	75 [55-95]	84 [65-103]	67 [53-81]
BMI, *kg/m^2 (median [IQR])*	25 [19-31]	28 [21-35]	23 [19-27]
Pregnancies *(median [IQR])*	1 [0-4]	2 [0-4]	0 [0-1]
Children *(median [IQR])*	0 [0-1]	1 [0-2]	0 [0-1]
Abortions *(median [IQR])*	0 [0-0]	0 [0-1]	0 [0-0]
Smoking current, *n (%)*	20 (8%)	5 (4%)	15 (12%)
Smoking one year ago, *n (%)*	45 (18%)	28 (22%)	17 (14%)
Use of alcohol current, *n (%)*	85 (34%)	1 (1%)	84 (68%)
Use of alcohol one year ago, *n (%)*	162 (65%)	79 (62%)	83 (67%)
Current use of medication, *n (%)*	87 (35%)	59 (46%)	28 (23%)
Systolic blood pressure at PUS, *mmHg (median [IQR])*	120 [100-140]	120 [100-140]	115 [105-125]
Diastolic blood pressure at PUS, *mmHg (median [IQR])*	70 [60-80]	70 [60-80]	70 [57-83]
Peripheral edema, *n (%)*	4 (2%)	4 (3%)	0 (0%)

Data are reported as mean ± standard deviation, median (interquartile range) or *n* (valid %).

BMI=body mass index, IQR = interquartile range, PUS=pulmonary ultrasound; mmHg=millimeters of mercury. SD = standard deviation.

Table 2

Baseline characteristics of pregnant women.

Characteristic	**Pregnant women (n=127)**
Weeks of pregnancy *(median [IQR])*	32 [24-40]
Reason visit to outpatient clinic - BMI, *n (%)*	9 (7%) 15 (12%) 9 (7%) 21 (17%) 2 (2%) 11 (9%
- Caesarian section in past, *n (%)*	
- Diabetes gravidarum, *n (%)*	
- Fetal indication, *n (%)*	
- Stillbirth in past, *n (%)*	
- Hypertension, *n (%)*	
- Medical history mother, *n (%)*	
- Gemelli, *n (%)*	
- Other, *n (%)*	
Use of medication before pregnancy, *n (%)*	34 (27%)
Systolic blood pressure at beginning of pregnancy, *mmHg (mean ±SD)*	115 [103-127]
Diastolic blood pressure at beginning of pregnancy, *mmHg (mean ±SD)*	70 [57-83]

Data are reported as mean ± standard deviation, median (interquartile range) or *n* (valid %).

SD = standard deviation, IQR = interquartile range.

Table 3

Outcomes of pulmonary ultrasound.

Ultrasound findings	**Total (n=251)**	**Pregnant (n=127)**	**Non-pregnant (n=124)**
No B-lines, *n (%)*	222 (88%)	110 (87%)	112 (90%)
1 B-line, *n (%)*	25 (10%)	14 (11%)	11 (9%)

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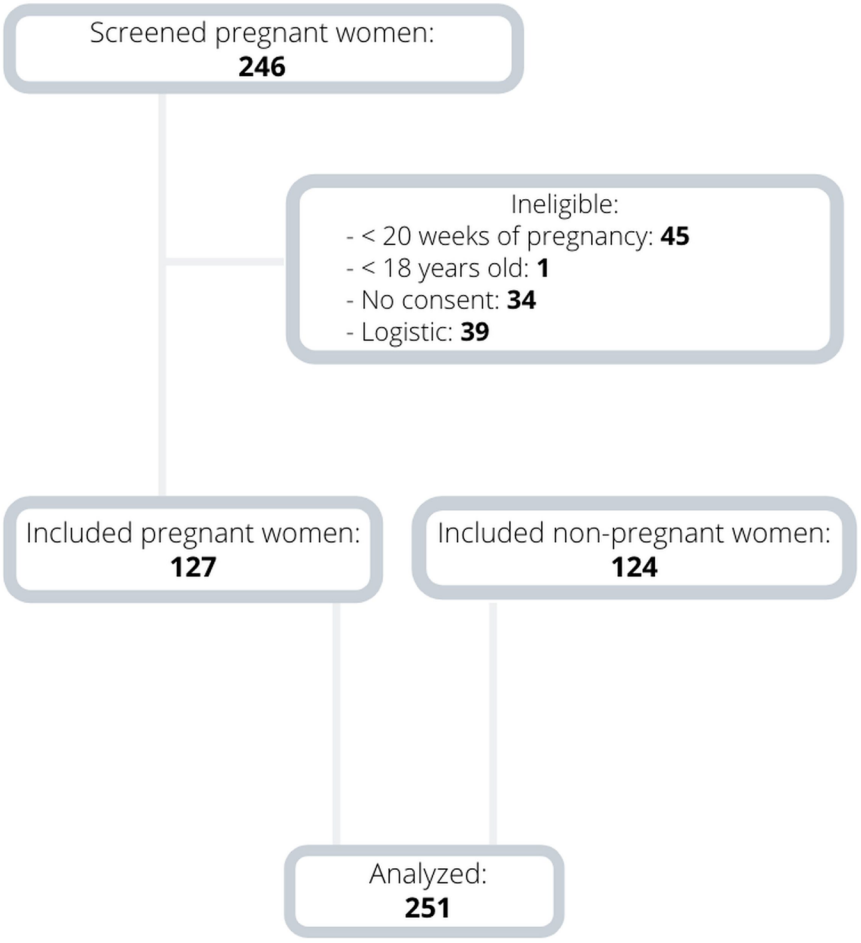
2 B-lines, *n (%)*	3 (1%)	2 (1%)	1 (1%)?¿?
3 B-lines, *n (%)*	1 (0.4%)	1 (1%)	0 (0%)
A-lines, *n (%)*	251 (100%)	127 (100%)	124 (100%)
Comet tails, *n (%)*	251 (100%)	127 (100%)	124 (100%)
Pleural effusion, *n (%)*	1 (0.4%)	1 (1%)	0 (0%)
Sub pleural consolidation, *n (%)*	0 (0%)	0 (0%)	0 (0%)
Hepatization, *n (%)*	0 (0%)	0 (0%)	0 (0%)

Data are reported as n (valid %).



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