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Outcomes of universal SARS-CoV-2 testing program in pregnant women admitted to hospital and the adjuvant role of lung ultrasound in screening: A prospective cohort study

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Abstract

Background

The emerging evidence for the asymptomatic carriers of SARS-CoV-2 infection emphasized the critical need for universal screening of pregnant women.

Objectives

This study aimed to present the prevalence of overall and asymptomatic SARS-CoV-2 infection rates in pregnant women admitted to the hospital, and assess the diagnostic accuracy of maternal symptoms and lung ultrasound (LUS) findings in detecting the infection.

Patients and methods

This prospective cohort study was conducted at a single tertiary centre in Istanbul, Turkey, for a month period starting from 27th April, 2020. Women with a confirmed pregnancy regardless of the gestational week admitted to the obstetric unit with any indication were consecutively underwent LUS and PCR testing for SARS-CoV-2.

Results

A total of 296 patients were included for the final analysis. The universal screening strategy diagnosed 23 pregnant women (7.77%) with SARS-CoV-2 infection. The rate of symptomatic and asymptomatic patients diagnosed with SARS-CoV-2 was found as 3.72% (n=11) and 4.05% (n=12), respectively. Four of nine women who underwent a second testing for SARS-CoV-2 upon abnormal LUS findings were found positive eventually (17.4%, n=4/23). The asymptomatic pregnant women with LUS score of 1 and those with normal LUS findings were considered as likely to be normal. Symptomatic patients with LUS score of 1 and those with score of 2 or 3 were considered as abnormal. On a secondary diagnostic performance analysis, the positive predictive value and the sensitivity were found as 44% and 47.8% for

the triage based on maternal symptoms and, 82.3% and 60.9% for the triage based on LUS, respectively.

Conclusion

A one-month trial period of universal testing for SARS-CoV-2 infection with RT-PCR in pregnant women who admitted to the hospital showed an overall and asymptomatic infection diagnose rate of 7.77% and 4%, respectively. Using lung ultrasound was found more predictive in detecting the infection than the use of symptomatology solely.

Keywords

COVID-19; Lung ultrasound; Pregnancy; SARS-CoV-2; Universal screening.

Introduction

Pregnant women represent a unique population in the COVID-19 pandemic being a vulnerable population both medically and socially [1,2] as they need to experience several encounters with the healthcare staff and most are hospitalized for birth during the outbreak [3] and it has been estimated that the risk of undiagnosed infection in pregnant women was about 4 – 9 undetected patients for 1 detected case due to maternal symptoms [4].

The emerging evidence for the asymptomatic carriers emphasized the critical need for universal screening of pregnant women [5-7]. Many symptoms of the COVID-19 infection may coincide with the common physiological changes of pregnancy, possibly contributing to delayed diagnosis of pregnant women [8]. Royal College of Obstetricians & Gynaecologists (RCOG) stated on 29 May, 2020 that all pregnant women should be offered reverse transcription-polymerase chain reaction (RT-PCR) testing for SARS-CoV-2 infection regardless of the maternal symptoms on the admission to the hospital [9]. This strategy mainly has the potential to control further transmission of the virus; to protect the pregnant women, their newborns and the healthcare staff from asymptomatic carriers and from themselves [4,10].

Although the rates cannot be generalized and may depend on the intensity of the outbreak for a specific localization, we also were concerned about the undetected asymptomatic carriers on our obstetric unit following the very high rate of asymptomatic infections reported from the first universal screening program in New York [6]. Therefore, from the 27th of April, 2020 we have started to screen all pregnant women admitted to the labour ward, antenatal or postpartum services with RT-PCR testing and lung ultrasound (LUS) regardless of maternal symptoms and contact history.

We have aimed to present the prevalence of overall and asymptomatic SARS-CoV-2 infection rates in pregnant women admitted to the hospital in a certain period of time, and assess the diagnostic accuracy of maternal symptoms and LUS findings in detecting the infection.

Patients and methods

Study design and patients

This observational study presented analysis of prospectively collected data yielded at a single tertiary "Coronavirus Pandemic Hospital" centre in Istanbul, Turkey, for a month period starting from 27th April, 2020. Our centre that has a high-volume of obstetrical care with ~4000 deliveries per year and caesarean delivery rate of 36.4%, has been prepared for the pandemic and organized with separate 'clean' and 'suspected/ infected' antepartum/ labour wards.

Women with a confirmed pregnancy regardless of the gestational week admitted to the obstetric unit with any indication including birth or the need for antepartum follow-up were consecutively included to the study and underwent SARS-CoV-2 testing and LUS. On admission, patients known to have previously been tested positive for SARS-CoV-2 infection were excluded from the study prior to the enrolment. Those patients were managed in a separate and dedicated COVID-19 infected ward. Pregnant women who refused LUS, who were referred from external hospitals or transferred through the national emergency ambulance services were excluded from the final statistical analysis.

Age, gestational week, parity, symptoms at presentation, results of RT-PCR testing and LUS scores were prospectively noted. Cough, dyspnoea, fever and anosmia were regarded as prominent symptoms to suspect COVID-19. The obstetric and the clinical outcomes of the

pregnant women who were tested positive for SARS-CoV-2 are the subject of another prospective study.

This study was approved by the local administration board (46059653-799-E.62), national scientific research platform (30T12_26_15) and the regional ethical committee (46418926-050.03.04). Informed consents were obtained from all patients for the research and the use of their LUS findings, anonymously.

Universal testing strategy

At the time of the initiation of this study, COVID-19 testing was recommended only for symptomatic patients and for those who had close contact history with confirmed positive patients. Following the first two emerging evidence on universal screening from New York, a universal screening in all obstetric units was initiated in our centre. All pregnant women admitted to either the labour ward or antepartum units with any indication were screened for SARS-CoV-2 using RT-PCR by nasopharyngeal swab regardless of the symptoms or contact history. Support personnel were not permitted to accompany the births according to the local protocols.

SARS-CoV-2 testing

SARS-CoV-2 was tested with reverse transcription-polymerase chain reaction of nasopharyngeal swabs (DirectDetect™ SARS-CoV-2 Detection Kit (PCR-Fluorescence Probe), Coyote Bioscience Co, Ltd., Beijing, China) that targets the ORF1ab and N gene of SARS-CoV-2. The samples were stored at 2-8°C and were sent to the centralized assessment centre located 13 kilometres away with a return time of maximum 24 hours. During the test period, strict use of personal protective equipment (PPE) was implemented until RT-PCR results were available [11], and pregnant women were managed according to our infection-control guidelines for women classified as patients under investigation or positive for

COVID-19 infection. Women who had a positive RT-PCR result received care as per national protocol for COVID-19 in a multi-disciplinary approach.

Lung ultrasound as an adjunct to SARS-CoV-2 testing in the universal screening strategy

According to our local protocol, all pregnant women admitted to the obstetrics unit systematically underwent a routine LUS within 24 hours of their arrival at the hospital as a first-line imaging technique. Following the recommended high-level protection rules [12], all lung images and videoclips were obtained with a dedicated machine [Esaote S.p.a., Italy; Manufactured by: Eizo Nanao Corp., Model: EA720] and a 1-8 MHz convex transducer on regular obstetric preset for patients with suspected or confirmed COVID-19 [12]. A standardized 14-areas scanning protocol [13,14] was applied for each patient and for 10 seconds for each area along the indicated lines. Each area was given a score between 0 and 3 according to the specific patterns [14]. At the end of the procedure, the highest score obtained from each area was noted. Patients who refused the LUS or whose images or videos that could not have been scored were excluded from the final analysis related to LUS. Women with abnormal LUS findings were approached as a suspected case until their RT-PCR results arrived. Patients who had a negative RT-PCR result and abnormal LUS findings were offered a second RT-PCR testing in the following week.

Statistical analysis

Testing results were characterized as positive or negative and presented by proportions. The diagnostic performance of symptoms and LUS were assessed separately by constructing 2x2 tables and calculating sensitivity, specificity, positive predictive value (PPV), negative predictive value (NPV), likelihood ratios (PLR and NLR) and accuracy. The comparison of the diagnostic performance between LUS and maternal symptoms were

analysed according to Hawass [15]. The diagnostic performance of LUS was calculated in two different scenarios: (1) LUS score of 0 was considered negative and LUS score of 1 – 3 was considered positive; (2) LUS score of 0 and score of 1 without symptoms on presentation were considered negative, and score of 1 with symptoms on presentation and score of 2 – 3 were considered positive. The collected data were analysed with IBM SPSS Statistics version 22.0 (IBM Corporation, Armonk, NY). Draw.io, an open source diagramming software, was used to construct the algorithm proposed for the initial management based on lung ultrasound findings of pregnant women admitted to the obstetric unit while waiting for their RT-PCR results.

Results

A total of 311 patients were included in the study. Fifteen were excluded from the diagnostic performance analysis of universal screening due to external referral. The mean age of the pregnant women screened during the universal screening program was 26.8 ± 5.51 years and ranged between 17 and 43 years. The mean gestational week was 35.18 ± 6.58 and ranged between 5 and 42 weeks. The median parity of the cohort was 1 (Interquartile range, 2) and ranged between 0 and 7 births.

Out of 15 excluded patients who were referred from other hospitals or transferred through the national emergency ambulance services, 46.67% (n =7) were symptomatic and 53.33% of excluded patients were asymptomatic (n = 8). All but one of the symptomatic patients had significant contact history (85.71%, n = 6/7). All maternal symptoms on presentation were mild as dyspnoea (n = 3), cough (n = 2) and anosmia (n = 2). All asymptomatic patients had significant contact history (100%), n = 8).

A total of 296 pregnant women were tested for SARS-CoV-2 during the universal screening. The strategy diagnosed 23 pregnant women (7.77%) with SARS-CoV-2 infection. Out of those, the rate of symptomatic and asymptomatic patients diagnosed with SARS-CoV-2 was found as 3.72% (n = 11) and 4.05% (n = 12), respectively (Figure 1a). Out of 23 patients with positive SARS-CoV-2 testing, 11 were symptomatic (47.82%) and 12 were asymptomatic (52.17%) on admission. Out of 273 patients with negative SARS-CoV-2 testing, 14 were symptomatic (5.13%) and 259 were (94.87%) asymptomatic on admission (Figure 1b).

Median (± Interquartile range) scores of all abnormal LUS findings observed during the universal testing period (11.15%, n = 33 / 296) were 1 ± 1 and ranged between 1 and 3.

Nine patients (3.04%) were initially found negative for SARS-CoV-2 infection and underwent a second testing after a week due to their abnormal LUS findings. Four of those patients were found positive in their subsequent testing (17.4%, n = 4/ 23). The imaging features of the five patients who underwent a second testing due to abnormal LUS findings and found negative were as follows: Three were asymptomatic on admission and with LUS score 1 and two were asymptomatic and with LUS score 2 (one had suspicious CT findings with focal wide atelectasis and one had CT findings consistent with viral pneumonia).

Distribution of pregnant women according to maternal symptoms, and lung ultrasound during the universal screening is summarized in Table 1. The sensitivity, specificity, PPV, NPV, PLR, NLR and accuracy results of maternal symptoms and lung ultrasound in predicting COVID-19 infection is summarized in Table 2, and the outcomes and diagnostic performance of lung ultrasound were analysed in two different scenarios. The area of under curve (AUC) in the Receiver operating characteristic (ROC) analysis was found as 0.799 (95% CI = 0.674 – 0.923) and 0.713 (95% CI = 0.581 – 0.846), respectively (Figure 2).

In the main proposed scenario, patients with LUS score of 0 and asymptomatic patients with score 1 were defined as negative, and symptomatic patients with score 1 and those with score 2 – 3 were defined as positive. Sensitivity and specificity differed significantly between the LUS interpretation based on the proposed scenario and the maternal symptoms ($\chi^2_{(2)} = 8.12$, $P = 0.017$) when the RT-PCR testing was considered as the reference test. The confidence intervals of difference of the sensitivity and the specificity between LUS and maternal symptoms were 0.120 and -0.011, respectively.

Discussion

In this study, less than 1 in every 13 women admitted to the labour ward and antepartum unit were diagnosed with SARS-CoV-2 by the universal screening program. Asymptomatic carriers accounted for 4% of all screened women and for half of the women who were found positive for SARS-CoV-2. Abnormal LUS findings were present in 1 of every 10 women screened for SARS-CoV-2. A screening method based on the LUS findings was found more sensitive and predictive than maternal symptoms for SARS-CoV-2 infection.

It has become clear that most cases of COVID-19 result from the spread of the virus by asymptomatic persons [7]. Therefore, the universal screening of pregnant women admitted to the obstetric units offered several advantages including reducing the risk of transmission of SARS-CoV-2 from asymptomatic carriers to other pregnant women and healthcare staff on a shared antepartum or postpartum unit, by practicing the proper isolation rules and the best management of the patient and the neonate [3,5,16]. In settings with unrecognized high asymptomatic transmission rates, depletion of inpatient resources including expensive imaging modalities, respiratory support, infectious or pulmonologist consultations, the amount of PPE and the medical staff in operating rooms is inevitable [7,17]. Universal

screening may ensure the accurate counselling of both the pregnant women and the staff, thus enabling the routine neonatal care, newborn skin-to-skin contact and the breastfeeding [1,6,8].

Since the first initiation of implementing universal screening programs by Sutton *et. al.* [6] and Vintzileos *et. al.* [7], several studies were reported from all over the world [18-20]. Following high overall and asymptomatic infection rates from New York studies, results from London were reasonable with a soft decrease from almost one in every five women to one in fourteen [3]. Khalil *et. al.* has questioned the generalizability of the report from New York [6], and speculated that the high rate of asymptomatic SARS-CoV-2 infection may have been caused by the inadequate infection control strategies [3]. Our results were comparable with London with an overall detection rate of 7.75%, and they were also compatible with the timeline of both the spread of the pandemic and the time of the undertaken screening program. It has been assumed that the wide variety in the prevalence of SARS-CoV-2 infection during the several screening programs for pregnant women was due to differences in community transmission rates, socio-economic features and the intensity of the pandemic in that region [3].

Performing lung ultrasound by the obstetricians was proposed to be effective, safe and a practical way to manage and monitor pregnant women with COVID-19 [13,21,22]. It is also beneficial in the triage of the patient and assessing the severity of the disease [23]. LUS steps forward with its simplicity and non-ionizing, rapid and portable nature [24]. The interobserver agreement between obstetricians with different levels of experience was found to be good [25]. The increasing prevalence of asymptomatic infected patients and decreasing prevalence of symptomatic infections have raised the thoughts that universal testing possibly detects patients in a convalescent period or patients with subclinical active infection [18]. Therefore, the clinical utilization of LUS while waiting for the RT-PCR results may have an important role when compared to checking for symptoms only. This may particularly be very useful in

the low-resource settings, e.g. countries that do not have adequate access to liberal use of fast RT-PCR testing or centres with slow centralized testing programs. Tassis *et. al.* suggested that a universal screening policy with swabs can be preferred over symptomatology if only swabs can be processed within a few hours [20]. However, rapid testing may not be possible for most of the health care centres where the pandemic progresses intensely.

In the current study, performing LUS right after the fetal assessment was found feasible in predicting the SARS-CoV-2 infection while waiting the RT-PCR results from a centralized testing centre. In our experience, 17% of the pregnant women who had undergone a LUS assessment and eventually found RT-PCR-positive were initially RT-PCR-negative and underwent repeated testing of RT-PCR after a week due to their abnormal LUS findings. The increased PPV values from 44% to 82% justified the benefit of the triage based on the combination of LUS findings and maternal symptoms. Basically, the proposed algorithm considers the asymptomatic pregnant women with LUS score of 1 and those with normal LUS findings (Score 0) as likely to be normal. One of the main advantages of this approach is that it has the potential to reduce the number of pregnant women who undergo a chest CT or x-rays. Those patients who may require ionizing imaging modalities to investigate for deeper, central and apical pulmonary lesions that do not extend to the pleural surface were very limited in our cohort with around 1% (n = 3/296).

As the world enters the next stage of the pandemic, testing all patients regardless of their symptoms or their contact history may not be practical or cost-effective. It has been highlighted that routine SARS-CoV-2 testing would rapidly consume the valuable PPE although it is already limited and mostly used beyond the manufacturer's proposed shelf life [7]. Similarly, another universal screening program has been terminated after a seven day period due to the excessive consume of PPE and in the absence of asymptomatic infected cases during the testing period [19]. Testing all patients may not be eligible in the close

future, however, obstetricians may consider to perform a quick assessment for maternal lungs right after a sonographic assessment of fetus.

Conclusion

A one-month trial period of universal testing for SARS-CoV-2 infection in pregnant women who admitted to the hospital showed an overall and asymptomatic infection diagnose rate of 7.77% and 4%, respectively. Using lung ultrasound was found more predictive in detecting the infection than the use of symptomatology solely. As the transition of the COVID-19 pandemic into new phases occurs, combining the findings from LUS with the maternal symptoms is promising in the initial management of pregnant women who admitted to the obstetric units.

Declaration of Interest

The authors report no conflicts of interest.

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None.

Data accessibility

Processed data can be shared upon request.

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Legends of figures and tables

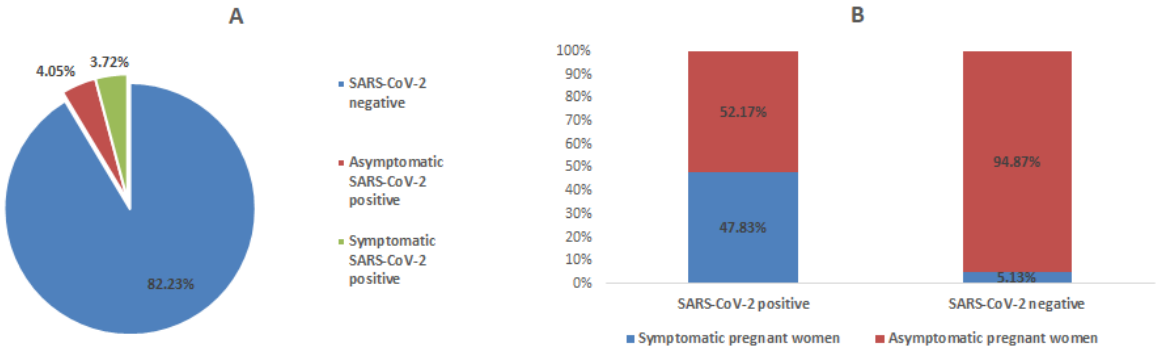

Figure 1. Percentage of infected pregnant women with SARS-CoV-2 detected during the universal screening program.

(A) The rates of asymptomatic and symptomatic pregnant women infected with SARS-CoV-2. (B) The rates of asymptomatic and symptomatic pregnant women stratified by the SARS-CoV-2 test result.

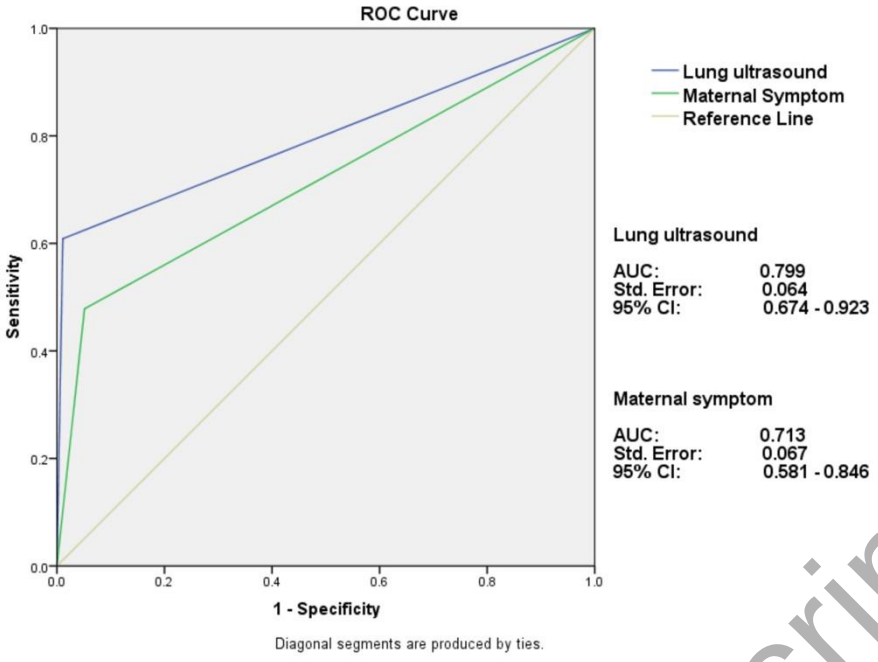

Figure 2. Receiver operating characteristic analysis for the sensitivity and specificity of lung ultrasound and maternal symptom in detecting COVID-19 infection.

Table 1. Distribution of pregnant women according to maternal symptoms, and lung ultrasound (with two different scenarios) during the universal screening.

	Positive COVID-19	Negative COVID-19	Total
Symptomatic[a]	11 (3.72%)	14 (4.73%)	25 (8.45%)
Asymptomatic[a]	12 (4.05%)	259 (87.50%)	271 (91.55%)
LUS-positive[b]	17 (5.74%)	16 (5.41%)	33 (11.15%)
LUS-negative[b]	6 (2.03%)	257 (86.82%)	263 (88.85%)
LUS-positive[c]	14 (4.73%)	3 (1.01%)	17 (5.74%)
LUS-negative[c]	9 (3.04%)	270 (91.22%)	279 (94.26%)
Total	23 (7.77%)	273 (92.23%)	296 (100%)

[a]: Maternal symptoms on presentation to suspect from COVID-19 during the universal screening, including cough, dyspnoea, fever and anosmia.

[b]: In the first scenario, LUS-negative was defined as patients with LUS score 0. LUS-positive was defined as patients with LUS score 1 – 3.

[c]: In the second scenario, LUS-negative was defined as patients with LUS score of 0 and asymptomatic patients with score 1. LUS-positive was defined as symptomatic patients with score 1 and those with score 2 – 3.

Table 2. Diagnostic performance of maternal symptoms, and lung ultrasound (two different scenarios) in predicting COVID-19 infection

	Symptoms[a]	LUS[b]	LUS[c]
Sensitivity	47.83% (26.82% - 69.41%)	73.91% (51.59% - 89.77%)	60.87% (38.54% - 80.29)
Specificity	94.87% (91.55% - 97.17%)	94.14% (90.66% - 96.61%)	98.9% (96.82% - 99.77%)
PPV	44% (28.77% - 60.45%)	51.52% (38.39% - 64.44%)	82.35% (59.11% - 93.78%)
NPV	95.57% (93.58% - 96.97)	97.72% (95.56% - 98.84%)	96.77% (94.74% - 98.04%)
PLR	9.33 (4.8 - 18.15)	12.61 (7.39 - 21.51)	55.39 (17.16 - 178.84)
NLR	0.55 (0.37 - 0.81)	0.28 (0.14 - 0.56)	0.4 (0.24 - 0.67)
Accuracy	91.22% (87.39% - 94.18%)	92.57% (88.96% - 95.28%)	95.95% (93.03% - 97.89%)

[a]: Maternal symptoms on presentation to suspect from COVID-19 during the universal screening, including cough, dyspnoea, fever and anosmia.

[b]: In the first scenario, LUS-negative was defined as patients with LUS score 0. LUS-positive was defined as patients with LUS score 1 – 3.

[c]: In the second scenario, LUS-negative was defined as patients with LUS score of 0 and asymptomatic patients with score 1. LUS-positive was defined as symptomatic patients with score 1 and those with score 2 – 3.

PPV: Positive predictive value, NPV: Negative predictive value, PLR: Positive likelihood ratio, NLR: Negative likelihood ratio.