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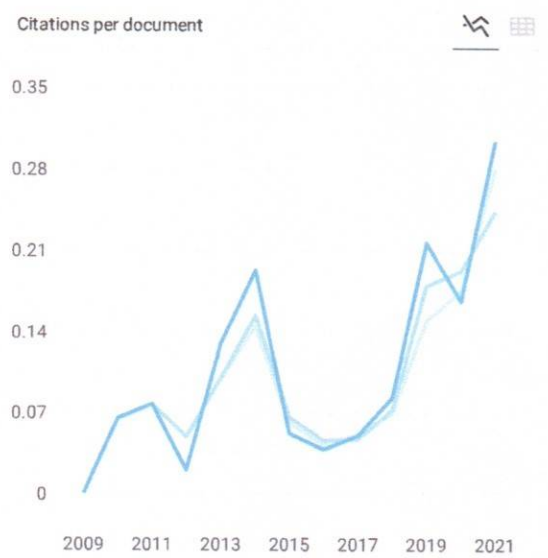
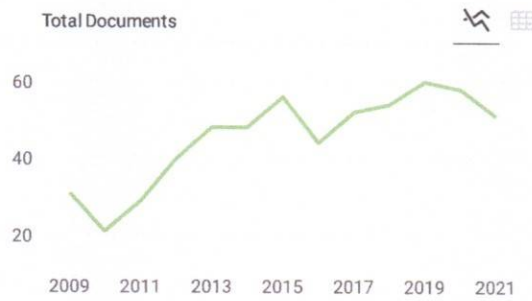


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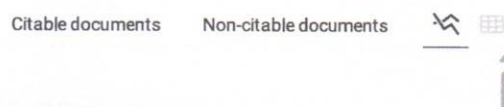
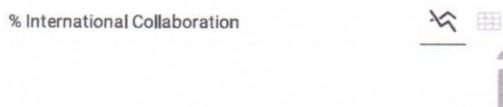
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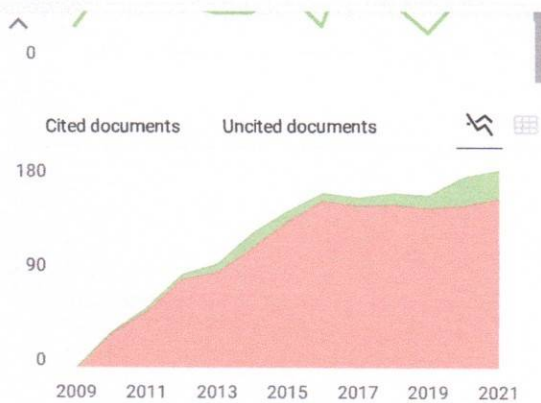
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SARS-COV-2 ANTIBODY TEST FOR THE HOSPITALISED EMERGENCY OBSTETRIC CASES: USEFUL OR WASTEFUL

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ABSTRACT

Background: The emergency, labor and delivery conditions in obstetric cases need a clinical decision in a timely manner. The identification of Covid-19 especially in asymptomatic obstetric cases with ease and rapid antibody test need further investigation.

Objective: To analyze the usability and performance of rapid antibody test in obstetric cases.

Methods: Case control study using medical record on Covid-19 obstetric cases over 9 months with paired nasopharyngeal reverse transcriptase polymerase chain reaction severe acute respiratory syndrome coronavirus 2 and rapid antibody test results.

Results: There were 92 Covid-19 obstetric cases (incidence: 17.4%) and 210 reactive rapid antibody test (seroprevalence: 39.6%). The sensitivity, specificity, positive predictive value and negative predictive value of rapid antibody tests was 89%, 24%, 40%, 80%. Symptomatic cases have lower sensitivity (73% vs. 96%) and higher specificity (48% vs. 20%). The presence of Covid-19 symptoms ($p < 0.05$) and reactive rapid antibody test ($p < 0.001$) were associated with Covid-19. Rapid antibody test will identify larger Covid-19 obstetric cases compare with the presence of symptom only (89.4% vs. 27.7%).

Conclusion: Screening by rapid antibody test had a high sensitivity but low specificity. This test will identify more Covid-19 cases compared by symptoms only due to majority asymptomatic obstetric cases. This simple, cheap and rapid antibody test still has a place in initial screening to help identify Covid-19 in areas with widespread transmission and has limited capacity to carry out universal screening.

KEYWORDS: Covid-19 infection, pregnant, perinatal

INTRODUCTION

It has been a year since the first notification of a new type of pneumonia in Wuhan on December 31, 2019 [Adhikari SP et al, 2020], but there is no sign that we can overcome this Coronavirus Disease (Covid-19) pandemic which currently contributes to around half a million new cases every day [WHO-CD, 2020]. This fast-spreading Covid-19 pandemic can affect various types of groups, without exception the vulnerable population, preg-

nant women [Rasmussen SA et al., 2020]. The obstetric case population has unique characteristics in that emergency, labor and delivery conditions can appear suddenly, unpredictably and cannot be postponed like some other health services so all clinical decisions and treatments must be made in a timely manner.

Studies from Vintzileos and also Sutton showed that the majority of pregnant women who were admitted to hospital were asymptomatic [Sutton D et al., 2020; Vintzileos WS et al., 2020]. Identification of Covid-19 cases in obstetric patients who require hospitalization were very important to prevent the spread of infection transmission to the newborn and also inside the hospital and this process will

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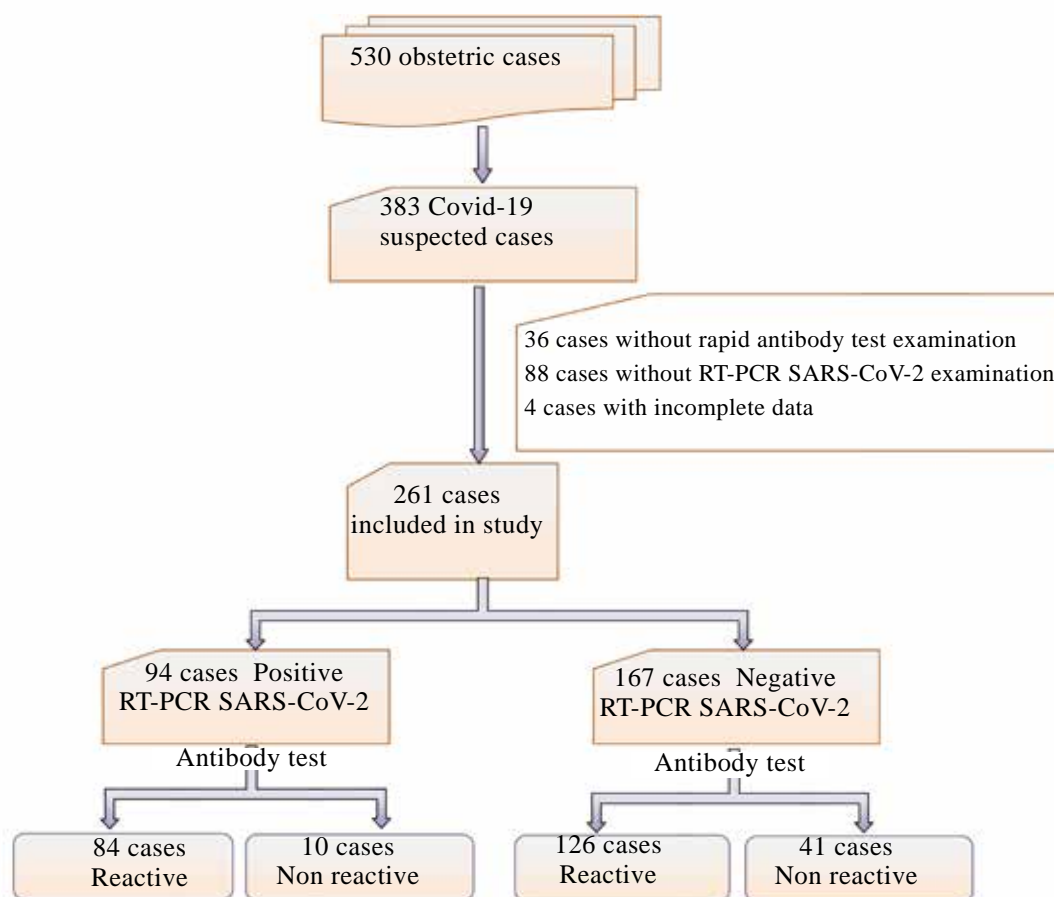


FIGURE 1. Study Population Description

become more problematic in identifying asymptomatic cases. Although the reverse transcriptase polymerase chain reaction (RT-PCR) of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is still the gold standard, the limited capacity especially in the developing country potentially delay obstetric care which often requires quick decision and action. The use of antibody testing is no longer recommended in the detection of Covid-19 by food and drug administration (FDA) with inconclusive results [Kontou PI et al., 2020; CDC-OT, 2021], but the ease and speed of this tests and its use in assessing seroprevalence in certain populations will certainly be very interesting for further investigation especially in the obstetric cases in hospital. Will it be useful or wasteful?

MATERIAL AND METHODS

Retrospective cross sectional design study using data from medical records were used in this study. We conducted an analysis of all obstetric

cases performed by nasopharyngeal RT-PCR SARS-CoV-2 paired with a rapid antibody examination of SARS-CoV-2 on the whole blood samples. This examination was carried out at Academic Soetomo General Hospital as a tertiary referral hospital and also a Covid-19 referral hospital in East Java, Indonesia. Admitted obstetric patient for 9 months from March to November 2020 in which both examinations were carried out were included in this study.

The RT-PCR SARS-CoV-2 examination was performed using The Abbott m2000 with Abbott Real Time SARS-CoV-2 assay for the qualitative detection of nucleic acids from SARS-CoV-2, the results were reported positive when

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RdRp or N-gene tested positive, while the examination of Rapid antibodies test were performed using an immunochromatographic assay with lateral flow method in detecting qualitative total SARS-CoV-2 antibody. All examinations and ethical approvals were carried out at the Academic Soetomo General Hospital. Other data included in this study were basic maternal data (maternal age, gestational age, parity, referral status) and Covid-19 infection related data (comorbidity, symptoms).

Categorical variables were expressed as numbers (percentage) and continuous variables were expressed as means (Standard Deviation / SD) or medians (interquartile ranges /IQRs). SPSS version 24.0 software for windows (IBM Corp., Armonk. N.Y., USA) was used for statistical analysis. Chi-square and Fisher exact test as an alternative were used to compare the difference in the categorical variables, independent T-test and Mann-Whitney test as an alternative were used to compare the continuous variables between groups. A p value of < 0.05 was taken to signify statistical significance. We extracted 2x2 contingency table data and calculating the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV), likelihood ratio and accuracy to evaluate the performance of SARS-CoV-2 antibody test compared with RT-PCR SARS-CoV-2 result. We calculated the antibody performance on all cases and also divided based on the presence of symptoms.

RESULTS

During our study period, there were 530 obstetric cases admitted to our emergency obstetric room. Since March until now, we have been unable to carry out universal RT-PCR tests due to capacity limitations. There were several changes in the screening method from our center, starting from only evaluating symptoms and history of Covid-19 contact to expanding by examining the neutrophil to lymphocyte ratio, X-ray thorax and rapid antibody test for every patient who came. For all patients who are suspected of Covid-19 from the initial screening, a SARS-CoV-2 RT-PCR swab examination will be carried out. There were 261 obstetric cases who had paired RT-PCR and rapid

TABLE 1.

Sample characteristic of the study				
Sample characteristics	Swab RT-PCR SARS-CoV-2			
	Total (n=261)	Negative (n=167)	Positive p (n=94)	
Material age				
Mean ±SD y.o	29.9±6	30.4±6.2	28.8±5.6	0.062
Gestational age (n=259)				
Mean ±SD y.o	35.8±6	35.4±6.4	36.7±5.1	0.069
Gestational age classification- n(%)				
postpartum	2 (0.8%)	0 (0%)	2 (2.1%)	0.062
<20 weeks	12 (4.6%)	10 (6%)	2 (2.1%)	
preterm	76 (29.1%)	53 (31.7%)	23 (24.5%)	
at term	171 (65.5%)	104 (62.3%)	67 (71.3%)	
Parity – n(%)				
nulipara	105 (40.2%)	65 (38.9%)	40 (43.5%)	0.329
multipara	156 (59.8%)	102 (61.1%)	54 (56.5%)	
Referral tastus – n(%)				
by herself	71 (27.2%)	42 (25.1%)	29 (30.9%)	0.474
rejected by other hospital	78 (29.9%)	49 (29.3%)	29 (30.9%)	
referred	112 (42.9%)	76 (45.5%)	36 (38.3%)	
Comorbid – n(%)				
No	149 (57.1%)	93 (55.7%)	56 (59.6%)	0.603
Yes	112 (42.9%)	74 (44.3%)	38 (40.4%)	
Covid-19 symptom-(%)				
No	208 (79.7%)	140 (83.8%)	68 (72.3%)	0.027
Yes	53 (20.3%)	27 (16.2%)	26 (27.7%)	
Rapid antibody test				
non reactive	51 (19.5%)	41 (24.6%)	10 (10.6%)	0.006
reactive	210 (80.5%)	126 (75.4%)	84 (89.4%)	

antibody tests with 92 (35.2%) confirmed Covid-19 cases (figure 1). We had an incidence of 17.4% from all obstetric cases admitted during our study period. All samples characteristics can be found in table 1. A high proportion of Covid-19 symptoms ($p=0.027$) and reactive antibody tests ($p=0.006$) were associated with confirmed covid-19 cases.

We had a total of 210 (80.5%) obstetric cases with reactive rapid antibody test or 39.6% of seroprevalence in our obstetric cases population. The antibody examination carried out in this study was intended to perform an initial screening for the possibility of acute Covid-19 infection when the patient was admitted to the obstetric emergency room. The ability of this examination to detect Covid-19 is compared to the results of the SARS-CoV-2 RT-PCR examination which can be seen in table 2. We also classify the performance of this rapid antibody test based on the presence of Covid-19 symptoms experienced by patients. There was a higher sensitivity in the asymptomatic group (95.59% vs. 73.08% whereas the specificity was higher in the symptomatic group (48.15% vs. 20%).

TABLE 2.

Performance of the rapid antibody test compared with RT-PCR SARS-CoV-2 test in admitted obstetric cases

Total Obstetric Cases	Swab	
	RT-PCR	SARS-CoV-2
Rapid Antibody Test	Positive (n = 92)	Negative (n = 167)
Reactive n(%)	84 (89.4%)	126 (75.4%)
Non Reactive n(%)	10 (10.6%)	41 (24.6%)
Screening Test Evaluation	%	95% CI
Sensitivity	89.36	81.30 - 94.78
Specificity	24.55	18.23 - 31.80
Positive Predictive Value	40.00	37.36 - 42.69
Negative Predictive Value	80.39	68.30 - 88.64
Positive likelihood ratio	1.18	1.06-1.32
Negative likelihood ratio	0.43	0.23 - 0.82
Accuracy	47.89	41.69 - 54.14

DISCUSSION

To date, all health facilities have tried to adapt, especially in terms of Covid-19 testing and identification for patients who need hospitalization. Particularly in obstetric patients, which of course cannot be postponed like some other services in this pandemic era. The majority of obstetric cases with Covid-19 who were admitted to hospital in our study were cases of term pregnancy (65.5%) for labor and delivery purposes. Zaigham's systematic review also showed the same results where the majority of cases were in the 3rd trimester and delivery occurred in 80% of cases [Zaigham M, Anderson O. 2020]. Our study revealed many referral cases and rejection from other hospitals for obstetric cases with suspicion of Covid-19 infection because of the rapid spread in our area and many other health facilities that are not yet ready principally in identifying Covid-19 cases due to limited testing capacity [Cahya Laksana MA et al., 2020].

Emergency obstetric, labor and delivery cases which are very time-related have become problematic conditions in this pandemic era. Accurate and fast identification is noteworthy for determining the need of isolation room, allocating personal protective equipment and how to treating patients which is very important to prevent the transmission of Covid-19 in the hospital for the newborn, other patients, their surrounding families and also health workers. Although in this study, the Covid-19 symptoms clearly associated with Covid-19 cases ($p < 0.05$), it should be underlined that the majority of Covid-19 cases identified in this study were asymptomatic (72.3%). This is in line with Igbinsosa study which found 63% proportion of asymptomatic cases [Igbinsosa I et al., 2020] and Sutton which revealed 87.9% women who were admitted for delivery had no Covid-19 symptom [Sutton D et al., 2020]. Several other studies have shown the opposite results, such as in Kayem's study which showed the proportion of symptomatic cases up to 80.6% [Kayem G et al., 2020], but this happened due to the differences in Covid-19 identification strategy because the two previous stud-

ies used universal screening. Based on these findings, screening based on symptoms alone will not be effective enough to identify Covid-19 cases in obstetric conditions. Some literature suggests the use of universal RT-PCR screening especially in areas with widespread transmission [Sutton D et al., 2020].

It is not easy to implement universal screening, the limited capacity, expensive price, need of special personnel for sampling and the long duration of the results were the main problems, especially as fast decisions are needed and often cannot be postponed in obstetric cases [Kontou PI et al., 2020]. The need for screening test that is easy, cheap, valid and reliable is clearly needed in this condition [Akobeng AK 200]. Rapid antibody test that is fast, easy to do without the need of special personnel for sampling and inexpensive [Tang YW et al., 2020] may be used as an alternative for Covid-19 screening. Our study revealed the higher proportion of reactive rapid antibody test in Covid-19 Cases ($p < 0.01$). However, it should be understood that this rapid antibody test does not constantly indicate an active Covid-19 condition, research shows that antibodies are formed mostly 1-3 weeks after infection onset where theoretically the infectious period begins to decrease and immunity begins to build [CDC-IG, 2021]. Therefore the RT-PCR SARS-CoV-2 is absolutely necessary if a rapid reactive antibody result was obtained, to confirm the presence of acute Covid-19 infection in the patient.

The sensitivity of the rapid antibody test is quite high (89%). The sensitivity was higher in asymptomatic cases than in symptomatic cases, but vice versa for its specificity was higher in symptomatic cases. Other studies from larger samples (1.293 parturient) showed lower sensitivity, there were 46 positive PCR tests from 72 seropositive women (sensitivity 64%) [Flannery DD et al., 2020]. Other evidence showed that the antibody test had lower sensitivity in the first week (30.1%) and also second weeks (72.2%) from the infection onset [Deeks JJ, et al., 2020; Watson J et al., 2020]. The low specificity in this study is due to the high false negatives, which in theory can be

due to cross reactivity with rheumatoid factor and other viral infection such as influenza A, respiratory syncytial virus and some other coronavirus [CDC-IG, 2021; Okba NMA, et al., 2020]. In addition, as previously explained, this rapid antibody test can not always detect acute cases, but it also shows that patients who came may have previously been infected with Covid-19 without being noticed so that antibodies can be detected in their bodies [Deeks JJ, et al., 2020].

The predictive value will be higher in cases which have a high probability such as Covid-19 symptoms [CDC-IG, 2021], and this is consistent with our study result. Fabre's study also reported low PPV (50%) for rapid antibody test in pregnancy [Fabre M et al., 2020]. Although the overall positive predictive value and the accuracy is not too high, the decision to use this rapid antibody test is very important. In a situation where we were unable to perform universal screening due to limitations, using only symptom-based screening would only identify 26 cases of Covid-19 (28% of total positive obstetric cases) and we will absolutely miss the asymptomatic cases. Evidence showed the infectious ability of asymptomatic patients can be very long up to 14 days and samples isolated from the respiratory tract can also have the same viral load as symptomatic patients [Lee S et al., 2020]. The rapid antibody test will actually help to find such asymptomatic cases, where the rapid antibody can detect 84 true positive cases (89.4%) in this study. So that regardless of the accuracy, if this test is good enough to separate infected patients to prevent wider transmission.

Another advantage that can be taken from the antibody examination is gaining seroprevalence data of immunity status from our population study [Tang YW et al., 2020], it is interesting to know that the seroprevalence in our place reaches 39.6%. More than the reports obtained by Savirón-Cornudella that only revealed 6.7% positive serological test. However, there were differences in this method since they carried out universal screening and obtained only a low incidence of SARS-CoV-2 (6 Covid-19 positive from 266 patients; 2.2%) [Savirón-Cornudella R, et al.,

2021]. Study from Crovetto revealed 14% of SARS-CoV-2 seroprevalence in pregnancy (14%) with a comparable proportion of seroprevalence in 1st and 3rd trimester. Sixty percent of pregnant women with positive antibody had never complained about any Covid-19 symptoms at all [Crovetto F et al., 2020]. The highest previous seroprevalence reported was 16.1% [Haizler-Cohen L et al., 2021]. Apart from the risk of false positivity as described earlier, the high seroprevalence in our study showed that there were probably many asymptomatic obstetric cases which can certainly further expand the spread in community because they never feel sick, and identification of the cases when this patient is admitted to hospital is very important and absolutely necessary. In addition, the appearance of this immunity cannot always be in line with the protective condition, the presence of this antibody does not always indicate the presence of a high neutralizing antibody titer so that the patient is immune from infection [Wu F et al., 2020]. Viral load also does not always decrease rapidly after seroconversion so that some people can remain infectious even after they get a positive antibody test [Wölfel R et al., 2020].

Some of the weakness of this study is that we did not apply universal screening so that we cannot anticipate some Covid-19 cases that were not identified. There is still a chance of false negatives from this rapid antibody test due to the possibility of some cases that were not forming Covid-19 antibodies even though they are infected. Some other possibility is the time of collection, if it is too fast during an acute infection, the antibodies have not been formed or too slow so that the antibody levels have started to fall [Kontou PI et al., 2020]. Although the production of IgM and IgG increases, especially at 2-3 weeks, they can be found more quickly from day-4 [Sethuraman N et al., 2020]. Guo's study even showed 85.4% IgM has appeared in the first 7 days of symptoms [Guo L et al., 2020]. This research was also conducted at tertiary referral centers, which although serving the majority of obstetric cases with covid-19 in the

East Java area, are not necessarily generalizable in the community.

However, the important points to get from this study are the high possibility of obstetric Covid-19 asymptomatic cases and the importance of several simple alternative tests to identify, such as rapid antibody test. This examination can help identify groups at high risk of infection and also previously infected individuals, even if they are asymptomatic as they show a viral humoral immune response. This of course can help support the diagnosis in the Covid-19 case that came some time after being infected with Covid-19 especially in asymptomatic and mild symptoms [CDC-IG, 2021; Sethuraman N et al., 2020]. Some protocols from Zullo also stated that reactive rapid antibody test will first be isolated and planned to do RT-PCR SARS-CoV-2 test. If it is impossible to postpone for the RT-PCR result, then the patient will be treated as a Covid-19 patient [Zullo F et al., 2020]. The complexity of the immune response to Covid-19 especially in obstetric cases of course. Deep understanding and caution must always be taken to interpret the results if we use antibody testing in part of our services protocol [Fabre M et al., 2020].

CONCLUSION

There were an association between both symptoms and rapid antibody test with SARS-CoV-2 RT-PCR result in admitted obstetric cases. Screening by rapid antibody test will identify more Covid-19 cases compared by symptoms only due to majority asymptomatic cases. The rapid antibody test had a high sensitivity but low specificity; the asymptomatic cases group had higher sensitivity and lower specificity than symptomatic. The strategy of using a rapid antibody test that is simple, cheap and fast, by all means still has a place in initial screening to help identify Covid-19 in areas with quite extensive transmission and has limited capacity to carry out universal screening. This test should not solely be used for diagnosis and the clinician should understand the risks and benefits of antibody testing and always provide information about the limitations of this test.

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