Research clinical study

Early Experience of Pre-Operative Screening For Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in a Developing Country

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ABSTRACT

Early Experience of Pre-Operative Screening for Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2) in a Developing Country.

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The global spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its disease known as the COVID-19 changed medical practice worldwide. Surgery had to incorporate pre-operative screening for SARS-CoV-2 for safety. Although real-time reverse transcriptase-polymerase chain reaction (RT PCR) is the gold standard for testing, many hospitals have limited access to this equipment early in the pandemic and had to use other screening tools. The objective of this study was to assess the results of an available pre-operative screening for suspected patients with COVID-19 undergoing surgery during the early months of the pandemic using rapid antibody test, clinical scoring and RT PCR.

A retrospective study involving 43 patients with suspected COVID-19 underwent pre-operative assessment for emergency surgery in a tertiary referral hospital. A standard Rumah Sakit Hasan Sadikin (RSHS) scoring, rapid antibody IgG/IgM, and the RT-PCR assay were carried out as a

diagnostic test for COVID-19. The sensitivity and specificity were evaluated and confirmed with RT-PCR on the nasopharyngeal swab.

Patients were female predominant (65.1%), with the most common indication for surgery was emergency cesarean section (46.5%). The sensitivity of RSHS score, rapid IgM and rapid IgG test were 50.0 %, 16.7%, and 16.7%, respectively. Moreover, the specificity of RSHS score, rapid IgM, and rapid IgG test were 38.71%, 32.2%, and 100%, respectively.

Both antibody tests and scoring systems were unsatisfactory to replace RT-PCR for the diagnosis of COVID-19. Hence, without RT-PCR availability, infection control protocol and the use of appropriate personal protective equipment should be maintained in the operating room.

Keywords: COVID-19; emergency surgery; preoperative evaluation; SARS-CoV-2; screening

INTRODUCTION

The COVID-19 pandemic was caused by the severe acute respiratory syndrome corona virus-type 2 (SARS-CoV-2) that started in late 2019 in Wuhan, China. COVID-19 has infected 60.074.174 people, including 1.416.292 deaths by November 26^{th,} 2020[1]. Globally, hospitals were forced to stop most surgeries and redirected resources and staff to accommodate the growing burden of COVID-19. Anesthesia and surgical practice worldwide suffer from radical changes in protocols, especially those related to pre-operative screening, testing, and infection control policies[2,3].

World Health Organization (WHO) reported that SARS-CoV-2 is transmitted via droplets and possible aerosol, which is produced frequently in medical procedures such as intubation, ventilation, and suctioning, and those procedures are a routine part of surgery and anesthesia practice. Adding to the complexity is the possibility of air and surface contamination in the operating room. The operating room (OR) may be a ground for hospital outbreaks because of several factors, such as a relatively contained enclosed space, densely populated with health care workers, and many working surfaces. Reports from Spain, United States (US), and the United Kingdom showed hospital staff infection rates as high as 10-60%[3-5]. Compared to the general community, health care workers are at higher risk for COVID-19 infection and although the severity is low but leads to extended sick leave, reducing health care capacity, and increasing workload among other staff[4,5].

Hospitals in Italy and Singapore were early on reporting their preparedness of surgery during the pandemic that included testing and adjustments of workflow in the emergency and the operating room. Reports from these hospi-tals may not be relevant to many developing countries such as Indonesia since these hospi-tals reported rapid use of the gold standard real-time polymerase chain reaction (RT PCR) as the ba-

sis of their pre-operative testing[6,7]. Reports from a similar developing country, Brazil, also reported the use of RT PCR later on the second half of the pandemic that saw 7.6% of their elective patients having COVID-19[8]. There has been a limited report on how centers or hospitals with limited access to RT PCR could systematically screen their surgical pati-ents and whether or not other testing tools can have any practical use in a pre-operative setting, especially for those who were suspected with COVID-19.

Our study aimed to determine the pre-operative screening for suspected patients with COVID-19 undergoing surgery in a tertiary referral hospital using a rapid antibody test, clinical scoring system, and RT PCR.

MATERIAL AND METHODS

Research design

This study was a retrospective observational study. We included patients suspected of COVID-19 who were consulted to the emergency operating room between May 1st to June 31st, 2020, at Dr. Hasan Sadikin National Referral Hospital (RSHS) Bandung Indonesia, a tertiary referral teaching hospital.

Research subjects

A total of 43 subjects with suspected COVID-19 were included in the study. The inclusion criteria were patients with suspected COVID-19 infection undergoing emergency surgery, and the exclusion criteria were the unavailability of the medical record.

Screening

The infection and re-emerging disease team conducted the initial screening for potential COVID-19 infection (PINERE). Patients were screened for COVID-19 before surgery by PINERE using a standard RSHS questionnaire, laboratory, radiology and rapid antibody IgG / IgM examination. Suspected COVID-19 was declared based on RSHS COVID-19 score, in which either values above or equal to 5 or a positive antibody test was declared as a suspected COVID-19 case (Supplement File). The antibody was tested using a rapid antibody anti-SARS-CoV-2 test kit (lateral flow method, Guangzhou Wondfo, Biotech Co Ltd China) with blood serum as a test sample.

Nasopharyngeal swabs for SARS-CoV-2 were tested by PCR either pre-operative or post-operative, but surgery was not delayed until test results came out surgery was possible to delay. Real-time reverse transcriptase-polymerase chain reaction testing was done in a provincial referral laboratory using the Sansure reagent (Sansure Biotech, China). No testing during this time was done in our local laboratory equip-ment was not available during this time at our hospital.

Data collection

Patient's clinical data were collected including sex, age, patient's origin, referral data, American Society of Anesthesiologist (ASA) classification and type of surgery. Pre-operative COVID-19 screening includes a history of

fever, upper respiratory tract infection history, contact with COVID-19 patients, history of travel, and laboratory examination, including leucocyte, absolute lymphocyte count values neutrophil-lymphocyte ratio, chest radiography and rapid antibody test results. Not all patients had antibody results since the test not constantly available during the study period, nevertheless if available, data was noted. No rapid antigen testing was also available during this period, so data was not available.

Statistical analysis

A normality study was done using the Shapiro-Wilk test since data was less the 50. Data were generally distributed if the significance value was more than 0.05, but all variable has significance below 0.05; hence data were not normally distributed—the non-parametric test Mann-Whitney, Fischer exact and or Chi-square test. The test was considered significant if the p-value was < 0.05. The sensitivity and specificity of the rapid antibody test and covid score were also evaluated.

Ethical clearance

This research was approved by the Institution's Review Board (IRB) (LB.02.01/X.6.5/161/2020). Written or oral informed consent was obtained upon the hospital admission to utilize data for future scientific purposes.

RESULTS

Demographic and clinical characteristics

During the study, according to the screening procedure done in our hospital (Supplement File), 166 patients were planned for surgery in the emergency operation room, with 43 subjects (25.9%) declared as patients with suspected COVID-19.

Table 1. Characteristics of patients with suspected COVID-19 (n=43) presenting to emergency operation room in a tertiary referral hospital.

Characteristics	n (%)
Age, median (in years)	35.6 .(min 5, max 71)
Sex	
Male	15 (34.9)
Female	28 (65.1)
Case origin	
Local	27 (62.8)
Referred	16 (37.2)
Type of surgery	
General pediatric	2 (4.7)
Maxillofacial	3 (7)
Vascular	4 (9.3)
Digestive	4 (9.3)
Neurosurgery	3 (7)
Obstetric/Gynaecological	20 (46.5)
Orthopaedic	4 (9.3)
Plastic	1 (2.3)
Urology	2 (4.6)
Timing of SARS-CoV-2	
Pre Op	9 (20.1)
Post Op	34 (74.9)

The median age was 35.6 years old, with two pediatric patients aged below 18 years old. Of 43 subjects, nine subjects (20.1%) had pre-operative RT PCR, while 34 (79.9%) had

results within seven days post-operative. Most cases were female (n=28;65.1%) with obstetric as the most common group (n= 20;46.51%). The majority of subjects came from within the city (n=27;62.8%), and only 16 patients (37.2%) were referred from other cities (Table 1). Subjects were then separated into two groups depending on their RT-PCR results, with 12 subjects (27.9%) positive for SARS-CoV-2 and 31 subjects with negative SARS-CoV-2 (Table 2).

Table 2. Comparison of patient characteristics and laboratory between SARS-CoV-2 (-) and SARS-CoV-2 (+).

Characteristics	**SARS-CoV-2 (-) (n=31)**	**SARS-CoV-2(+) (n=12)**	**p value**
Sex			
Female	20 (46.5)	9 (20.9)	0.511*
Male	11 (25.6)	3 (7.0)	
Symptoms			
None	17 (39.5)	8 (18.6)	0.007*
Fever	11 (25.6)	0 (0)	
Cough	2 (4.7)	0 (0)	
Dyspnoea	1 (2.3)	0 (0)	
Close contact to suspected/confirmed COVID-19			
Individual	0 (0)	3 (7)	
Healthcare worker treatingCOVID-19 patients	0 (0)	1 (2.3)	
Travel History	17 (39.5)	8 (18.6)	
Laboratory Results (mean±sd)			
Average Leukocyte count (/ul)	12142.4 (5390-21420)	8202.5 (4820-20290)	0.016
Absolute lymphocyte (/ul)	1587.6 (170-4630)	2110 (810-4670)	0.079
Lymphocyte percentage (%)	14.88 (1-37)	53.12 (4-82)	0.002
Neutrophil-Lymphocyte Ratio (NLR)	10.944 (1.54 -94.29)	5.1875 (0.78-23.8)	0.023
Radiological Examination			
No	19	9 (20.9)	0.398*
Suspected pneumonia on Chest X-Ray	12 (75.0)	3 (25.0)	
Immunology tests			
Positive IgM rapid test	21 (48.8)	1 (2.3)	0.000*
Positive igG rapid test	0	1 (2.3)	
Negative IgM/IgG rapid test	10 (23.3)	4 (9.3)	
Test Not available	0	6 (14)	
RSHS COVID-19 Score			
≥ 5	12 (27.9)	6 (14.0)	0.501*
< 5	19 (44.2)	6 (14.0)	

*Test statistics : *Chi-Square test; ** Asymp. Sig. (2-tailed)*

Chi-Square test showed there was no significant correlation between sex and COVID-19 (p> 0,05).There was no significant correlation between radiological examination with COVID-19 (p =0.398). There was a significant correlation between symptoms and COVID-19 (p = 0.007). Data showed that the negative group has more positive symptoms such as fever, cough, and dyspnoea. Close contact with the suspected patient probably had some correlation on the positive group, but data was not adequate for analysis. There is a significant correlation between rapid antibody test and COVID-19 (p= 0,000).The negative group generally has a more positive IgM rapid antibody test than the negative IgG rapid antibody test, while the positive group immunology test was more likely for a positive IgG rapid antibody test.

Evaluation of RSHS scoring system and rapid antibody test compared to RT-PCR.

Sensitivity for rapid antibody test IgM, IgG and RSHS scores were 16.7%, 16.7% and 50%. Specificity rapid antibody test IgM, IgG and RSHS scores were 32.2%, 100% and 38.71%. Note that the total number of rapid antibody testing and RSHS scores differsfrom the total subject number. This difference is due to the low availability of rapid antibody tests during the early pandemic; hence, some patients did not have antibody tests. RSHS score total subject number was also lower since scoring requires a chest x-ray score while chest x-ray was not routinely done to all surgical patients, especially pregnant women (Table 3).

Table 3. Sensitivity and specificity of rapid test IgM, IgGantibody and RSHS COVID-19 score to SARS-CoV-2 RT-PCR**.**

	SARS-CoV-2 RT-PCR		**Total**
Rapid test IgM antibody	**Positive**	**Negative**	
Positive	1	21	22
Negative	5	10	15
Total	6	31	37
Sensitivity = 16.7% ; 95% Confidence interval (0.42-64.12%)			
Specificity =32.2% ; 95% Confidence interval (16.68-51.37%)			
Rapid test IgG antibody			
Positive	1	0	1
Negative	5	31	36
Total	6	31	37
Sensitivity = 16.7%; 95% Confidence interval (0.42-64.12%)			
Specificity =100%; 95% Confidence interval (88.78-100%)			

Abbreviation: IgM: immunoglobulin M;IgG: immunoglobulin G;RSHS: RumahSakit Hasan Sadikin, SARS-CoV-2: severe acute respiratory syndrome coronavirus 2;RT-PCR: real-time polymerase chain reaction.

RSHS Score			
< 5	6	19	25
≥ 5	6	12	14
Total	12	29	39
Sensitivity = 50%; 95% Confidence interval (21.09-78.91%)			
Specificity = 38.75%; 95% Confidence interval (21.85-57.81%)			

DISCUSSION

Female predominant for emergency surgery and suspected to have COVID-19 is similar to previous studies in the US and Italy since the cesarean section is the most common surgery done in all three countries, including Indonesia[8-10].This proportion of obstetric cases might unbalance the risks of sex in COVID-19 for the perioperative period, and an adjustment should be made before taking a conclusion.

All of the patients presenting to our emergency room in the SARS-CoV-2 positive group had no typical fever, cough, or dyspnoea symptoms. Our results were consistent with other cohortsof surgical patients that reported 56-77% of all surgical patients with SARS-CoV-2 did not present any symptoms during admission, and around 15.6% of all COVID-19 patients were asymptomatic[9]. It should be noted that previous studies concluded that surgical patients with symptomatic COVID-19 have a worse outcome than patients without COVID-19. This study found that 30-day mortality was significantly higher for those with COVID-19 than control patients without COVID-19, who have higher complications, especially pulmonary complications, and thrombotic complications[10]. Different models (cumulative link model and classification tree) identified COVID-19 as the primary variable associated with complications. These findings and our data suggest that although an asymptomatic patient is typical for surgery, an asymptomatic patient must be assessed carefully since the outcome differs between these groups[11,12].

Comparing both groups shows a significant difference in symptomswith alerting findings that symptoms occurred more on the negative PCR group and more patient in the positive group was asymptomatic. A meta-analysis from 50,155 patients with confirmed SARS-CoV-2 infection from 41 studies showed the pooled percentage of asymptomatic infection was 15.6% (95% CI, 10.1% -23.0%)[12]. As our study also included pediatric patients who are a lesser infected age group in the COVID-19, the findings on this study is similar to another study that reported that among 1,152 COVID-19 children from 11 studies, asymptomatic cases were higher than adults at 27.7% (95% CI, 16.4%-42.7%)[12]. We noted the possibility of presymptomatic patients since another study reported that presymptomatic among initially

asymptomatic patients was relatively high at 48.90%[12].There is the possibility of untraced presymptomatic patients since this study did not follow up all PCR-positive patients who may develop symptoms.

Our data pool shows that tabulated risks in positive contact with a suspected or confirmed COVID-19 patient yielded a very high risk for a positive result. An anesthesiologist must remain alert and apply safety and prevention measures in the operation room primarily related to the manipulation of the airway and patient handling since there is a risk of contamination from asymptomatic/presymptomatic person especially in Indonesia, where the current infection trend remains on the upslope and more so if no PCR screening test is done in the pre-operative period[12].

To improve the efficacy of the anamnesis, some atypical symptoms reported by other studies such as myalgia, arthralgia, dysphagia and anosmia not assessed on this paper could be studied further. Another interesting finding in our study was that even though all SARS-CoV-2 positive patients denied having typical COVID-19 symptoms, three patients (25%) had suspicious chest x-ray findings. Although this result is consistent with other studies that reported a low correlation between one-point chest radiology and positive RT-PCR and a serial x-ray might better correlate with positive SARS-CoV-2 infection, this suggests that in an asymptomatic patient, particular lung pathology existed. Studies in Indonesia[13] and China[14] show that chest CT has a sensitivity of > 90%. Although specificity is < 65% but in the setting of emergency surgery, chest CT may provide rapid valuable insight into the patient's possible infectious state, especially in those who are asymptomatic.

Our laboratory result comparison findings show that patients with positive SARS-CoV-2 RT-PCR results had lower leukocytes, higher lymphocyte percentage, lower neutrophil percentage, and lower NLR. Interestingly our positive group has a higher absolute lymphocyte count, although it was statistically not significant. This result is consistent with two previous studies in China that shows patient may show lower NRL. However, a metanalysis shows that NLR values were significantly increased in patients with COVID-19 with severe disease[15-17]. The patient in the opposing group has more positive symptoms and more suggestive radiological findings, which may cause more false-positive diagnoses on a clinical basis.

Another significant finding in our study was the low sensitivity and specificity of the rapid antibody test, especially IgM, in correlation to a positive SARS-CoV-2 antigen testing using PCR. This finding supports the WHO, and Indonesian Ministry of Health directives reference not to use rapid antibody tests in clinical settings[18,19].The antibody developed against SARS-CoV-2 is reported to relate to sample

collection and viral load time. The antibody will appear approximately on the third week of infection, so rapid antibody test results depend on symptom and time for result interpretation[16,18]. Seeing that all positive patient in our study was asymptomatic during admission impairs objective interpretation of both negative or positive rapid antibody test result since the probable infection timeline is unknown.

At the early timeframe of the 2020 pandemic, emergency procedures needed to proceed, and hospitalshad to develop a local screening protocol to ensure that patients do not pose a risk to our staff. Due to the limited availability of a specific scoring system for preanesthetic and presurgical screening, the RSHS COVID-19 score was developed with specific marks in the history of close contact and chest X-ray findings. The RSHS COVID-19 score shows relatively low sensitivity at 50% andspecificity at 38.75%. This result is unsatisfactory, and we concluded that we had use a chest x-ray as one of the scored items. Other studies have revealed that chest x-ray has low values in predicting COVID-19, and a chest CT scan has a better prognostic value[13,14]. The utilization of Chest CT would provide a more sensitive diagnosis on asymptomatic patients, which comprises a major percentage of the SARS-CoV-2 positive population. Among the items studied, close contact history with a COVID-19 patient has a possible strong association with positive SARS-CoV-2 PCR, consistent with the WHO and Indonesian Ministry of Health briefing that contact history is a strong item of suspicion on COVID-19[18,19].

All results and conclusions from this research should be matched with an individual person-to-person case and measuring the constant infection rate in the local population in which a hospital resides. Another weakness of the study was using our local scoring for COVID-19 screening, named the RSHS COVID-19 screening, a score authorized by our hospital as an emergency response to the pandemic. Keeping in mind that this paper was written and data collected was during the early months of the pandemic, many emergency authorizations had to be taken to manage the situation. It would be imperative to compare these scorings with data found further as more COVID-19 patients undergo surgery in the future.

Further study is needed on rapid diagnostic testing for COVID-19 in an emergency surgery setting. A possible option is the use of GeneXpert for the diagnosis of COVID-19. The GeneXpert MTB/RIF molecular platform (Xpert; Cepheid, Sunnyvale, CA, USA) was for tuberculosis diagnostic testing, available in many middle and low-income countries. In response to the COVID-19 pandemic, multiplex RT-PCR assays, including the Cepheid Xpert Xpress SARS-CoV-2, have received authoriza-tion for emergency use from the US Food and Drug Administration.This RT-PCR-based assay could provide results within 50 minutes and

provides a better time-targeted result critical for emergency surgery[20].

CONCLUSIONS

Generally, in the perioperative period, no other diagnostic tool has the accuracy of RT-PCR to diagnose SARS-CoV-2 infection. Our study supports the World Health Organization and Indonesian Ministry of Health's recommendation not to use rapid antibody tests in clinical settings.

Additional materials: Supplement File 1

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Authors' contributions:

GG contributed to conceptualization, methodology, investigation, writing the original draft. I and YH contributed to writing the draft preparation. AF contributed to editing and supervision. All authors have read and approved the final manuscript. This paper was highly influenced by the RSHS Bandung operating room team and their work during the COVID-19 pandemic. We acknow-ledge our system contributors: Ms. Tita Setiawati, Mr. Dani Gandani, Ms. Rita Purnamasari, Mr. Wawan Arif Sawana, Ms. Lia Nugraha, Mr. Ilman Sinalas, and Mr. Maudy Dirgahayu Hussein.

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The authors declare that they have no competing interests.

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