นิพนธ์ต้นฉบับ

การศึกษาความแม่นยำของชุดตรวจ ใบยาแอนติบอดี ต่อเชื้อไวรัสโควิด 19 ในผู้ป่วยก่อนการผ่าตัดมะเร็ง นรีเวชเปรียบเทียบกับผู้ป่วยที่หายจากโรค

วัชรินทร์ เฉิดฉิ้ม, พ.บ., ปร.ด., พิพัฒน์ คงทรัพย์, พ.บ.
โรงพยาบาลพระปกเกล้า จังหวัดจันทบุรี

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บทคัดย่อ

ที่มาของปัญหา: การระบาดอย่างรวดเร็วและรุนแรงของโรคโควิด 19 จำเป็นต้องมีเครื่องมือในการวินิจฉัย การใช้ Rapid antibody test kit มีความสะดวก รวดเร็ว ราคาไม่สูง เหมาะสำหรับสถานการณ์ ใช้คัดแยกผู้ป่วย จำเป็นต้องมีการตรวจสอบ Diagnostic accuracy index โดยเทียบกับ Gold standard คือ RT PCR เพื่อนำไปใช้งานทางคลินิกต่อไป

วัตถุประสงค์: ศึกษาความแม่นยำของชุดตรวจ Baiya Rapid Covid-19 IgM/IgG test kit

วิธีการศึกษา: Cross sectional study ระหว่างวันที่ 1 พฤษภาคม พ.ศ. 2563 ถึงวันที่ 30 มกราคม พ.ศ. 2564 ณ แผนกสูติ-นรีเวชกรรม โรงพยาบาลพระปกเกล้า จังหวัดจันทบุรี เจาะเลือดจากปลายนิ้วตรวจหา Antibody IgM/IgG ในผู้ป่วยก่อนผ่าตัดโรคมะเร็งนรีเวชจำนวน 23 คน (control group) เปรียบเทียบกับสตรีที่หายป่วยจากโรคโควิด-19 ที่กลับบ้านจากโรงพยาบาลสนามหลังกักตัวครบ 14 วัน จำนวน 27 คน (case group)

ผลการศึกษา: Preoperative จำนวน 23 คน PCR positive จำนวน 0 คน Rapid antibody test positive จำนวน 1 คน และผู้ป่วยจากโรงพยาบาลสนามจำนวน 27 คน PCR positive จำนวน 27 ราย Rapid test antibody test positive จำนวน 27 ราย พบ Sensitivity ร้อยละ 100 Specificity ร้อยละ 95.6 Accuracy ร้อยละ 98

สรุป: Diagnostic accuracy index of Baiya Rapid Covid-19 IgM/IgG test kit อยู่ในระดับสูงมาก สามารถนำมาใช้ในทางคลินิกได้

คำสำคัญ: Baiya Rapid Covid-19 IgM/IgG test kit, diagnostic accuracy index, preoperative gynecologic cancer surgery

ORIGINAL ARTICLE

Diagnostic Accuracy Index of The Baiya Rapid COVID–19 IgM/IgG Test Kit in Preoperative Gynecologic Cancer Surgery Compared with Cured COVID–19 Patients

Watcharin Chirdchim, M.D., Ph.D., Pipat Kongsap, M.D.

Prapokklao Hospital, Chanthaburi Province

ABSTRACT

BACKGROUND: With the rapid and severe outbreak of COVID-19, diagnostic tools are needed. Rapid antibody test kits are convenient and fast, and the price is not high, suitable for screening patients. In addition, the diagnostic accuracy index compared to the gold standard, RT-PCR, is required for further clinical use.

OBJECTIVES: To study the accuracy of the Baiya Rapid Covid-19 IgM/IgG test kit.

METHODS: Cross-sectional studies were collected between 1 May 2020 and 30 January 2021 at the Department of Obstetrics and Gynaecology, Prapokklao Hospital. Blood was taken from the fingertips to analyze to detect IgM/IgG antibodies in 23 preoperative gynecological cancer patients (control group) compared with 27 women with COVID-19 infection sent home from field hospitals after 14-day quarantine (case group).

RESULTS: For the preoperative 23 cases, 0 were positive PCR, and 1 case of the positive rapid antibody test. Of the 27 patients from field hospitals, 27 cases were positive PCR, 27 cases were positive rapid antibody tests, the sensitivity was 100.0%, specificity 95.6%, and accuracy 98%

CONCLUSIONS: Diagnostic accuracy index of the Baiya Rapid Covid-19 IgM/IgG test kit is very high. It can be for clinical use.

KEYWORDS: baiya rapid covid-19 IgM/IgG test kit, diagnostic accuracy index, preoperative gynecologic cancer surgery.

INTRODUCTION

In December 2019, a patient diagnosed with pneumonia emerged in China. They were confirmed to be infected with a new strain of SARS-CoV-2. It is similar to the first SARS-CoV epidemic in 2003.[1] The current gold standard confirmation test for SAR-COV-2 is Real-time PCR. However, real-time PCR examination takes a long time, is expensive, and few hospitals have the ability to diagnose.[2] In vitro diagnostic immunoassay test kit is an important external diagnostic tool for quick and safe patient screening, especially with a rapid outbreak of the Covid-19. The development of assays requires proteins, antibodies, or antigens to be screening agents. Recently, Thailand can produce antigens, fragments of the SAR-COV-2 spike, by Waranyoo Phoolcharoen, Department of Pharmacognosy and Pharmaceutical Botany, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Bangkok, Thailand[3] that can produce molecular proteins such as antigens or monoclonal antibodies in large numbers and quickly. A rapid diagnostic test kit using the lateral flow immunoassay technique capable of detecting IgM and IgG antibodies from the blood of infected patients is produced and registered in various countries. According to a study in China, part of the antigen from the virus was used to develop this assay. IgM can be detected from day 3-6 after infection, while IgG can be detected from day eight onwards. The results showed that the diagnostic sensitivity was 88.66%, and the diagnostic specificity was 90.63%[4]

This research aimed to study the Diagnostic accuracy index of the "Baiya Rapid Covid-19 IgM/IgG test kit" which is used to detect antibodies (IgG, IgM).

METHODS

Research Methodology

Data were collected after reviewing human research ethics from the Research Ethics Committee. A cross-sectional study was collected between 1 May 2020 and 30 January 2021 at the Department of Obstetrics and Gynaecology, Prapokklao Hospital. Among the 23 preoperative gynecological cancer patients (control group) compared with 27 women with COVID-19 infection who were sent home from field hospitals after 14-day quarantine (case group).

The sample size was calculated based on Li Z et al., 2020. The diagnostic sensitivity is 88%, and the diagnostic specificity is 90%. Therefore, the hypothesis is that the Baiya Rapid Covid-19 IgM/IgG test kit has a diagnostic sensitivity of 100% and diagnostic specificity of 100%. Calculated by using two-sample comparison of proportion power 80% one side and significant at 0.05. Approximately 40-60 samples were used. In this study, 50 samples were used.

The "Baiya Rapid Covid-19 IgM/IgG test kit" places 1-2 drops of a blood sample from a fingertip into the sample receptacle on the kit, followed by 2-3 drops of dilution buffer. Then, the sample runs through the test kit. Read the results after the examination within 15 minutes.

Data Analysis and Statistics

Data were analyzed using descriptive statistics such as percentage, mean, median, range, and standard deviation. The quartile deviation, Diagnostic accuracy index includes sensitivity, specificity, positive predictive value, negative predictive value, prevalence and accuracy.

RESULTS

The 23 preoperative included 7 Endometrial cancer (30.4%), 2 Molar pregnancy (8.7%), 1 Vulva

cancer (4.4%), 4 CIN and cervical cancer (17.4%), 7 Ovarian cancer (30.4%), 2 Sarcoma (8.7%). 27 Patients were discharged from field hospitals. Basic clinical characteristics are shown in Table 1.

Table 1 Basic clinical characteristics

Parameter	Preoperative (n=23)	Discharge from the hospital (n=27)	*p*-value
Age	49.2 (17.1)	52.7 (1.8)	0.36
Endemic area	0	27	<0.001
Closed contact	0	27	<0.001
Cough	0	1	0.5
PCR positive	0	27	<0.001
Rapid test positive	1 (4.4)	27 (100)	<0.001
IgG positive	1 (4.4)	19 (70.4)	<0.001
IgM positive	1 (4.4)	27 (100)	<0.001

Expected or Anticipated Benefit Gain and diagnostic accuracy index of Baiya Rapid Covid-19 IgM/IgG test. The kit is shown in Table 2

Table 2 A 2 x 2 table for the diagnostic accuracy index

Rapid antibody test	PCR	
	Positive	negative
Positive	27 A	1 B
Negative	0 C	22 D

Sensitivity=A/(A+C)=27/(27+0)=1=100.0%

Specificity=D/(B +D)=22/(1+22)=0.956=95.6%

Positive predictive value=A/(A+B)=27/(27+1)=0.9643=96.4%

Negative predictive value=D/(C+D)=22/(0+22)=1=100.0%

Accuracy=A+D/(A+B+C+D)=27+22/(27+1+0+22)= 49/50=0.98=98.0%

DISCUSSION

Using the rapid test kit, whether a rapid antibody test kid or a rapid antigen test kit (ATK), is a test kit that is easy, convenient, cheap, and gives a fast interpretation. It is necessary to test the diagnostic accuracy index compared to the gold standard, especially for emergencies[5]. This study chooses the rapid antibody test kit because there are clear case and control groups. The control group was a preoperative gynecologic cancer surgery group who had been in quarantine for more than 14 days before surgery, had no previous symptoms of COVID-19 and gave negative PCR tests for COVID-19 before surgery[6]. The antibody detection in this group is classified as a false positive test. In a study of gynecological cancer patients undergoing surgery in Spain, up to 50% of infections were reported[7]. The case group was a group of women patients diagnosed with COVID-19; the diagnosis was based on mild clinical symptoms and positive PCR detection. Blood testing was done before discharge for those in the field hospital for 14 days until they recovered. It was found that all of them had a level of detection antibody by Baiya rapid antibody test kid, especially IgM 100%, IgG 70%. The sensitivity and specificity of the Baiya Rapid Covid-19 IgM/IgG test kit were higher than other studies such as Li Z et al.[3] found a sensitivity of 80% and specificity of 90%[8] showed the sensitivity

of 89.22% and specificity of 96.86%[9] presented sensitivity 72.7%-100% and specificity 98.7%-100%, Uwamino Y et al.[10] indicated sensitivity 15%-67% and specificity 91%-92%.

Application of Rapid Covid-19 IgM/IgG test kit in clinical use[7-9,11-13]

1. Proactive disease screening with antigen rapid test kit (ATK), in which case RT-PCR cannot easily be used to test. Using both methods of testing enhances the accuracy of the diagnostic test (rapid diagnostic test) and may interpret results in four cases:

1.1 Positive antigen rapid test kit and positive antibody rapid test kit; there is a very high chance of infection.

1.2 Negative antigen rapid test kit and negative antibody rapid test kit; there is a very high chance of not being infected.

1.3 Positive antigen rapid test kit and negative antibody rapid test kit; there is a high probability of early infection.

1.4 Negative antigen rapid test kit and positive antibody rapid test kit; there is a high probability of late infection.

1. Interpretation of the results requires clinical symptoms and confirmation by RT-PCR.

2. Before discharge, quarantined patients to the community, especially those with IgG detected, usually after 14 days.

3. In case of emergency preoperative or emergency pre-procedure, use an antigen rapid test kit (ATK) before sending for RT-PCR.

4. Epidemiological survey for infected people

The rapid antibody test kit should be used with an antigen rapid test kit (ATK) or RT-PCR to determine the stage of infection and disease progression for diagnosis, monitoring, treatment, and disease control. Self-testing is not recommended; a healthcare professional must interpret results only.

The Baiya rapid antibody test kit has very high sensitivity and specificity. Therefore, it can be applied clinically under appropriate contexts and practical situations.

Conflict of Interest: None

Financial Support: None

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