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Real-Life Sensitivity and Specificity of a COVID-19 Ag Rapid Test Device in Haematology-Oncology Cases in a Tertiary-Care Educational University Hospital

COVID-19 Hızlı Antijen Testinin Üçüncü Basamak Eğitim Hastanesindeki Hematoloji-Onkoloji Vakalarında Gerçek Yaşam Duyarlılığı ve Özgüllüğü

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ABSTRACT

Introduction: *The Panbio™ coronavirus diseases-2019 (COVID-19) antigen rapid test device (PANCOVIDRTD, Abbott Germany) is commonly used in our setting. According to the manufacturer, its sensitivity, specificity, and agreement are 98.1%, 99.8%, and 99.4% respectively when compared to polymerase chain reaction (PCR) as the golden standard. We aimed to investigate these parameters of PANCOVIDRTD in hematology-oncology patients, who may have different viral loads due to their immunosuppressive conditions.*

Materials and Methods: *Our setting is a 164-bed educational hemato-oncology hospital. This study encompassed all patients who underwent PCR and PANCOVIDRTD testing from May to October 2022. The sensitivity and specificity of PANCOVIDRTD were evaluated with PCR as the reference standard.*

Results: *A total of 227 patients (122 patients with PCR positivity and 105 patients with PCR negativity) were included in the study. The mean age was 56 ± 14 years. One hundred forty six (64%) were female. Thirty-seven patients (16.2%) had hematologic underlying diseases, while 190 patients (83.7%) had oncologic underlying diseases. On the test day, 124 (54.6%) patients were symptomatic and 103 (52.4%) were asymptomatic for COVID-19. In the entire study group, PANCOVIDRTD demonstrated a sensitivity of 79.5% (97/122), a specificity of 100% (105/105), and an overall agreement rate of 89% (202/227). Within the symptomatic group, PANCOVIDRTD exhibited a sensitivity of 82% (73/89), a specificity of 100% (35/35), and an overall agreement of 87.1% (108/124). Conversely, in the asymptomatic subgroup, these values were 72.7% (24/33) for sensitivity, 100% (70/70) for specificity, and 91.2%*

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(94/103) for overall agreement. The positivity rates of PANCOVIDRTD for samples with Ct values ≥30, ≥25 to <30, and 20 to <25 were 67.5% (27/40), 84.7% (39/46), and 85.7% (30/35), respectively.

Conclusion: *The real-life sensitivity of PANCOVIDRTD in the hemato-oncology patient group was approximately 80%, rather than 95+%, while its specificity closely aligned with the manufacturer's reported results.*

Key Words: *COVID-19; Polymerase chain reaction; Rapid antigen test; SARS-CoV-2; Diagnosis*

ÖZ

COVID-19 Hızlı Antijen Testinin Üçüncü Basamak Eğitim Hastanesindeki Hematoloji-Onkoloji Vakalarında Gerçek Yaşam Duyarlılığı ve Özgüllüğü

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Giriş: *Panbio™ koronavirüs hastalığı 2019 (COVID-19) hızlı antijen testi (PANCOVIDRTD, Abbott Germany), hastanemizde yaygın olarak kullanılmaktadır. Üreticiye göre, altın standart olarak polimeraz zincir reaksiyon (PZR) ile karşılaştırıldığında duyarlılığı, özgüllüğü ve iki testin uyumu sırasıyla %98.1, %99.8 ve %99.4'tür. Bu çalışmada, immünsupresif durumları nedeniyle farklı viral yüklere sahip olabilecek hematoloji-onkoloji hastalarında, PANCOVIDRTD'nin duyarlılık, özgüllük ve PZR ile uyumunun araştırılması amaçlanmıştır.*

Materyal ve Metod: *Çalışma 164 yataklı bir üçüncü basamak eğitim ve hematoloji-onkoloji hastanesinde yapıldı. Çalışmaya, Mayıs-Ekim 2022 tarihleri arasında PZR ve PANCOVIDRTD testi yapılan tüm hastalar dahil edildi. PANCOVIDRTD'nin duyarlılığı ve özgüllüğü, PZR altın standart alınarak değerlendirildi.*

Bulgular: *Çalışmaya toplam 227 hasta (122'si PZR pozitif ve 105'i PZR negatif) dahil edildi. Ortalama yaş 56 ± 14 yıl idi. Hastaların 146 (%64)'sı kadındı. Olguların 37 (%16.2)'sinin hematolojik ve 190 (%83.7)'ının onkolojik malignite tanısı vardı. Tanı testleri uygulandığı anda, 124 hasta (%54.6) COVID-19 için semptomatik ve 103 hasta (%52.4) asemptomatikti. Tüm çalışma grubunda, PANCOVIDRTD'nin duyarlılığı %79.5 (97/122), özgüllüğü %100 (105/105) ve iki testin genel uyumu %89 (202/227) olarak belirlendi. Semptomatik grup içinde, PANCOVIDRTD'nin duyarlılığı %82 (73/89), özgüllüğü %100 (35/35) ve genel uyumu %87.1 (108/124) idi. Buna karşın, asemptomatik alt grup içinde bu değerler duyarlılık için %72.7 (24/33), özgüllük için %100 (70/70) ve genel uyum için %91.2 (94/103) idi. PANCOVIDRTD'nin Ct değeri ≥30, ≥25 Ct < 30 ve 20 ≤ Ct < 25 ile pozitiflik oranları sırasıyla %67.5 (40'tan 27'si), %84.7 (46'dan 39'u) ve %85.7 (35'ten 30'u) idi.*

Sonuç: *Hemato-onkoloji hasta grubunda PANCOVIDRTD'nin gerçek yaşam duyarlılığı %95+ değil yaklaşık %80 olarak saptandı. Buna karşın, özgüllüğü üreticinin sonuçlarına çok yakındı.*

Anahtar Kelimeler: *COVID-19; Polimeraz zincir reaksiyonu; Hızlı antijen testi; SARS-CoV-2; Tanı*

INTRODUCTION

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) [coronavirus diseases-2019 (COVID-19)] virus, first identified in December 2019, spread rapidly worldwide. On March 11, 2021, the World Health Organization (WHO) declared the situation as a pandemic. COVID-19 ranges from asymptomatic infection to mild/moderate pneumonia and/or severe respiratory syndrome with fatal outcomes[1-3]. The virus remains a serious global issue with fluctuations in the epidemic curve, with over 775 million

reported cases and over seven million reported deaths as of March 14, 2024[4]. Unfortunately, hematology-oncology patients are not exempt from the worldwide risk of COVID-19. In fact, their risk of adverse outcomes is often higher than that of the general population[5].

Currently, COVID-19 polymerase chain reaction (PCR) is the primary method for diagnosing COVID-19[6]. However, it has certain drawbacks, including high costs, technical complexity, and the requirement for substantial technical expertise and support[7]. In contrast, rapid COVID-19 tests are cheaper, easier to perform, and do not require complex technical abilities[7]. Rapid tests with relatively high sensitivity and specificity are commonly used in the community[8]. Recently, certain countries like the Kingdom of Bahrain have started utilizing rapid tests independently to confirm the disease without requiring additional PCR testing[8].

One of the most commonly used rapid tests in our country is the Panbio™ COVID-19 antigen (Ag) rapid test device (PANCOVIDRTD) (Abbott Diagnostics, Jena, Germany). As per the manufacturer, when PCR is considered to be the golden standard, the test's sensitivity, specificity, and overall agreement are 98.1%, 99.8%, and 99.4%, respectively[9]. Nevertheless, there is limited data on the effectiveness of antigen tests in immunocompromised patients, whose COVID-19 presentation and viral load may differ from those of individuals with a healthy immune system[10]. In this study, we aimed to investigate the sensitivity, specificity, and overall agreement of PANCOVIDRTD with PCR in a group of hematology-oncology patients in a real-life setting.

MATERIALS and METHODS

Our facility is a 164-bed educational hemato-oncology university hospital. After January 2022, patients routinely underwent both PANCOVIDRTD and COVID-19 PCR testing prior to hospital admission and cytotoxic chemotherapy. This study included all patients who underwent COVID-19 PCR and PANCOVIDRTD testing between May and October 2022.

The rapid antigen test kits were stored in the hospital according to the instructions in the manual. PANCOVIDRTD was performed in accordance with the manufacturer's recommendations[9]. Both rapid antigen and PCR tests were performed by the same two proficient nurses to reduce technical and practical variations. Samples for PCR were transported to the laboratory in viral nucleic acid transport medium, immediately after collection, without storage. TaqPath RT-PCR COVID-19 kit (Thermo Fisher Scientific, Waltham, USA) was used for PCR as recommended by the manufacturer[11]. Cycle threshold (CT) values of the related PCR cycles were retrieved from the hospital's electronic system. The sensitivity and specificity of PANCOVIDRTD were analyzed using PCR as the gold standard. To evaluate the agreement between the tests, Cohen's kappa coefficient (κ) was used.

RESULTS

The study included 227 patients, of whom 122 tested positive and 105 tested negative by PCR. The mean age of the patients was 56 ± 14 years, and 64% of them were female. Among the 227 patients, 16.2% had hematologic underlying diseases, while 83.7% had oncologic underlying diseases.

On the day of the COVID-19 test, 124 (54.6%) patients were symptomatic while 103 (52.4%) were asymptomatic.

In the overall cohort, PANCOVIDRTD showed a sensitivity of 79.5% (97/122), a specificity of 100% (105/105), and an overall agreement of 88.9% (202/227) in the entire study cohort. In the symptomatic COVID-19 cohort, the sensitivity, specificity, and overall agreement were 82% (73/89), 100% (35/35), and 87.1% (108/124), respectively. Meanwhile, the same parameters were 72.7% (24/33), 100% (70/70), and 91.2% (94/103) in the asymptomatic COVID-19 subgroup. The Cohen's kappa test indicated substantial agreement in the overall (κ= 0.782), symptomatic (κ= 0.720), and asymptomatic (κ= 0.784) subgroups. COVID-19 PCR and rapid antigen test results are summarized in Table 1.

Table 1. COVID-19 PCR and rapid antigen test results based on the symptoms on the test date

	PCR Positive	PCR Negative	Total
All Patients			
COVID antigen test positive	97	0	97
COVID antigen test negative	25	105	130
COVID antigen test total	122	105	227
	79.5% (97/122)	100% (105/105)	89% (202/227)
	Sensitivity	**Specificity**	**Overall Agreement**
Symptomatic			
COVID antigen test positive	73	0	73
COVID antigen test negative	16	35	51
COVID antigen test total	89	35	124
	82% (73/89)	100% (35/35)	87.1% (108/124)
	Sensitivity	**Specificity**	**Overall Agreement**
Asymptomatic			
COVID antigen test positive	24	0	24
COVID antigen test negative	9	70	79
COVID antigen test total	33	70	103
	72.7% (24/33)	100% (70/70)	91.2% (94/103)
	Sensitivity	**Specificity**	**Overall Agreement**

Data are derived from the BOC patients who underwent both COVID-19 PCR and antigen testing on the same day.

Table 2. The positivity rate of Panbio™ rapid antigen test based on RT-PCR Ct value results

	Panbio™ Rapid Antigen Test		
RT-PCR Ct Value (n)	**Negative**	**Positive**	**Positivity Rate**
<20 (n= 1)	0	1	100%
20≤ Ct <25 (n= 35)	5	30	85.7%
25≤ Ct <30 (n= 46)	7	39	84.7%
≥30 (n= 40)	13	27	67.5%

RT-PCR: Real-time reverse transcription polymerase chain reaction, Ct: Cycle threshold.

CT values and related PANCOVIDRTD sensitivity

The positivity rate of the rapid antigen test was 67.5% (27 out of 40) for samples with Ct values ≥30, 84.7% (39 out of 46) for Ct values ≥25 and <30, and 85.7% (30 out of 35) for samples with Ct values between 20 and <25. There was only one patient with a Ct value <20 (Ct= 18) and rapid antigen test positivity (Table 2).

DISCUSSION

The purpose of this study was to evaluate the number of potentially missed COVID-19 diagnoses in our hematology-oncology patient subgroup if the diagnosis relied solely on a COVID-19 rapid test without performing a COVID-19 PCR test. The PANCOVIDRTD test had a real-life sensitivity of around 80%, but not 95% or higher in our study cohort[9]. However, its specificity was in line with the manufacturer's results. Nevertheless, since the test missed approximately 20% of COVID-19-positive cases, we decided to continue screening the patients with both PCR and the rapid antigen test.

COVID-19 is associated with a high incidence of adverse outcomes in immunocompromised

hosts. A recent study by Baskol-Elik et al. examined the clinical results of 170 cases of febrile neutropenia and COVID-19, revealing a 30-day mortality rate of 44.8%[12]. Yekedüz et al. conducted a meta-analysis evaluating the effect of active cancer treatment on the severity of COVID-19. A total of 16 studies were included in the meta-analysis and it was shown that, chemotherapy administration during COVID-19 or within the last 30 days before COVID-19 diagnosis increased the risk of death (OR= 1.85; 95%, confidence interval= 1.26-2.71)[13]. Likewise, in a study by Lièvre et al., it was observed that administering cytotoxic chemotherapy to patients with detectable SARS-CoV-2 by RT-PCR was linked to a slight rise in the risk of mortality (OR= 1.53; 95%, CI= 1.00-2.34; p= 0.05)[14]. Considering these findings, continuing to screen patients with both PCR and rapid antigen tests, despite the technical challenges, appears reasonable to avoid missing any active COVID-19 infections before initiating cytotoxic chemotherapy.

RT-PCR positivity is identified by the buildup of a fluorescent signal. The Ct value indicates the number of cycles needed for the fluorescent signal to surpass a certain threshold. Ct values are inversely proportional to the target nucleic acid amount in the sample. Hence, a greater Ct value represents the lower viral load in the sample[15].

In comparative studies, SARS-CoV-2 rapid antigen tests have been shown to have reduced sensitivity compared to PCR[10]. The sensitivity is reported to be relatively lower, particularly in cases with low viral load [those with a high (Ct) (value >30)][10]. However, in cancer patients, even low viral loads may be clinically significant as infectious viruses have been isolated from the samples. Moreover, viral loads might be low or even undetectable in throat swabs of the patients presenting with lower respiratory tract involvement[16-18]. Hence, the German Society for Hematology and Medical Oncology does not recommend performing SARS-CoV-2 rapid antigen tests for COVID-19 diagnosis in cancer patients[19]. However, the IDSA COVID-19 antigen testing guidelines do not provide a definitive recommendation regarding point-of-care tests for specific populations, such as immunocompromised individuals, due to insufficient data[10]. The Kingdom of Bahrain's COVID-19 guidelines recommend the exclusive use of antigen tests for diagnosis but do not provide specific guidance regarding their use in cancer patients[8]. Nevertheless, in this study, we aimed to evaluate the performance of PANCOVIDRTD in our cohort of immunocompromised patients.

A study comparing PANCOVIDRTD with PCR in oncology patients included 556 cancer patients. The sensitivity and specificity of the PANCOVIDRTD were found to be 69.6% and 100%, respectively. In addition, the Panbio™ COVID-19 Ag rapid test device demonstrated high sensitivity (91.8%) for samples with qRT-PCR Ct values below 20, which decreased to 77.5% for Ct values between 20 and 30. Performance significantly declined for higher Ct values, with sensitivity dropping to 18.2% for Ct values between 30 and 34, and 0% for Ct values between 35 and 40[16]. In a similar study conducted in Ethiopia, a total of 120 patients were enrolled from various departments. The study found that the sensitivity and specificity of the PANCOVIDRTD were 74.2% and 100%, respectively. The sensitivity of the PANCOVIDRTD test in symptomatic patients was 79.4% (95% CI= 68.3-90). Additionally, all samples with a Ct value less than 24 tested positive. However, PANCOVIDRTD failed to detect most positive cases with a Ct value above 24; for Ct values of 32 or higher (with an upper cut-off of 40), PANCOVIDRTD identified only 1 out of 12 positive cases (8%)[17]. In the prospective study conducted in Mallorca by Bulilete et al. evaluating the diagnostic performance of PANCOVIDRTD, the overall sensitivity was reported as 71.4% (95% CI= 63.1%, 78.7%), and the specificity was 99.8% (95% CI= 99.4%, 99.9%). The test sensitivity was acceptable according to WHO recommendations (The WHO advises utilizing antigen rapid diagnostic tests that achieve at least 80% sensitivity and 97% specificity as minimum performance standards) for symptomatic patients (n= 556; 83.1%, 95% CI= 71.9%, 90.5%) and those referred by their general practitioners for symptoms (n= 418;

86.0%, 95% CI= 71.3%, 94.2%)[20]. However, the test sensitivity was below the acceptable threshold set by WHO criteria (less than 80%) for asymptomatic patients (n= 390; 65.5%, 95% CI= 45.6%, 82.0%)[21]. Hence, the sensitivity of rapid antigen tests (RATs) is strongly linked to viral load, the presence of symptoms, and the timing of the test in relation to the symptom onset[10]. In the systematic review and meta-analysis published by Khandker et al., the sensitivity of COVID RATs in asymptomatic cases was lower than in symptomatic cases (54.5% vs. 78.5%)[22]. Similarly, in our study, PANCOVIDRTD sensitivity was lower in asymptomatic cases compared to symptomatic cases and in patients with higher Ct values vs. lower Ct value cohort. When evaluating the performance of PANCOVIDRTD against WHO criteria in our immunocompromised host cohort, specificity was within the WHO-recommended range. However, sensitivity fell below the WHO-recommended threshold in both the asymptomatic cohort and the high Ct (≥30) cohort[20].

The limitations of this study include its retrospective nature and the relatively small sample size. Another limitation is that only PCR-positive COVID-19 cases were analyzed, acknowledging that some cases might test negative due to mutations in the genome of the virus[23]. Additionally, no viral cultures were performed for the patients. Despite these limitations, to the best of our knowledge, this is the first study in the literature to specifically evaluate the sensitivity and specificity of PANCOVIDRTD in cancer patients.

CONCLUSION

While PANCOVIDRTD offers the benefit of early COVID-19 detection for prompt treatment initiation, it is important to consider its reduced sensitivity, especially in hematology-oncology patients, and to resort to PCR testing when needed.

ETHICS COMMITTEE APPROVAL

This study was approved by the Bahrain Defence Force Royal Medical Services Military Hospital Ethics Committee (Decision no: 2023-719, Date: 12.11.2023).

CONFLICT of INTEREST

The authors have no conflicts of interest to declare that are relevant to the content of this article.

AUTHORSHIP CONTRIBUTIONS

Concept and Design: UE, HE, ORS, EF

Analysis/Interpretation: UE, SH, TY, SPS, ZI, EF, HE, ORS

Data Collection or Processing: CSDR, JP, CV, NA, ORS

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Review and Correction: HE, CSDR, JP, CV, SH, TY, SPS, ZI, EF, HE, ORS

Final Approval: UE, NA, CSDR, JP, CV, SH, TY, SPS, ZI, EF, HE ORS

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