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Sección evidencias

Diagnostic Test: Is It Enough to Consider Sensitivity and Specificity?

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The medical act is based on making decisions under conditions of uncertainty. Everything we do to reduce it increases our probability of success. For this, it is essential to make an adequate interpretation of the results of the diagnostic tests.

We are going to remember the main definitions that establish the precision of a diagnostic test. The two basic measures are sensitivity (S) and specificity (E). Stands for is the probability of having a positive test, result in patients who have the disease and E is the probability of having a negative result in patients who do not have the disease. When we speak of disease we are referring to the condition that the test is capable of detecting. [1]

When performing a diagnostic test, we will find four possible situations. The true positives (TP) are those patients with the disease in whom the test is positive and the true negatives (TN) are those patients without the disease in whom the test is negative. False negatives (FN) are those with the disease in whom the test is falsely negative, whereas false positives (FP) are those without the disease in whom the test is false positive. Then, we can define S as the probability of finding a TP among patients who have the disease (TP + FN) and E as the probability of having a TN among those without it (TN + FP) (Table 1). [1]

Table 1
Diagnostic accuracy of a test

Test	**Disease**		
	Present	**Absent**	
Positive	True positive (TP)	False positive (FP)	VP + FP
Negative	False negative (FN)	True negative (TN)	FN + VN
	TP + FN	FP + TN	

To interpret the results of a diagnostic test, it is necessary to answer the following questions: what is the probability that a patient has the disease if he has a positive result? and, what is the probability that a patient does not have the disease if he has a negative result? The answers to these questions are the positive predictive value (PPV) and negative predictive value (NPV), respectively. [1]

In summary, the clinical context and the prevalence of the disease in the population studied, in addition to the diagnostic performance of the test, must be considered for the interpretation of the results.

We will try to incorporate these concepts by applying them to a problem of epidemiological relevance such as the COVID-19 pandemic. It is known that the early detection and isolation of patients infected with SARS-CoV2 is one of the fundamental pillars to reduce the spread of this disease.

Since the first genetic sequencing of SARS-CoV-2, nucleic acid amplification tests (RT-PCR) have been developed to detect the virus in various types of clinical samples, frequently nasopharyngeal and oropharyngeal swabs. The World Health Organization (WHO) currently continues to recommend the diagnosis of COVID-19 using molecular tests that detect the RNA of the SARS-CoV-2. [2]

The diagnostic accuracy of RT-PCR for the detection of active SARS-CoV-2 infection has been reported with a sensitivity of 81.5-92.2% and a specificity of 87-100%. Although they are very specific tests that can detect low levels of viral RNA, their sensitivity in the clinical context depends on the type and quality of the sample obtained, the duration of the disease at the time of evaluation, and the characteristics of the test. When the pre-test probability is high, a positive result should be considered confirmatory. Instead, a negative one should make us consider retesting (because the tests are not 100% sensitive). [2,3,4]

Let us consider a first scenario of a patient with symptoms compatible with COVID-19, belonging to a population that has a low prevalence of SARS-CoV2 infection, with an estimate pre-test probability of disease of 20% and we perform an RTPCR test that has, according to the manufacturer, an S 90% and an E 95%. First, we will answer our first question: what is the probability that a patient will have the disease if the test is positive? PPV = TP / (TP + FP) = 90 / (90 + 5) = 0.95 or 95%. Now, we will answer our second question: what is the probability that a patient does not have the disease if he has a negative result? For this, we will calculate the NPV. NPV = TN / (TN + FN) = 95 / (95 + 10) = 0.9 or 90%.

However, it is more useful to calculate the positive and negative post-test probability (P) from Bayes' theorem, which allows estimating them from the S and E of the test and the pre-test probability of the disease. By incorporating the probability of having the disease before performing the test, the clinical context in which it is performed is taken into account. The pre-test probability (p) will depend, as mentioned, on the patient's history, clinical manifestations and the prevalence of the disease in the population.

We will apply these concepts to our first example.

The positive post-test probability (P) is the probability of having the disease given a positive test.

P (disease | test+) = [S x*p*] / [S x*p* + (1-E) x (1 - *p*)] = [0.9 x 0.2] / [0.9 x 0.2 + (1 - 0.95) x (1 - 0.2)] = 0.81 or 81%

The negative post-test probability is the probability of not having the disease given a negative test.

P (no disease | test-) = [E x (1 - *p*)] / [E x (1 - *p*) + (1 - S) x*p*] = [0.95 x (1 - 0.2)] / [0.95 x (1 - 0.2) + (1 - 0.9) x 0.2] = 0.97 or 97%.

We will see a second scenario of a patient with symptoms compatible with COVID-19, to whom we perform the same RT-PCR test (S 90% and E 95%); although, this time the patient comes from a population with a high prevalence of SARS-CoV2 in which we estimate a pre-test probability of 50%. The estimation of the theoretical PPV and NPV will be the same as in the previous case, but not the post-test probability based on the pre-test probability.

P (disease | test+) = [S x*p*] / [S x*p* + (1-E) x (1 - *p*)] = [0.9 x 0.5] / [0.9 x 0.5 + (1 - 0.95) x (1 - 0.5] = 0.95 or 95%

P (no disease | test-) = [E x (1 - *p*)] / [E x (1 - *p*) + (1 - S) x*p*] = [0.95 x (1 - 0.5)] / [0.95 x (1 - 0.5) + (1-0.9) x 0.5] = 0.90 or 90%.

We observe that, as the pre-test prevalence increases, the probability of not having the disease decreases given a negative test (even keeping the S and E constant) (Fig. 1).[5] In our example, we go from a P (no disease | test-) from 97% to 90%. For this reason, in an epidemiological context of high viral circulation, a negative test result, even if it has high S and E, does not rule out SARS-CoV-2 infection.

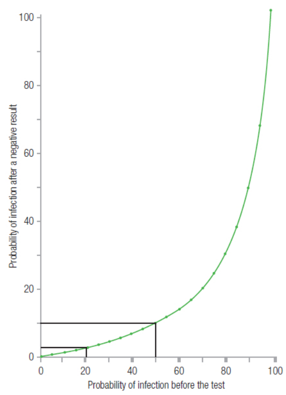

Figure 1

Probability of SARS-CoV2 infection after a negative result, compared to different pre-test probabilities (for a test with a sensitivity of 90% and a specificity of 95%)

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Notes

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