CME

Diagnostic Statistical Measures and Their Utilities in Clinical Decision Making

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As an additional study design, understanding diagnostic studies consisting of various statistical measures plays an important role for healthcare professionals to make informed clinical decisions. They help in the evaluation of the test accuracy of newer diagnostic tests in comparison to available gold standard tests for a disease through measures of concordance (e.g., sensitivity; specificity); measures of discordance (e.g., 1-sensitivity; 1-specificity); and some others (e.g., predictive values; receiver operating characteristic curve; likelihood ratios). Through more accurate diagnosis, they provide guidance regarding treatment decisions and monitoring of disease progression. Through their better understanding, healthcare professionals can select the most appropriate diagnostic tests, make more accurate diagnoses and develop effective treatment plans. In other words, it can help in improving patient outcomes and optimizing resource utilization. Along with basic terminologies, various indices used under diagnostic studies, and their applications, are briefly described in the present write-up so that readers become fully aware of them and use them in day-to-day clinical decision-making.

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Introduction

Background

To make informed clinical decisions, as another study design,[1] understanding diagnostic studies plays an important role for healthcare professionals. A diagnostic study is mainly carried out to assess the accuracy and validity of a newer diagnostic test in comparison to the available gold standard test regarding the presence of a particular disease or condition to be useful in clinical practice.[2] As a first step to carry out diagnostic studies, as emphasized earlier,[3] one needs to prepare a detailed research proposal following various steps under the required research methodology. As such, its study designs[1] are primarily observational (e.g., cross-sectional; case-control; cohort), but if necessary, diagnostic randomized controlled trials[4] may also be carried out (not covered here).

Regardless of study designs, usually measures of concordance (e.g., sensitivity; specificity), measures of discordance (e.g., 1-sensitivity; 1-specificity), and many other measures (e.g., predictive values; receiver operating characteristic curve; likelihood ratios) are assessed.[2,5-7] Through better understanding, these indices can help healthcare professionals in making more accurate diagnoses, determining the most effective treatment options, monitoring patient response to treatment, tracking disease progression or regression, and making informed decisions about adjusting treatment plans. By using these indices, healthcare professionals can provide more personalized and effective care, ultimately improving patient outcomes. In other words, this can lead to better patient care, reduced healthcare costs, and more efficient use of resources. The present write-up provides an overview of definitions and explanations of key basic terms used in diagnostic studies; the various indices used to evaluate diagnostic tests; and practical uses of these indices in clinical decision-making, disease diagnosis, and treatment monitoring. It aims to make the readers fully aware of major issues related to diagnostic studies so that they can use them in research activities and day-to-day clinical decision-making.

Key Basic Terms

These terminologies facilitate a better understanding of various issues related to diagnostic studies; they are briefly described below:[2]

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Index Test

This is usually a new diagnostic test regarding a specific disease whose diagnostic accuracy is assessed in comparison to an available gold standard test among the considered study sample. For example, as an index test, a chest X-ray is used to diagnose tuberculosis.

Gold Standard Test

This is the best test available to know the true status of a specific disease among a considered study sample. For example, as a gold standard test, culturing Mycobacterium tuberculosis from patients' sputum/ blood/ tissue samples to diagnose tuberculosis.

Clinically Relevant Population

An aggregate of those patients among whom the index test has to be finally used in day-to-day clinical practice. For instance, all the patients attending the respiratory/ tuberculosis clinic at RD Gardi Medical College, Ujjain, and suffering from severe respiratory symptoms for at least a week.

Study Sample

This is a representative sample of the clinically relevant population/patients among whom the comparative assessment of index tests against gold standard tests is carried out. Obviously, it involves considerations of inclusion criteria, exclusion criteria, and feasible & appropriate sampling methodology. For example, a representative sample of the patients attending the respiratory/tuberculosis clinic at RD Gardi Medical College, Ujjain, and suffering from severe respiratory symptoms for at least a week.

Minimum Sample Size:

Keeping in view of the primary objective under the proposed diagnostic study (e.g., estimation of sensitivity/ specificity/agreement of an index test in comparison with gold standard test; comparison of sensitivity/ specificity/agreement of two index tests in comparison with gold standard test), a minimum number of patients required for the study may be explored using appropriate approaches discussed in earlier published CME,[8] and/ or those available in other sources.[5-7]

Comparative Performance of Index Test with Gold Standard Test:

For this, primarily each of the study participants undergoes both the tests, the index test (e.g., chest x-ray) and the gold standard test (e.g., culturing the sputum sample) to diagnose tuberculosis (TB). As such, for assessing the accuracy & validity of the index test (e.g., chest x-ray) in comparison to the gold standard test (e.g., culturing sputum sample), such data may be presented in tabular form (table-1). To elaborate further, TP is the number of TB cases as per the index test, which are also TB cases truly as per the gold standard test; whereas FN is the number of non-TB cases under the index test but truly TB cases as per the gold standard test. Likewise, TN is the number of non-TB cases under the index test, which are also non-TB cases, truly as per the gold standard test; whereas FP is the number of TB cases under the index test but truly non-TB cases as per the gold standard test.

Using this tabulation, for comparison of the index test with the standard test, various measures of concordance, discordance, and predictive values may be calculated.

Measures of Concordance

They are broadly of two types:

Sensitivity (i.e., True Positive Rate)

Intuitively, as shown in table-1, the sensitivity of an index test may be expressed as the proportion of the total number of positive results under the index test out of the total number of positive results under the gold standard test [i.e., TP/ (TP+FN)]. In other words, it is the chance/ probability of obtaining true positive results under the index test in comparison to the gold standard test. Likewise, it may be expressed in the case of a specific disease. For example, the proportion of the total number of TB patients as per the index test out of the total TB patients as per the gold standard test. To be more specific, as evident from table-2, the sensitivity of the chest x-ray test in comparison to culturing the sputum sample for diagnosing TB is 0.57 [i.e., 20/ 35]. As conventionally in practice, sensitivity may be expressed in percentage as 57%. The higher the sensitivity, the better the index test. But, its acceptable threshold may rely on various factors

Table 1: Comparative Performance of Index Test with Gold Standard Test

Index Test (Chest x-ray)	*Gold Standard Test (Culturing sputum sample)*		*Row -wise Total*
	Positive	*Negative*	
Positive	True Positive (TP)	False Positive (FP)	TP + FP
Negative	False Negative (FN)	True Negative (TN)	FN + TN
Column-wise Total	TP + FN	FP + TN	N= TP+FP+FN+TN

like the type of disease, its public health implications, and levels of other diagnostic measures of the index test.

Specificity (i.e., True Negative Rate):

As is obvious, as presented in Table 1, the specificity of an index test may be expressed as the proportion of the total number of negative results under the index test out of the total number of negative results under the gold standard test [i.e., TN/ (TN+FP)]. In other words, it is the chance/ probability of obtaining true negative results under the index test in comparison to the gold standard test. Likewise, it may be expressed in the case of a specific disease. For example, the proportion of the total number of non-TB patients as per the index test out of the total non-TB patients as per the gold standard test. To be more specific, as evident from table-2, the specificity of the chest x-ray test in comparison to culturing a sputum sample for diagnosing TB is 0.67 [i.e., 10/ 15]. As conventionally in practice, specificity may be expressed in percentage as 67%. The higher the specificity, the better the index test. But, its acceptable threshold may also rely on various factors like the type of disease, its public health implications, and levels of other diagnostic measures of the index test.

Measures of Discordance

They are broadly of two types:

False Negative Rate (i.e., 1- Sensitivity)

As is obvious, under diagnostic analysis, it is complementary to sensitivity (i.e., 1-sensitivity). From table-1, the false negative rate of an index test may be expressed as the proportion of the total number of negative results under the index test out of the total number of positive results under the gold standard test [i.e., FN/ (TP+FN)]. In other words, it is the chance/ probability of obtaining false negative results under the index test in comparison to the gold standard test. Likewise, it may be expressed in the case of a specific disease. For example, the proportion of the total number of non-TB patients as per the index test out of the total TB patients as per the gold standard test. To be more specific, as evident from Table 2, the false negative rate of the chest x-ray test in comparison to culturing the sputum sample for diagnosing TB is 0.43 [i.e., 15/ 35]. As conventionally in practice, the false-negative rate (i.e., 1-sensitivity) may be expressed in percentage as 43%.

False Positive Rate (i.e., 1- Specificity):

As such, the false positive rate of an index test is complementary to its specificity (i.e., 1-specificity). It may be expressed as a proportion of the total number of positive results under the index test out of the total number of negative results under the gold standard test [i.e., FP/(TN+FP)]. In other words, it is the chance/ probability of obtaining false positive results under the index test in comparison to the gold standard test. Likewise, it may be expressed in the case of a specific disease. For example, the proportion of the total number of TB patients as per the index test out of the total number of non-TB patients as per the gold standard test. To be more specific, as evident from Table 2, the false positive rate of the chest x-ray test in comparison to culturing a sputum sample for diagnosing TB is 0.33 [i.e., 5/ 15]. As conventionally in practice, the false positive rate (i.e., 1-specificity) may be expressed in percentage as 33%.

Predictive Value:

This is another way to describe the comparative performance of the index test and the gold standard test. They are also broadly of two types:

Positive Predictive Value:

In contrast to sensitivity, as shown in Table 1, the positive predictive value of an index test may be expressed as the proportion of the total number of positive results under the gold standard test out of the total number of positive results under the index test [i.e., TP/ (TP+FP)]. In other words, it is a chance/probability that a positive result under the index test is truly positive. Likewise, it may be expressed in the case of a specific disease. For example, the proportion of the total number of true TB patients out

Table 2: Hypothetical example for comparative performance of index test with gold standard test among referred cases for TB

Index Test (Chest x-ray)	*Gold Standard Test (Culturing sputum sample)*		*Row -wise Total*
	Positive	*Negative*	
Positive	20	5	25
Negative	15	10	25
Column-wise Total	35	15	50

of the total TB patients as per the index test. To be more specific, as evident from Table 2, the positive predictive value of the chest x-ray test in comparison to culturing the sputum sample for diagnosing TB is 0.80 [i.e., 20/ 25]. As conventionally in practice, the positive predictive value of a chest X-ray may be expressed in percentage as 80%.

Negative Predictive Value:

In contrast to specificity, as shown in table-1, the negative predictive value of an index test may be expressed as the proportion of the total number of negative results under the gold standard test out of the total number of negative results under the index test [i.e., TN/ (TN+FN)]. In other words, it is a chance/probability that a negative result under the index test is truly negative. Likewise, it may be expressed in the case of a specific disease. For example, the proportion of the total number of true non-TB patients out of the total non-TB patients as per the index test. To be more specific, as evident from table-2, the negative predictive value of the chest x-ray test in comparison to culturing the sputum sample for diagnosing TB is 0.40 [i.e., 10/ 25]. As is conventionally the case in practice, the negative predictive value of a chest X-ray may be expressed as 40%.

Limitations of Predictive Values:

Predictive values may vary from one population to another population:

- *Disease Prevalence:*

s such, predictive values are dependent on the prevalence of disease (i.e., TB in the present example) in the considered population. To be more specific, let us consider another hypothetical example (i.e., Table-3).

As evident from Table 3, the prevalence of TB among primary health care patients is far below that among referred cases (i.e., Table 2). Regardless of prevalence, TPR, TNR, FPR and FNR remain the same. However, the predictive values vary as per the considered study population (Table 4). In other words, predictive values are dependent on the prevalence of the considered disease in the study population.

Biased Selection of Study Patients:

To facilitate a better understanding of this limitation of predictive values, one needs to differentiate between predictive value and posterior probability. Both seem to be similar in answering the question, given the test results under the index test, what is the probability that the patient has TB? However, in contrast to being an observable proportion under predictive values, posterior probability is computed using Bayes' theorem, which takes into account a prior probability of TB through an opinion about the chance of this disease prior to receiving test results. As such, expressing uncertainty in a more structured and numerical way using posterior probability, more informed decisions and better understanding of potential outcomes may be possible. In addition, through posterior probability, known results on TPR and FPR may be used to interpret the findings in any population.

Under the above-referred examples, if risk factors of TB (e.g., diabetes) among referred cases are lower than those among primary health care patients, TPR and FPR of TB under the index test might be lower among referred cases than those among primary health care patients. As such, the posterior probability of TB may be affected by the TPR and FPR of a test. To be more specific, the probability of TB if the chest x-ray is positive is dependent especially on the FPR of the chest x-ray. On the other hand, the probability of TB if the chest x-ray is negative is dependent especially on the TPR of the chest x-ray.

Keeping in view the above facts, a clinician may be curious to know whether he can use Bayes theorem to interpret a result under a chest x-ray, and use the test performance data from a published article earlier. To answer this, issues related to the measurements of TPR and FPR of chest x-ray under the published article need to be discussed. To focus further, an important source of error in the measurement of the performance of chest x-ray may be mainly due to differences between the population in which the performance of chest x-ray is measured, and in which the chest x-ray has to be used

Table 3: Hypothetical example for assessing comparative performance of index test with gold standard test among primary health care patients with suspected TB

Index Test (Chest x-ray)	*Gold Standard Test (Culturing sputum sample)*		*Row -wise Total*
	Positive	*Negative*	
Positive	114	264	378
Negative	86	536	622
Column-wise Total	200	800	1000

Table 4: Comparison of Predictive Values between both Hypothetical Examples: Referred Cases (i.e., Table-2) and Primary Health Care Patients (i.e., Table-3)

Type of Study Population	*TB*	*Positive*	*Negative*
	Prevalence	*Predictive Value*	*Predictive Value*
Referred Cases	0.70	0.80	0.40
Primary Health Care Patients	0.20	0.30	0.86

in day-to-day practice. This problem is referred to as spectrum bias.

Spectrum Bias

As stated earlier, an important source of error in the measurement of performance of chest x-ray in comparison to sputum culturing may be mainly due to differences between the populations in which performance of chest x-ray is measured, and in which the chest x-ray has to be used in day-to-day practice. In other words, spectrum bias means the spectrum of disease presentation and severity that may vary between the above two populations. To overcome this problem, various approaches may be adopted:

Phase I of Test Evaluation:

To begin with, a major concern is about the accuracy of an index test, suggesting a need for further diagnostic study involving this test. In other words, an index test should not remain positive for every patient. To rule out this, the following assessments may be carried out:

The Sickest of the Sick

Among the sickest of the sick patients, an index test may reveal a very high TPR because of the obvious, easy detection of advanced disease. Further, if the study involves a broader spectrum of patients, a fall in TPR may be noticed.

The Wellest of the Well

An index test may also be carried out among healthy volunteers who are often younger than those among whom this test is likely to be used in day-to-day practice. Being free from disease, an index test among such participants might cause a false-positive result. Further, if the study involves more representative patients, a rise in the FPR may be noticed.

Phase II of Test Evaluation

Under this phase, based on results under the index test, patients are referred for testing under the gold standard test. Before the marketing of the index test, this evaluation also becomes necessary. However, as is obvious, consideration of such referred patients alters the representativeness of the study sample required for evaluation of an index test. Hence, similar to spectrum bias due to the presence of more sick patients in the study sample under the first phase of test evaluation, another form of spectrum bias is referral bias under the second phase of test evaluation.

Based on results under either of the above two evaluations, adoption of an index test may be expedited due to optimism generated by high TPR & low FPR, along with their effective advertisements by the manufacturers. As a matter of fact, often TPR becomes higher, and FPR becomes lower under studies involving the above spectrum biases. Hence, clinicians need to be cautious while using evidence derived from such studies for calculating the post-test probability of disease.

Calibration of Estimated TPR and FPR:

In the presence of earlier described spectrum biases in study samples, while using the estimated TPR and FPR of an index test in clinical practice, they need to be appropriately adjusted. For instance, under the earlier example of measurement of performance of chest x-ray in comparison to sputum culturing, if there are more severely diseased people in the populations in which performance of chest x-ray is measured than in which the chest x-ray has to be used in day-to-day practice, the TPR needs to be adjusted downward. Likewise, if the study sample is dominated by healthy volunteers, the FPR needs to be adjusted upward. However, if the study sample had sick patients referred based on a positive index test, the FPR needs to be adjusted downward. As such, levels of all the suggested adjustments rely on the clinician's wisdom until further related research explorations.

Receiver Operating Characteristic Curve (ROC Curve)

Using quality data free from biases[9] under a diagnostic study, the dealing between the TPR and FPR of an index test may also be described using the ROC curve[2,5]. For this, to begin with, TPR and FPR need to be calculated

for each of the various definitions of the index test. Under ROC curve (Figure 1), TPR [i.e., Sensitivity (i.e., Sn)] of the index test is plotted on the vertical axis, whereas FPR [i.e., 1-Specificity (i.e., 1-Sp)] on the horizontal axis. In other words, each point on the ROC curve represents one of the four definitions of the test result (that is, TPR, FPR, FNR, and TNR), which are defined by four different positions of the cut-off value. On the other hand, each point on the diagonal line (i.e., 45-degree line) represents focus points for test results at which the TPR equals the FPR. In other words, at each of these points, the likelihood ratio (described later) remains 1. As is obvious, they do not have any effect on the probability of disease. The area above the diagonal line indicates a likelihood ratio above one, which implies that the test result increases the probability of disease. On the contrary, the area below the diagonal line indicates a likelihood ratio below one, which implies that the test result decreases the probability of disease.

For completeness, the lower left-hand corner of the ROC curve consists of a point where both TPR and FPR are zero. Further, a perfect diagnostic test is denoted at the upper left-hand corner where TPR equals to 100%, and FPR equals zero percent. As is obvious, the cut-off corresponding to this point for the index test remains best in terms of making the smallest mistakes when prevalence is around 50%. In other words, under a diagnostic study, 50% of the required sample should be positive under the gold standard test, and the remaining 50% negative to ensure optimal comparison of the index test with the gold standard test. As such, a test consisting of a substantial area under its ROC curve is considered better. The cut-off value of an index test may be computed with the help of its ROC curve (estimation method not discussed here). Further, the ROC curve is often used to compare two or more index tests and also to compare the performance of two or more epidemiological models.

Diagnostic Measures which do not take into account Disease Prevalence:

Basically likelihood ratio of an index test determines the post-test probability of disease which is defined as[2,11]:
Likelihood Ratio = (Chance of a disease among diseased patients) / (Chance of that disease among non-diseased patients)

Keeping in view the above fact, the researchers may opine that TPR and FPR may affect one another due to the effect of selection bias on both of them. As a result, the selection bias may barely affect the post-test probability of disease. Further, they may also advocate that the numerator and denominator of the likelihood ratio may experience a change in the same direction. Hence, differences in the study population and the population in which the index test is likely to be used may hardly affect the ratio of these two measures. In other words, such measures do not take into account disease prevalence. Therefore, the likelihood ratio (LR) is a valuable tool to describe findings under a diagnostic study. In this regard, intuitively, there might be two types of likelihood ratios for an index test, first corresponding to the presence of disease (LR_+), and second corresponding to the absence of disease (LR_-).

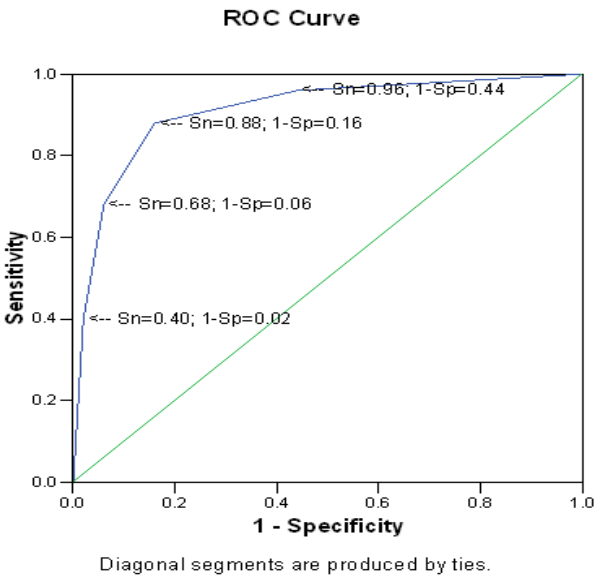

Figure 1: Reproduced ROC Curve[2]

Positive Likelihood Ratio (LR_+):

The positive likelihood ratio of an index test is ratio between its sensitivity and 1-specificity. In other words:

LR_+ = [Probability of positive test among diseased patients] / [Probability of positive test among non-diseased patients]

= TPR / FPR

For instance, considering data in table-2, the positive likelihood ratio comes as (20 / 35) / (5 / 15) = 1.714. A literal understanding of a positive likelihood ratio of 1.71 means those having TB are 1.71-fold more likely to have a positive x-ray test result than those without TB. Likewise, considering data in table-3, the positive likelihood ratio comes as (114 /200) / (264/ 800) = 1.73. From both results, it is amply evident that a positive likelihood ratio does not get influenced much by the prevalence of TB.

Negative Likelihood Ratio (LR_-)

The negative likelihood ratio of an index test is the ratio between its 1- sensitivity and specificity. In other words:
LR_- = [Probability of negative test among diseased patients] / [Probability of negative test among non-diseased patients]
= FNR / TNR

As in the case of a positive likelihood ratio, considering data in table-2, the negative likelihood ratio comes as (15 / 35) / (10 / 15) = 0.643. Likewise, considering data in table-3, the negative likelihood ratio comes as (86 /200) / (536/ 800) = 0.641. It is amply evident that the negative likelihood ratio also does not get influenced much by the prevalence of the disease. It means that those having TB are 0.64 times as likely to have a negative x-ray test result as those without TB. In other words, those having no-TB are 1.56 (1/0.64) times more likely to have negative x-ray test results than those with TB.

Interpretation of Likelihood Ratio:

A positive likelihood ratio (LR+) of an index test of 1 implies that the probability of positive tests does not differ between those with and without the disease. Likewise, a negative likelihood ratio (LR-) of an index test of 1 implies that the probability of negative tests does not differ between those with and without the disease. Under each of the two cases (i.e., LR+; LR-), a likelihood ratio more than 1 implies that the respective index test result (positive or negative) is more likely to occur in those with the disease than in those without the disease. Likewise, under each of the two cases (i.e., LR+; LR-), a likelihood ratio less than 1 implies that the respective index test result (positive or negative) is less likely to occur in those with the disease than in those without the disease. As is obvious, these associations get further strengthened as likelihood ratios move farther away from 1. For instance, as a rule of thumb, presence of disease is suggested strongly by LR+ more than 10; moderately by LR+ between 5-10; and mildly by LR+ between 2-5. Likewise, as a rule of thumb, absence of disease is suggested strongly by LR- less than 0.1; moderately by LR- between 0.2 and 0.4; and mildly by LR- between 0.5 and 1.0. As such, an index test with very high LR+ (e.g., >10) and very low LR- (e.g.,<0.1) will have the best discriminatory ability regarding diagnosis of a particular disease.

Diagnostic Measures which take into account Disease Prevalence

In addition to predictive measures described earlier, post –test odds are also such diagnostic measures that take into account disease prevalence. They are defined as a joint function of earlier defined positive likelihood ratio and pre-test odds:[11]

Post-Test Odds = (LR_+) * (Pre-test odds)

Where pre-test odds are basically a function of related disease prevalence as follows:
Pre-Test Odds = Pre-test probability / (1- Pre-test probability)
= (Prevalence) / (100- Prevalence), if prevalence is recorded in percentage.

For instance, considering data in Table 2, pre-test odds will be 70%/ 30% = 2.33. Therefore, multiplying this by the above calculated favorable likelihood ratio of 1.71, the post-test odds come as 3.99. However, considering data in Table 3, pre-test odds will be 20% / 80% = 0.25. Therefore, multiplying this by the above calculated positive likelihood ratio of 1.73, the post-test odds come as 0.433. Hence, it is amply evident that, like predictive measures (Table 4), post-test odds also get highly influenced by the prevalence of the disease.

Obtaining Post-Test Probability from Post-Test Odds

Once the index-test result is known, the probability of disease may be derived from post-test odds as follows:

Post-test probability = (Post-test odds) / (Post-test odds + 1)

Therefore, using data from Table 2, the post-test probability of disease will come as 3.99/ (3.99 + 1) = 0.80, i.e., 80%. This is higher than the initial probability of disease, as 70%. Similarly, using data from Table 3, the post-test probability of disease will come as 0.433/ (0.443 + 1) = 0.30, which means 30%; this is also consistently higher than the initial probability of disease, as 20%. This may be attributed to a higher positivity rate under the index test.

Summary

A diagnostic study evaluating a convenient new diagnostic test (e.g., often easy to do, cheaper and involving lesser side effects) with a related cumbersome gold standard test (e.g., often difficult to do, costly and involving higher side effects) regarding a particular disease provides ample evidence regarding diagnosis of that disease and boosts clinical decisions for appropriately managing the related patients timely. It mostly remains a cross-sectional study and involves various statistical measures, namely measures of concordance (e.g., sensitivity; specificity); measures of discordance (e.g., 1-sensitivity; 1-specificity);

and some others (e.g., predictive values; receiver operating characteristic curve; likelihood ratios). A report of a diagnostic study needs to be prepared following the related guidelines,[12] "STARD". As described earlier, keeping in view the merits and demerits of each of these diagnostic measures, one can use them appropriately in their routine clinical decision-making regarding a particular disease.

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