statstutor

community project

encouraging academics to share statistics support resources

stcp-rothwell-diagnostictests

Diagnostic Tests

Diagnostic tests attempt to classify whether somebody has a disease or not before symptoms are present. We are interested in detecting the disease early, while it is still curable.

However, there is a need to establish how good a diagnostic test is in detecting disease. In this situation a 2x2 table similar to the below would be produced to test how effective a diagnostic test is at predicting the outcome of interest. A number of different measures can be calculated from this information.

		True Diagnosis		
		Disease +ve	**Disease -ve**	**Total**
Test Results	**+ve**	a	b	a+b
	-ve	c	d	c+d
		a+c	b+d	N

Sensitivity: $\boldsymbol{sens} = \frac{\boldsymbol{a}}{(\boldsymbol{a}+\boldsymbol{c})}$ This is the proportion of diseased individuals *that are correctly identified by the test as having the disease.* $\boldsymbol{P}(+\boldsymbol{ve}|\boldsymbol{D})$

Specificity: $\boldsymbol{spec} = \frac{\boldsymbol{d}}{(\boldsymbol{b}+\boldsymbol{d})}$ This is the proportion of non-diseased individuals *that are correctly identified by the test as not having the disease.* $\boldsymbol{P}(-\boldsymbol{ve}|\boldsymbol{ND})$

Positive Predictive Value:** $\boldsymbol{PPV} = \frac{\boldsymbol{a}}{(\boldsymbol{a}+\boldsymbol{b})}$ This is the proportion of individuals with positive test results *that are correctly diagnosed and actually have the disease.* $\boldsymbol{P}(\boldsymbol{D}|+\boldsymbol{ve})$

Negative Predictive Value:** $\boldsymbol{NPV} = \frac{\boldsymbol{d}}{(\boldsymbol{c}+\boldsymbol{d})}$ This is the proportion of individuals with negative test results *that are correctly diagnosed and do not have the disease.* $\boldsymbol{P}(\boldsymbol{ND}|-\boldsymbol{ve})$

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Positive Likelihood Ratio: $LR^{+} = \frac{sens}{1-spec}$ This gives a ratio of the test being positive for patients with disease compared with those without disease. Aim to be much greater than 1 for a good test.

Negative Likelihood Ratio: $LR^{-} = \frac{1-sens}{spec}$ This gives a ratio of the test being negative for patients with disease compared with those without disease. Aim to be considerably less than 1 for a good test.

General rule – A screening test needs high sensitivity, a diagnostic test needs high specificity.

** These tests must have a **random** sample of the whole population; they depend on the prevalence of the disease which cannot be calculated if the sample is not random.

Worked Example

Here will be a worked example. Consider a test for diabetes which uses biomarkers in the patients' saliva to assess diabetic status; if the test returns a positive result then the patient is presumed to have the disease. The true diagnosis is whether the patient truly has diabetes or not. This can be assessed with what is termed a "gold standard", the conclusive test such as a blood test.

		True Diagnosis		
		Diabetic	**Not Diabetic**	**Total**
Test Results	**+ve**	900	1100	2000
	-ve	450	3550	4000
		1350	4650	6000

Sensitivity: $sens = \frac{a}{(a+c)} = \frac{900}{1350} = \mathbf{0.667}$ or 67%

Specificity: $spec = \frac{d}{(b+d)} = \frac{3550}{4650} = \mathbf{0.763}$ or 76%

Positive Predictive Value:** $PPV = \frac{a}{(a+b)} = \frac{900}{2000} = \mathbf{0.45}$ or 45%

Negative Predictive Value:** $NPV = \frac{d}{(c+d)} = \frac{3550}{4000} = \mathbf{0.8875}$ or 89%

Positive Likelihood Ratio: $LR^{+} = \frac{sens}{1-spec} = \frac{0.667}{1-0.763} = \mathbf{2.814}$

Negative Likelihood Ratio: $LR^{-} = \frac{1-sens}{spec} = \frac{1-0.667}{0.763} = \mathbf{0.436}$

Reporting

Based on these calculations this test has a sensitivity of 67% and a specificity of 76%. This means that if the patient truly has the disease, the test will return a positive result 67% of the time, if the patient does not have the disease then the test will return a negative result 76% of the time. If a patient gets a positive (or negative) test result, the probability of them having (or not having) diabetes is PPV=45% (or NPV=89%). Based on these results the test appears to be better at ruling out a diabetes diagnosis rather than confirming one. The negative likelihood ratio is much lower than 1, indicating that the test is good for picking up patients with negative results; however the positive likelihood value is slightly greater than 1 but isn't extremely large. This implies that the test does indicate positive results correctly but not as well as it indicates negative results.

ROC Curve

For tests with a continuous outcome, such as a blood biomarker measurement, it might be unclear where to best to divide the result between giving a positive or negative test result. This decision can be made by plotting a **ROC curve**. This plots sensitivity against (1-specificity) for different cut-off points for giving a positive result on a diagnostic test. The ROC curve is examined to determine where the most appropriate cut-off is. A good diagnostic test will give the point closest to the top left corner of the plot, maximising sensitivity and specificity.

There will be a trade-off between high sensitivity and high specificity. Ideally, both of these values are maximised.