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Original Research

Estimates of sensitivity, specificity, false rates and expected proportion of population testing positive in screening tests

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ABSTRACT:

This paper proposes and presents indices used as measures to evaluate or assess results obtained from diagnostic screening tests. These indices include sensitivity, specificity, prevalence rates and false rates. We here present statistical methods for estimating these rates and for testing hypotheses concerning them. An estimate of the proportion of a population expected to test positive in a diagnostic screening test is also provided. Further interest is also to estimate the sensitivity and specificity of the test and then the false rates as functions of sensitivity and specificity given knowledge or availability of an estimate of the prevalence rate of a condition in a population. The indices proposed ranges from -1 to 1 inclusively and therefore enables the researcher to determine if an association exists and if it exists between test results and condition as well as whether it is positive and direct or negative and indirect which will serve as an advantage over the traditional methods. The proposed indices provide estimates of the test statistic. When the proposed measures are applied, results indicate that it is easier to interpret and understand more than those obtained using the traditional approaches. In addition, the proposed measure is shown to be at least as efficient and hence as powerful as the traditional methods when applied to sample data.

Keywords:
Traditional odds ratio, prevalence, sensitivity, specificity, false rates.

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INTRODUCTION

In diagnostic screening tests indices used as measures to evaluate or assess results obtained include, sensitivity and specificity of the test and if the prevalence rate of a condition of interest in a population is known or can be estimated from a previous study, also the false positive and false negative rates of the test as well as the proportion of the population expected to test positive to the condition (Fleiss, 1973; Pepe, 2003). Hence research interest is often in statistical methods for estimating sensitivity, specificity, false rates and the proportion of a population expected to test positive to a condition in these screening tests. The sensitivity of a test is the proportion of subjects testing positive among the subjects known or believed to actually have a condition in nature, while the specificity of a test is the proportion of subjects who actually test negative to a condition among the subjects known or believed not to actually have the condition in nature. False positive rate of a test is the proportion of subjects who are known or believed not to actually have a condition in nature among the subjects testing positive, while false negative rate is the proportion of subjects who are known or believed to actually have a condition in nature among the subjects who never-the-less test negative (Fleiss,1973;Greenberg *et al.,* 2001;Linn, 2004).Sensitivity and Specificity of a test are independent of the population being studied and hence independent of the prevalence rate of a condition in the population. False rates of a test on the other hand are functions of the prevalence rate of a condition in a population and hence are dependent on the population of interest (Fleiss, 1973;Linn, 2004).

We here present statistical methods for estimating these rates and for testing hypotheses concerning them. An estimate of the proportion of a population expected to test positive in a diagnostic screening test is also provided.

Given that a researcher collects a random sample of $n_{.1}$ subjects known or believed, perhaps on the basis of previous results from a gold standard test to actually have a certain condition in nature from a population and also takes a second random sample of $n_{.2}$ subjects from the same population Keeping in mind that known or believed not to actually have the same condition in nature, thus giving a total random sample of size $n=n..=n_{.1}+n_{.2}$ subjects to be studied. It is always treated to confirm through a diagnostic screening test for whether or not each sampled subjects have or does not have the condition of interest. Further interest is also to estimate the sensitivity and specificity of the test and then the false rates as functions of sensitivity and specificity given knowledge or availability of an estimate of the prevalence rate of a condition in a population.

Now suppose $B \text{ and } \overline{B}$ are respectively the events that a randomly selected subject from a population has and does not have a condition in nature. Also let $A \text{ and } \overline{A}$ be respectively the events that the randomly selected subject tests positive, and negative to the condition in the test. We here assume that the prevalence rate P(B) of the condition in the population is either known or can be reliably estimated from previous studies. The results of such a screening test may be presented in the form of a four fold Table (Table 1).

In Table 1 above, of the n=n.. sample subjects studied, n.1 subjects are known or believed to have the condition in nature, that is in B and $n_{.2}$ are known or believed not to have the condition in nature, that is $\overline{B}$. Also $n_{1.}$ subjects respond positive that is in A and $n_{2.}$ subjects respond negative, that is in $\overline{A}$. Of the $n_{.1}$ subjects in B, n_{11} subjects actually have the condition and test positive that is in AB and n_{21} subjects actually have the condition but test negative, that is in $A\overline{B}$. Of the $n_{.2}$ subjects who are known or believed not to have the condition in nature,n_{12} subjects who do not have the condition test positive, that is in $\overline{A}\,\overline{B}$ while n_{22} subjects who do not have the condition in nature also test negative that is in $\overline{A}\,\overline{B}$. In an actual screening test usually only the total sample size n=n..,$n_{.1}$ subjects

Table 1.Format for Presentation of Results of a Diagnostic Screening Test

Screening Test Results	Condition Present	Condition Absent	Total
	(B)	B	($n_{i.}$)
Positive (A)	n_{11}	n_{12}	$n_{1.}$
Negative (Ā)	n_{21}	n_{22}	$n_{2.}$
Total ($n_{.j}$)	$n_{.1}$	$n_{.2}$	n..(=n)

in B, n_{11} subjects in AB,$n_{.2}$ subjects in $\overline{B}$ and n_{22} subjects in $\overline{A}\,\overline{B}$ are observed and actually known. The values n_{12} in $A\overline{B}$ and n_{21} in $\overline{A}B$ are not known and hence also are $n_{1.}$ and $n_{2.}$, the overall number of subjects who would test positive and negative respectively in the screening test. Hence only the known values namely total sample size n, the number of subjects, $n_{.1}$ known to have the condition in nature, n_{11}, the number of subjects who test positive among these known to have the condition in nature, the number of subjects $n_{.2}$ known not to have the condition in nature and n_{22} subjects who test negative among the subjects known not to have the condition in nature are used here to estimate the required indices and test statistics. Now the sensitivity (Se) and specificity (Sp) of a screening test expressed in terms of conditional probabilities or specific rates of events A and B are respectively

$$Se = P(A/B); Sp = P(\overline{A}/\overline{B}) \quad 1$$

The higher Se and Sp are more sensitive and specific is the screening test, the lower these rates, the weaker are the sensitivity and specificity of the test. The false positive rate and the false negative rate of a screening test also expressed in terms of conditional probabilities or specific rates of events A and B are respectively

$$F_{+ve} = P(\overline{B}/A) = \frac{1-P(\overline{A}/\overline{B})\;\;P(\overline{B})}{P(A)}; F_{-ve} = P(B/\overline{A}) = \frac{1-P(A/B)\;\;P(B)}{P(\overline{A})} \quad 2$$

Where P(A) consists of the probability of composition of the events AB and which is the probability of the union of events that a randomly selected subject tests positive and is known or believed to have a condition in nature or tests positive and is known or believed not to have the condition in nature. Notationally, we have that

$$P(A) = P(AB) + P(A\overline{B}) \quad 3$$

Now to develop sample estimates of these indices, sensitivity for instance, we may let,

$$u_{i1} = \begin{cases} 1, \textit{if the ith randomly selected and screened subject known or believed to actually have a condition in nature tests positive} \\ 0, \textit{otherwise} \end{cases} \quad 4$$

$$for\ i = 1, 2, \ldots n_{.1}\ subjects$$

Let

$$\pi_1 = P(u_{i1} = 1) \quad 5$$

and

$$W_i = \sum_{i=1}^{n_{.1}} u_{i1} \quad 6$$

Now the expected value and variances of u_{i1} are

$$E(u_{i1}) = \pi_1 : Var(u_{i1}) = \pi_1(1-\pi_1) \quad 7$$

Similarly the expected value and variance of are respectively

$$E(W_1) = \sum_{i=1}^{n_1} E(u_{i1}) = n_{.1}\pi_1; Var(W_1) = \sum_{i=1}^{n_1} Var(u_{i1}) = n_{.1}\pi_1(1-\pi_1) \quad 8$$

Now π_1 is the probability that a randomly selected and screened subject known or believed to have a condition in nature in a population tests positive; that is the proportion of subjects testing positive among the subjects in the population known or believed to actually have a condition in nature. This is in fact a measure of the sensitivity Se of the screening test. The sample estimate of π_1 is

$$\pi_1 = \hat{Se} = \frac{W_1}{n_{.1}} = \frac{f^+}{n_{.1}} \quad 9$$

Where f^+ is the number of subjects who test positive among subjects in the population known or believed to have the condition of interest in nature. In other words, f^+ is the number of 1s in the frequency distribution of the $n_{.1}$values of 1s and 0s in ui1,for i=1,2, …,n.1.Hence $f^+=n_{11}$ of Table 1.

The corresponding variance of is from equation (8)

$$Var\ \hat{\pi}_1 = Var\ \hat{Se} = \frac{Var\ W_1}{n_{.1}^1} = \frac{\hat{\pi}_1(1-\hat{\pi}_1)}{n_{.1}} = \frac{\hat{Se}(1-\hat{Se})}{n_{.1}} \quad 10$$

A researcher may sometimes wish to test a null hypothesis that sensitivity of a screening test is at most some value $\pi_{10=Se0}$. That is the null hypothesis,

$$H_0 : Se \le Seo = \pi_{10}\ versus\ H_1 : Se > Seo (0 \le Seo \le 1) \quad 11$$

This null hypothesis may be tested using the test statistic

$$\chi^2 = \frac{W_1 - n_{.1}Seo^{\ 2}}{Var\ W_1} = \frac{n_{.1}\ \hat{Se} - Seo^{\ 2}}{\hat{Se}(1-\hat{Se})} = \frac{n_{.1}\ \hat{\pi}_1 - \hat{\pi}_{10}^{\ 2}}{\hat{\pi}_1(1-\hat{\pi}_1)} \quad 12$$

Which under Ho has approximately the chi-square distribution with one (1) degree of freedom for sufficiently large n.1.the null hypothesis Ho is rejected at the level of significance if

$$\chi^2 \ge \chi^2_{1-\alpha;1} \quad 13$$

Similarly to develop a sample estimate of the specificity Sp of a screening test, we may let

$$u_{i2} = \begin{cases} 1, if\ the\ ith\ randomly\ selected\ and\ screened \\ subject\ in\ the\ population\ is\ known\ or\ believed\ not\ to\ actually \\ have\ a\ condition\ in\ nature\ tests\ negative \\ 0, otherwise \end{cases} \quad 14$$

$$for\ i = 1,2,...n_{.2}\ subjects$$

$$Define \quad 15$$

$$\pi_2 = P\ u_{i2} = 1$$

$$And$$

$$W_2 = \sum_{i=1}^{n_{.2}} u_{i2} \quad 16$$

$$Now$$

$$E\ u_{i2} = \pi_2; Var\ u_{i2} = \pi_2\ 1-\pi_2 \quad 17$$

$$And$$

$$E\ W_2 = n_{.2}\pi_2; Var\ W_2 = n_{.2}\pi_2(1-\pi_2) \quad 18$$

Note that π_2 is the probability that a randomly selected and screened subject tests negative to the condition given that the subject is known or believed not to actually have the condition in nature. In other words, π_2 is the proportion of subjects testing negative among the population of subject known or believed not to have a condition in nature. Thus π_2 is actually a measure of the specificity Sp of the screening test. Its sample estimate is from equation (18)

$$\hat{\pi}_2 = \hat{Se} = \frac{W_2}{n_{.2}} = \frac{f^-}{n_{.2}} \quad 19$$

Where f^- is the number of subjects whose test negative among the $n_{.2}$ subjects in the sampled population known or believed not to have a condition in nature. In other words f^- is the total number of 1s in the frequency distribution of the $n_{.2}$ values of 0s and 1s in u_{i2},for i=1,2,…$n_{.2}$.Thus f^-= n_{22} in Table 1. The variance of equation $\hat{\pi}_2 = \hat{Sp}$ (18)

$$Var\ \hat{\pi}_2 = Var\ \hat{Sp} = \frac{Var(W_2)}{n_{.2}^2} = \frac{\hat{\pi}_2(1-\hat{\pi}_2)}{n_{.2}} = \frac{\hat{Sp}(1-\hat{Sp})}{n_{.2}} \quad 20$$

A researcher may also wish to test a null hypothesis that specificity Sp of a diagnostic screening test is at least some value That is the null hypothesis

$$Ho : Sp \ge Spo\ versus\ H_1 : Sp < Spo, (0 \le Sp \le 1) \quad 21$$

This null hypothesis is tested using test statistic

$$\chi^2 = \frac{W_2 - n_{.2}Spo^{\ 2}}{Var\ W_2} = \frac{n_{.2}\ \hat{Sp} - Spo^{\ 2}}{\hat{Sp}(1-\hat{Sp})} = \frac{n_{.2}\ \hat{\pi}_2 - \hat{\pi}_{20}^{\ 2}}{\hat{\pi}_2(1-\hat{\pi}_2)} \quad 22$$

Which under Ho has approximately the chi-square distribution with one (1) degree of freedom for sufficiently large $n_{.2}$. The null hypothesis Ho is rejected at the level of significance if equation (13) is satisfied, otherwise Ho is accepted.

To develop sample estimate of the proportion of a population expected to test positive to a condition in a diagnostic screening test, we note that when expressed in terms of conditional probability using Bayes rule equation (3) becomes

$$P(A) = P(A/B).P(B) + P(A/\bar{B}).P(\bar{B}) = P(A/B).P(B) + 1 - P(\bar{A}/\bar{B})\ \ 1 - P(B) \quad 23$$

Or when expressed in terms of sensitivity Se and specificity Sp of the screening test and prevalence rate P(B) of a condition in a population becomes

$$P(A) = SeP(B) + (1 - Sp).P(\bar{B}) = 1 - P(\bar{A}/\bar{B}) - 1 - P(A/B) - P(\bar{A}/\bar{B}) \ .P(B) = 1 - Sp - 1 - Se - Sp \ .P(B) \quad 24$$

The sampled estimate of P(A) is using equation (9) and equation (19) in equation (24)

$$\hat{P}(A) = P(A) = \hat{S}eP(B) + (1 - \hat{S}p).P(\bar{B}) = 1 - \hat{S}p - \ 1 - \hat{S}e - \hat{S}p \ .P(B) \quad 25$$

The corresponding sample variance is

$$Var\ (P(A)) = Var(\hat{S}e)(P(B))^2 + Var\ (\hat{S}p)P((\bar{B}))^2 - 2P(B).P(\bar{B}).Cov\ \hat{S}e\hat{S}p) \quad 26$$

It is easily shown that

$$Cov\ (\hat{S}e; \hat{S}p) = Cov\left(\frac{W_1}{n_{.1}}; \frac{W_2}{n_{.2}}\right) = 0$$

To prove this it is sufficient to show that

$Cov\ u_{i1}; u_{i2} \ = 0$

Now

$Cov\ u_{i1}; u_{i2} \ = E\ u_{i1}.u_{i2} \ - E(u_{i1}).E(u_{i2}) = E\ u_{i1}.u_{i1} \ - \pi_1.\pi_2.$

Now $u_{i1}.u_{i1}$ can assume only the values 1 and 0 . It assumes the value 1 if u_{i1} and u_{i2} both assume the value 1 with probability it assumes the value 0 if assumes the values 1 and u_{i2} assumes the value 0 or u_{i1} assumes the value 0 and u_{i2} assumes the value 1 with probability $\pi_1(1-\pi_2) - \pi_2(1-\pi_1)$ Hence

$$Cov\ u_{i1}; u_{i2} \ = \pi_1\pi_2 - \pi_1\pi_2 = 0 \ so\ that$$

$$Var\ (P(A)) = Var(\hat{S}e) + Var(\hat{S}p) = \frac{\hat{S}e(1-\hat{S}e)}{n_1} + \frac{\hat{S}p(1-\hat{S}p)}{n_2} = \frac{\hat{\pi}_1(1-\hat{\pi}_1)}{n_1} + \frac{\hat{\pi}_2(1-\hat{\pi}_2)}{n_2} \quad 27$$

The researcher may also wish to test the null hypothesis that the proportion P(A) of subjects in a population expected to test positive to a condition in a diagnostic screening test is at most some value Po(A). That is the null hypothesis

$$Ho: P(A) \le Po(A)\ versus\ H_1: P(A) > Po(A), (0 \le Po(A) \le 1) \quad 28$$

This null hypothesis is tested using the test statistic

$$\chi^2 = \frac{P(A) - Po(A)\ ^2}{Var\ \ P(A)} \quad 29$$

Which under Ho has approximately the chi-square distribution with one (1) degree of freedom where P(A) and Var (P(A)) are given by equations (25) and (26) respectively and from Table 1

$$\hat{S}e = \hat{\pi}_1 = \frac{f_1}{n_{.1}} = \frac{n_{11}}{n_{.1}}; \hat{S}p = \hat{\pi}_2 = \frac{f_2}{n_{.2}} = \frac{n_{22}}{n_{.2}} \quad 30$$

The null hypothesis Ho is expected at the α level of significance if equation (13) is satisfied; otherwise Ho is accepted.

The researcher may also wish to obtain sample estimates of false rates in a diagnostic screening test if the prevalence rate P(B) of a condition in a population is known or can be determined.

Now from equations (2) and (25), the sample estimate of false positive rate in terms of sample estimates of sensitivity and specificity and the known or estimated prevalence rate is

$$\hat{F}_{+ve} = \frac{(1 - \hat{S}p).P(\bar{B})}{P(A)} = \frac{1 - \hat{S}p \quad 1 - P(B)}{1 - \hat{S}p - \ 1 - \hat{S}e - \hat{S}p \ .P(B)} \quad 31$$

Similarly the sample estimate of false negative rate is from equations (2) and (25)

$$\hat{F}_{-ve} = \frac{(1 - \hat{S}e).P(B)}{P(\bar{A})} = \frac{1 - \hat{S}e \ \ P(B)}{\hat{S}p + \ 1 - \hat{S}e - \hat{S}p \ .P(B)} \quad 32$$

Where $\hat{S}e$ and $\hat{S}p$ are given in equation (30).

Finally with further interest the researcher may use some elementary calculus or apply Fiellers convenience Theory to obtain approximate estimates of the variances of $\hat{F}_{+ve}$ *and* $\hat{F}_{-ve}$ and also test any desired hypotheses.

ILLUSTRATIVE EXAMPLE

It a clinician is collecting a random sample of 98 subjects from a certain population; twelve of whom are doubted for having prostrate cancer and 86 of whom are assumed not to have the disease. The clinician's interest is to confirm through a diagnosis screening test whether or not each of the sampled subjects are actually prostrate cancer positive or negative. The results of the screening test are presented in Table 2.

Now from Table 2 we have that the sample estimate of the sensitivity and specificity of the test are respectively

$$\hat{S}e = \frac{f^{++}}{n_{.1}} = \frac{n\left(f^{++}/n\right)}{n_{.1}} = \frac{98 \ \ 4/98}{12} = \ 8.167 \quad 0.041 \ = 0.335$$

and

$$\hat{S}p = \frac{f^{--}}{n_{.2}} = \frac{n\left(f^{--}/n\right)}{n_{.2}} = \frac{98 \ \ 84/98}{86} = \ 1.140 \quad 0.857 \ = 0.977.$$

These results show that the screening test is low in sensitivity but has high specificity.

Now from equations (13) and (14) the sample estimates of are respectively

$$\hat{\pi}^{+} = \frac{12\ \ 0.335\ \ +86\ \ 0.977}{98} = 0.898$$

and

$$\hat{\pi}^{-} = \frac{12\ \ 1-0.335\ \ +86\ \ 1-0.977}{98} = 0.102$$

Hence from equations (15) and (17) we have that

$$\hat{\pi} = \hat{\pi}^{+} - \hat{\pi}^{-} = 0.898 - 0.102 = 0.796$$

With estimated variance obtained from equations (16) and (18) as

$$Var(\hat{\pi}) = Var(\hat{\pi}^{+} - \hat{\pi}^{-}) = \frac{1-(0.796)^2}{98} = 0.004$$

Hence the test statistic of no association between screening test results and state of nature or condition (Prostrate Cancer) of equation (19) are obtained from equation (20) as

$$\chi^2 = \frac{0.796^{\ 2}}{0.004} = \frac{0.634}{0.004} = 158.500(P - value = 0.0000)$$

Which with one (1) degree of freedom is highly statistically significant indicating a strong degree of association between screening test results and state of nature or condition (presence of Prostrate cancer in the population). Also since $\hat{\pi} = \hat{\pi}^{+} - \hat{\pi}^{-} = 0.796$ is positive, the association is positive and direct.

It is commendable to compare the present results with what would have been obtained if we have used the traditional odds ratio to analyze the data of Table 2. In spite of odds ratio's short comings as already pointed out above, when used in the analysis of screening test results. The sample estimate of the traditional odds ratio for the data of Table 2 is

$$O = \frac{n_{11}n_{22}}{n_{12}n_{21}} = \frac{(4)(84)}{(2)(8)} = 21.00$$

This means, for every subject who has prostrate cancer among tested subjects and erroneously informed that they are free of the disease (21 subjects) among those tested and found to have prostrate cancer would be expected to be correctly informed. This probably makes more difficulty in understanding than the simple information conveyed by the simple difference in rates, $\hat{\pi} = \hat{\pi}^{+} - \hat{\pi}^{-} = 0.796,$ namely, the proportion of subjects testing positive among subjects who have prostrate cancer or testing negative among subjects who do not have prostrate cancer is 79.6 percent higher than the proportion of subjects testing positive among subjects who do not have prostrate cancer or testing negative among subjects who have the disease.

Table 2: Result of Prostrate Cancer Screening Test

Clinical diagnosis	Present (B)	Absent B	
Prostrate Cancer	$n_{11}=f^{++}=4$	$n_{12}=f^{+-}=4$	$n_{1.}=6$
Positive (A)	$n_{21}=f^{-+}=4$	$n_{22}=f^{--}=4$	$n_{2.}=92$
Negative (Ā)	$n_{.1}=12$	$n_{.2}=86$	$n_{..}=n=98$

$$Se(O) = O\sqrt{\frac{1}{n_{11}} + \frac{1}{n_{12}} + \frac{1}{n_{21}} + \frac{1}{n_{22}}} = 21.00\sqrt{\frac{1}{4} + \frac{1}{2} + \frac{1}{8} + \frac{1}{84}}$$
$$= (21.00)(0.942) = 19.782$$

This measure of the error of 'O' namely 19.782 is clearly much larger than the error of only $Se\ \hat{\pi}\ =\ \sqrt{0.004} = 0.063$ of the estimated value of for our sample data. The chi-square test statistic for the significance of 'O' is

$$X^2 = \frac{n(n_{11}n_{22} - n_{12}n_{21})^2}{n_{1.}n_{2.}n_{.1}n_{.2}} = \frac{98(94)(84) - (2)(8)^2}{(6)(92)(12)(86)} = 17.616 \text{ (p-value=0.0000)}$$

Which is also statistically significant again leading to a rejection of the null hypothesis of no association. However, the proposed method and the traditional odds ratio approach explained here (both) lead to a rejection of the null hypothesis, the relative sizes of the calculated chi-square values suggest that the traditional odds ratio method is less efficient and likely to lead to an acceptance of a false null hypothesis (Type II Error) more frequently and hence is likely to be less powerful than the proposed method.

CONCLUSION

In this paper, we proposed, developed and presented a statistical method for measuring the strength of association between test results and state of nature or condition in a population expressed to a diagnostic screening test. The proposed measure is based on only the sensitivity and specificity of the screening test which are independent of the population of interest and estimated using only observed sample values.

The proposed measure which ranges from -1 to 1 can be used to establish whether an association is strong and direct, strong and indirect or zero estimates of the standard error. Test statistics for the significance of the proposed measure are provided. The proposed measure of association is shown to be easier to interpret and explain than the traditional odds ratio, and the sample data used suggest that the measure is at least as efficient and powerful as the traditional odds ratio.

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