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Editorial

Per cent of predicted as the limit of normal in pulmonary function testing: a statistically valid approach

It has been traditional in pulmonary function testing to set the limits of normal as the predicted ±20%. Since most pulmonary function tests, and all spirometric tests, are abnormal only when below predicted, the rule of thumb for the limit of normal becomes 80% of predicted. How this factor came into being is unknown to this writer. It is a misfortune that it did since it has neither statistical nor physiological validity. It implies that all functions in pulmonary physiology have a variance around the predicted, which is a fixed per cent of predicted. Nowhere else in medicine is such a naïve view taken of the limit of normal. If the 80% rule held universally, then the lower limit of normal for serum sodium would be 122 mg% (predicted taken as 140), cardiac index 2·4 litres per minute (3·0 taken as predicted). Numerous other examples could be given. Some limits of normal do correspond quite closely to 80% of the predicted value, but when they do it is only fortuitous. They generally do not, even in pulmonary physiology.

For example, the normal for men of the fifth decade for the FEF_{25-75}% is 4·37 l/s and the standard deviation (SD) 1·1 (Leuallen and Fowler, 1955). The statistically determined lower limit of normal would then be 4·37 minus 2·2 (2 SD), that is 2·17 l/s or 50% of the predicted. Eighty per cent of predicted equals 3·50 l/s. Thus to use this rule of thumb would place all those between 3·5 and 2·17 l/s in the abnormal range when in point of fact by statistical criteria they are normal.

The criticisms that have been levelled against the 80% rule as limit of normal can also be applied to the use of "per cent" in general as a valid indicator of the degree of abnormality. For example, 75% of predicted for the first second volume will represent significant deviation from normal in a tall young man while it remains within the limits of normal for a small old man.

The problem is compounded when the predicted value is not merely a mean but a regression line based on two or more variables. Now the extent to which the 80% rule will deviate from statistical validity is a function not only of the scatter but the steepness of the regression line itself. Again, the coincidence of 80% of predicted and 2 SD is now not only fortuitous but it will occur only at a single point. Furthermore, and this factor will vary with the steepness of regression, those with normal functions that are small—for example, the forced expiratory volume of the short and elderly—will deviate more readily from the limit of normal than those with normal functions that are large—the tall and young. The statistically valid limits of normal parallel the regression line while a line representing a per cent of predicted deviates more and more from the line the further out one goes along it. This latter always strikes one as more sensible since it is entirely reasonable that large values should be surrounded by a larger variance than small. In point of fact both Needham *et al* (1954) and Sobol (1966) showed that this was not the case, that the scatter around regression is constant or homoscedastic, rather than varying with the size of the values, heteroscedastic, in pulmonary function measurements.

Despite the fact that there is no validity to the 80% rule or to the use of percentage of predicted to indicate severity, both practices are fully ingrained by usage. If they could be made statistically valid they would continue to provide the physician with a method with which he is comfortable and at the same time confer legitimacy on a time-honoured practice. Furthermore, it is certainly much handier to deal with one value, 80% of predicted, than face the impossible task of having differing limits of normal for all subjects for all tests.

There is a simple means of rendering the per cent of predicted and therefore the 80% of predicted not only statistically valid but having the same implication for all subjects. The method can be applied to all tests of pulmonary function where the predicted value is defined simply by a mean or by a regression equation. The method merely means "normalising" all subjects to a single value for each function. For a function whose value is represented by a simple mean and standard deviation the normalising process requires determining the value of the mean when the mean minus 2 SD represents 80% of the mean. Returning to

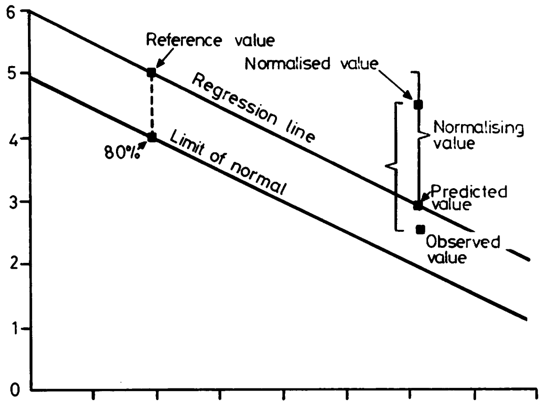
Leuallen and Fowler (1955), their prediction for the $FEF_{25-75}\%$ for men in the third decade is 4·68 with an SD of 1·1 (2 SD=2·2).

Normalising is done in the following manner:
4·68−2·2=2·48; Predicted−2 SD
2·48/4·68=0·53; Limit of normal/predicted normal
In order for this ratio to equal 0·8:
(2·48+X)/(4·68+X)=0·8; X=6·32=normalising value; 4·68+6·32=11·00
As an example of the normalising technique, take a male patient with an observed value of 2·48:
(2·48+6·32)/11·00=0·80; 0·80×100=80%.
Eighty per cent puts this subject just at the limit of normal, which is statistically correct since his observed value is just 2 SD below predicted.

However, the traditional method of determining his per cent of predicted would have found him at 53% of predicted, 2·48/4·68. By the same token if he were 1 SD below predicted his per cent of predicted by the traditional method would be 76% (4·68−1·1)/4·68. By the normalising technique he would be 90% of predicted (4·68−1·1+6·32)/11·00. Clearly, this normalising technique not only offers a statistically valid use of per cent of predicted but provides a handy rule of thumb for the number of deviations from the mean, 1 SD for every 10% deviation.

If the prediction value is determined from a regression equation the normalising process is only slightly more complicated (see figure). First one calculates the value for which the statistically determined limit of normal, that is, predicted minus 2 SD equals 80% of the predicted value. For example, assume that the SD for the forced expiratory volume equals 0·5 litres, then 2 SD= 1·0. In order for the reference value −1 to equal 80%, the reference value must equal 5 litres.

All patients are referred to this value. For example, to take an extreme case, an 80-year-old man 1·5 m tall would have a predicted FEV of 2·37 (from the prediction equations of Sobol *et al*, 1973). If his observed value is 1·37 the computation is as follows:
5·0−2·37=2·63; reference value minus predicted value=normalising value.
2·63+1·37=4·00; normalising value+observed value
4·00/5·00=0·8; normalised value/reference value =fraction predicted 0·8×100=80%.
If the conventional approach, the observed value divided by the predicted value, had been used the result would have been 58% (1·37/2·37×100). Thus again an observed value that is just at the statistically determined limits of normal would have been considered grossly abnormal by the conventional technique.



Upper sloping line represents a theoretical regression line (prediction line). Line below it parallels it in its entire extent and represents lower limits of normal statistically determined by 2 SD below regression. At one point on prediction line, the reference point, limit of normal equals 80% of predicted. It is this value to which all observed values will be normalised. Normalising value is determined by vertical distance between predicted value for a given subject and reference value. This normalising value is then added to observed. Per cent of predicted is determined by dividing the normalised value by reference value. Any observed value that falls exactly on regression line will be 100% of predicted and any point falling on line of limit of normal will be 80% of predicted value.

It goes without saying that those functions, such as residual volume/total lung capacity ratio that are abnormal when more than predicted lend themselves to the same approach. The use of per cent of the normalised per cent of predicted retains all the advantages that the conventional method was supposed to have but didn't. In addition it relates in simple fashion the per cent deviation from predicted to a number of standard deviations, 1 SD per each 10% deviation.

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