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The effect of random error on the results of laboratory tests: the role of biological variation

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ABSTRACT

In the nature, everything is moving and this movement creates physiochemical variations. The law, as acts in nature and outside our body, also affects our body. Every moment, millions chemical reaction occur and billions of atoms and molecules move in body and change their situation. New Therefore, the quantity molecules are created and many old and worn molecules get out in a way. of every molecule or matter in the blood and other biological liquids that is measured is changing constantly. The quantity of these factors is related to the different hours of the day in addition to age (childhood, adolescence, adulthood and aging).

INTRODUCTION

Accordingly, and due to these continuous variations, first it must be determined that how much are these variations that are called biological variations, and which laboratory experiments they affect, .Second, it must be specified that what the purpose of having an accurate result is and which affect and to what extent this farness and closeness to the true value is acceptable. Third, whether physiological variations should also be added to the total error or not?

The main question that physicians and laboratory staff confront with after investigating a series of tests include:

1 - Why do results of some tests change over time?
2 – Is change of the results of laboratories statistically important?
3 - Do this change show occurrence of a disease or old pathological changes?

To review and respond to the questions, source of these variations should be known and minimized.

The effect of random error on the results

The result of every test is given to the doctor as a number, while this number has inherently "variations originated from the trial time error testing of biological variations of the individual under experiment in addition to systematic error.

Because individual biological variations are almost constant "and if it is assumed that this amount is equal to variations due to experiment time error," CVA = CVI "would be:

$CV_T^2=CV^2_A+ CV_I^2$
$CV_T= (CV_A^2+ CV_I^2)^{1/2}$
$CV_T=(CV_A^2 + CV_I^2)^{1/2} = 1.414\ CV_I$

As it can be seen, biological variations increased experiment variations as 4.41 percent (1.414 - 1) × 100 =% 41. if this variations(biological) did not exist, total variations would be equal to variations due to experiment. Also, if the amount of "CVA" gets double "CVI" , rate of total variations will be equal to the "CV_A -2CV_I.

$$CV_T= [(2CV_I^2)^2+ CV_I^2]^{1/2} = (4CV_I^2)^{1/2}+ (CV_I^2)^{1/2}= (5CV_I^2)^{1/2}=2.236\ CV_I$$

The result shows that biological variations added 123.6 percent [(2.236 - 1) ×100 to experiment changes. Now, if biological variations are considered as 1/2 experimental changes, i.e. "CVA = ½ CVI":

$$CV_T= [CV_I^2+(1/2CV_I^2)]^{1/2}= (CV_I^2+ ¼\ CV_I^2)^{1/2}= (5/4\ CV_I)^{1/2}= 1.118\ CV_I$$

These calculations indicate that biological variations are increased as (1.18 to 1) × 100 = 11.8% because the test variations "CVI" got more.

Table (1) shows the relationship between "CVI" and "CVA". The more is added to real test value; "CVA / CVI" ratio to these variations is not linear. The more is added to preciseness, its effect on biological variations is greater. Therefore, if "CVA" increases, "CVI" increases much more.

Table (1) - The percentage of variations of experiment result due to increasing the inaccuracy against physiological variations

Ratio of precision to within subject biological variation (CV_A/CV_I)	Amount of variation added to true test result variability (as percentage of true variation)
0.25	**3.1**
0.50	**11.8**
0.75	**25.0**
1.00	**41.4**
1.50	**80.3**
1.73	**100.0**
2.00	**123.6**
2.50	**169.3**
3.00	**216.2**
4.00	**312.3**
5.00	**409.9**

The effect of random error on the results of an experiment:

To have better understanding of the effect of random error on the results of an experiment, the following example is brought:

Example: The 65-year-old man with high blood pressure has serum cholesterol of 6.6 mmol / l. Individual biological variation of cholesterol is determined as 6%. Considering these biological variations it is found that the patient's serum cholesterol is 6% of the CV cholesterol i.e. 6 × 6.6/100 = 39.6/100 or 0.4mmol / l will be real change rate. According to normal distribution curve of Cholesterol:

Includes 68.3 percent of the curve mean ± 1Sd = 68.3
Includes 95.5 percent of the curve mean ± 2Sd = 95.5
Includes 99.7 percent of the curve mean ± 3Sd = 99.7

Therefore, by calculating 6.6 ± 1 × 0.4, cholesterol level of the patient is between 6.2-7mmol / l. by Calculating 6.6 ± 2 × 0.4 cholesterol level of the patient is between mmol / l 5.8-7.4 and by

calculating 6.6 ± 3 × 0.4 the mean cholesterol level of the patient is between 5.4-7.8 mmol / l . If the CVA is equal to 3% of the CVT will be equal to:

$$\mathbf{CV_T= (CV_A^2+CV_I^2)^{1/2}}$$

$$\mathbf{CV_T= (3\times3+6\times6)^{1/2}}$$

$$\mathbf{CV_T= (9+36)^{1/2}=\sqrt{45}=\%6.7}$$

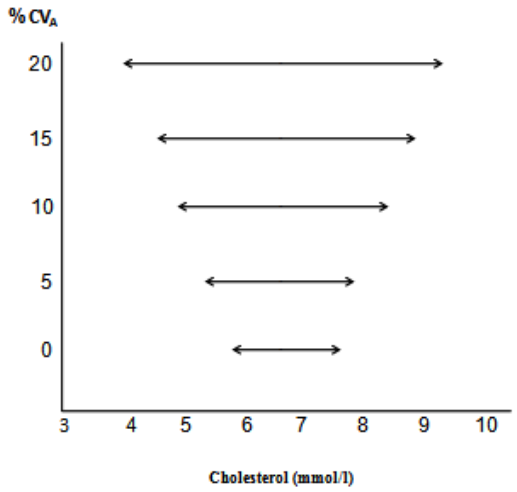
6.7% of 6.6mmol / l are equal to:

%6.7×6.6/100=0.44 mmol/l

So, with a 95.5% probability, cholesterol level would be equal to 6.6 ± 2 × 0.44 or 5.72-7.48mmol / l to be. If the CV value of cholesterol is considered as 5%instead of 3%, the amount of CVT = (5 × 5 +6 × 6) 1/2 = (25 +36) 1/2 = √ 62 =% 7.8

7.8% of 6.36mmol / l is equal to: 7.8 × 6.6/100 = 0.52mmol / l .with this calculation is found that by 95.5% of probability, cholesterol value would be 6.6 ± 1.04 or 6.6 ± 2 × 0.52 or 5.56-7.64 mmol / l. also, if the CV equal is considered 5 instead of 10, 15 and 20 ,the domain of these probabilities extends. Figure (1) and Table (1) indicates that with increasing accuracy, range of (Sd1) by 95.5% of probability increases and the variations are not linear.

Figure (1) - serum cholesterol variations range 6.6mmol / l due to inaccuracy variations (including 95.5 percent):



With regard to the physiological variations of each individual depends on the person, the tests and sample received and these variations are obtained between one person or some people who have been tested in a similar conditions.

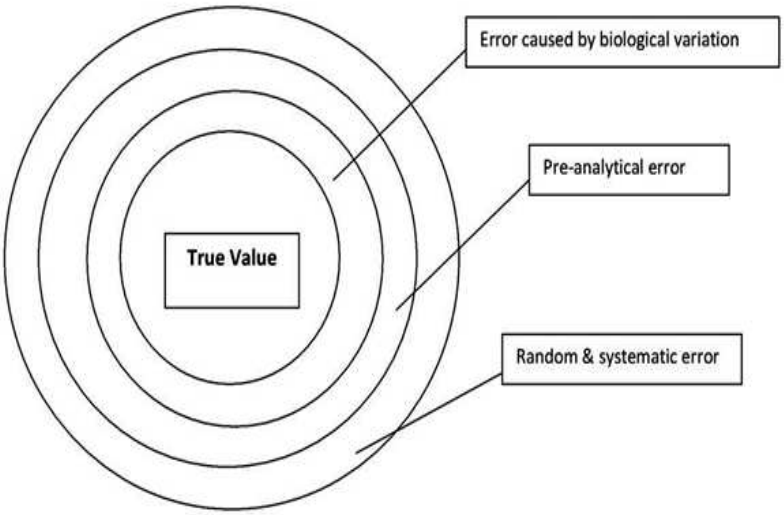
These variations have been effective as a result of test or tests should not be ignored. Usually the "extent of these variations between an individual or a group is shown by coefficient of variation (CV):

CV_W= within (intra) Subject Bio- Vari

CV_b= between (inter) Subject Bio – Vari

According to laboratory errors, such as errors before testing (which can usually be ignored), random error and systematic error or Bias is completed as figure (2).

Figure (2) total error with regard to the biological variations:



Factors that affect the occurrence of random errors:

- Variations in temperature, current, voltage of electricity of devices or laboratory and humidity of work place
- When solutions are prepared or remained within the device.
- Using Solutions of anonymous Companies
- Using the control serum s that is produced from other than the human body serum.
- Using the control serums for keeping them which, significant amount of various materials have been used.

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