

Chapter 32

Validating Quantitative Diagnostic Tests (17 Patients)

1 General Purpose

The usual method for testing the strength of association between the x-data and y-data in a linear regression model, although widely applied for validating quantitative diagnostic tests, is inaccurate. Stricter criteria have to be applied for validation (For background information check *Statistics applied to clinical studies* 5th edition, Chap. 50, Springer Heidelberg, Germany, from the same authors). A stricter method to test the association between the new-test-data (the x-data) and the control-test-data (y-values) is required. First, from the equation $y = a + bx$ it is tested whether the b-value is significantly different from 1,000, and the a-value is significantly different from 0,000.

2 Schematic Overview of Type of Data File

Outcome	predictor
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3 Primary Scientific Question

Are the regression coefficient significantly different from 1,000 and the intercept significantly different from 0,000. If so, then the new test can not be validated.

4 Data Example

In a study of 17 patients the scientific question was: is angiographic volume an accurate method for demonstrating the real cardiac volume. The first ten patients of the data file are given underneath. The entire data file in extras.springer.com, and is entitled “chapter32validatingquantitative”. Start by opening the data in SPSS.

Cast cardiac volume (ml)	Angiographic cardiac volume (ml)
494,00	512,00
395,00	430,00
516,00	520,00
434,00	428,00
476,00	500,00
557,00	600,00
413,00	364,00
442,00	380,00
650,00	658,00
433,00	445,00

5 Validating Quantitative Diagnostic Tests

For analysis the statistical model Linear in the module Regression is required.

Command:

Analyze....Regression....Linear....Dependent: cast cardiac volume....Independent (s): angiographic cardiac volume....click OK .

Coefficients^a

Model		Unstandardized coefficients		Standardized coefficients	t	Sig.
		B	Std. error	Beta		
1	(Constant)	39,340	38,704		1,016	,326
	VAR0000	,917	,083	,943	11,004	,000

^aDependent Variable: VAR00002

Four tables are given, but we will use the bottom table entitled “coefficients” only.

B = regression coefficient = $0,917 \pm 0,083$ (std error)

A = intercept (otherwise called B_0 or Constant) = $39,340 \pm 38,704$ (std error)

95 % confidence intervals of B

should not be different from 1,000.

= $0,917 \pm 1,96 \times 0,0813$

= between 0.751 and 1.08.

95 % confidence intervals of A

should not be different from 0,000.

= $39,340 \pm 1,96 \times 38,704$

= between $-38,068$ and $116,748$.

Both the confidence intervals of B and A are adequate for validating this diagnostic test. This diagnostic test is, thus, accurate.

6 Conclusion

Quantitative diagnostic tests can be validated using linear regression. If both the regression coefficient and the intercept are not significantly different from 1,000 and 0,000, then the diagnostic test is valid. Alternative methods are reviewed in the references given below.

7 Note

More background, theoretical and mathematical information about validating quantitative diagnostic test are given in Statistics applied to clinical studies 5th edition, the Chaps. 50 and 51, Springer Heidelberg Germany, 2012, from the same authors.