

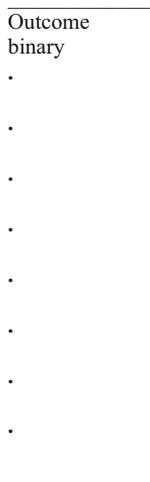
Chapter 34

One-Sample Binary Data (One-Sample Z-Test, Binomial Test, 55 Patients)

1 General Purpose

In clinical studies the outcome is often assessed with numbers of responders and nonresponders to some treatment. If the proportion of responders is statistically significantly larger than zero, then the treatment is efficacious.

2 Schematic Overview of Type of Data File



3 Primary Scientific Question

Is the proportion of responders significantly larger or smaller than zero.

4 Data Example

Underneath are the first 10 patients of a 55 patient file of patients responding to hypertensive treatment or not. We wish to test whether the number of patients who respond is significantly larger than a number of 0.

Outcome

0
0
0
0
0
0
0
0
0

outcome = responder to antihypertensive-drug-treatment or not (1 or 0)

5 Analysis: One-Sample Z-Test

The 55 patient data file is in extras.springer.com, and is entitled “chapter 34onesamplebinary”. Open it in SPSS.

Command:

Analyze....Descriptive statistics....Descriptives....Variable(s): responder....Options:
mark: mean, sum, SE, mean....click Continue....click OK.

Descriptive statistic

	N	Sum	Mean	
	Statistic	Statistic	Statistic	Std. error
afdeling	55	20,00	,3636	,06546
Valid N (listwise)	55			

The z-value as obtained equals $0,3636/0,06546 = 5,5545$. This value is much larger than 1,96, and, therefore, the nullhypothesis of no difference from 0 can be rejected at $p < 0,001$. A proportion of 20/55 is significantly larger than 0.

6 Alternative Analysis: Binomial Test

If the data do not follow a Gaussian distribution, this method will be required, but, with Gaussian distributions, it may be applied even so. For analysis the statistical model One Sample in the module Nonparametric Tests is required.

Command:

Analyze...Nonparametric Tests...click One Sample...click Fields...Test Fields: enter "responder"....click Settings....click Choose Tests....mark Customize tests ...mark Compare observed binary probability. . .(Binomial test)....click Options ...Hypothesized proportion: enter 0,00....click OK.....a warning comes up: SPSS does not accept 0,00....click Fix....replace 0,00 with 0,00001....click OK....click Run.

The underneath table is in the output. The proportion observed is significantly different from 0,00 at $p < 0,0001$. This result is similar to that of the above z-test.

Hypothesis test summary

	Null hypothesis	Test	Sig.	Decision
1	The categories defined by responder = 0,000 and 1,000 occur with probabilities 0 and 1.	One-sample binomial test	,000	Reject the null hypothesis.

Asymptotic significances are displayed. The significance level is ,05

7 Conclusion

The significant results indicate that the nullhypothesis of no effect can be rejected. The proportion of responders is significantly larger 0,00. It may be prudent to use nonparametric tests, if normality is doubtful, like in the small data example given.

8 Note

The theories of nullhypotheses and frequency distributions for binary outcome data are reviewed in Statistics applied to clinical studies 5th edition, Chap. 3, Springer Heidelberg Germany, 2012, from the same authors.