

Chapter 215

Equivalence Tests for the Odds Ratio of Two Proportions

Introduction

This module provides power analysis and sample size calculation for equivalence tests of the odds ratio in two-sample designs in which the outcome is binary. The equivalence test is usually carried out using the Two One-Sided Tests (TOST) method. This procedure computes power and sample size for the TOST equivalence test method. Users may choose between two popular test statistics commonly used for running the hypothesis test.

The power calculations assume that independent, random samples are drawn from two populations.

Example

An equivalence test example will set the stage for the discussion of the terminology that follows. Suppose that the response rate of the standard treatment of a disease is 0.70. Unfortunately, this treatment is expensive and occasionally exhibits serious side-effects. A promising new treatment has been developed to the point where it can be tested. One of the first questions that must be answered is whether the new treatment is therapeutically equivalent to the standard treatment.

After thoughtful discussion with several clinicians, it is decided that if the odds ratio of the new treatment to the standard treatment is between 0.8 and 1.2, the new treatment would be adopted.

The developers must design an experiment to test the hypothesis that the odds ratio of the new treatment to the standard is between 0.8 and 1.2. The statistical hypothesis to be tested is

$$H_0: o_1/o_2 < 0.8 \text{ or } o_1/o_2 > 1.2 \quad \text{versus} \quad H_1: 0.8 \leq o_1/o_2 \leq 1.2$$

Technical Details

The details of sample size calculation for the two-sample design for binary outcomes are presented in the chapter “Tests for Two Proportions,” and they will not be duplicated here. Instead, this chapter only discusses those changes necessary for equivalence tests.

This procedure has the capability for calculating power based on large sample (normal approximation) results and based on the enumeration of all possible values in the binomial distribution.

Suppose you have two populations from which dichotomous (binary) responses will be recorded. Assume without loss of generality that higher proportions are better. The probability (or risk) of cure in group 1 (the treatment group) is p_1 and in group 2 (the reference group) is p_2 . Random samples of n_1 and n_2 individuals are obtained from these two groups. The data from these samples can be displayed in a 2-by-2 contingency table as follows

Group	Success	Failure	Total
Treatment	a	c	m
Control	b	d	n
Totals	s	f	N

The following alternative notation is also used.

Group	Success	Failure	Total
Treatment	x_{11}	x_{12}	n_1
Control	x_{21}	x_{22}	n_2
Totals	m_1	m_2	N

The binomial proportions p_1 and p_2 are estimated from these data using the formulae

$$\hat{p}_1 = \frac{a}{m} = \frac{x_{11}}{n_1} \quad \text{and} \quad \hat{p}_2 = \frac{b}{n} = \frac{x_{21}}{n_2}$$

Let $p_{1.0}$ represent the group 1 proportion tested by the null hypothesis H_0 . The power of a test is computed at a specific value of the proportion which we will call $p_{1.1}$. Let δ represent the smallest difference (margin of equivalence) between the two proportions that still results in the conclusion that the new treatment is equivalent to the current treatment. The set of statistical hypotheses that are tested is

$$H_0: |p_{1.0} - p_2| \geq \delta \quad \text{versus} \quad H_1: |p_{1.0} - p_2| < \delta$$

These hypotheses can be rearranged to give

$$H_0: p_{1.0} - p_2 \leq \delta_L \quad \text{or} \quad p_{1.0} - p_2 \geq \delta_U \quad \text{versus} \quad H_1: \delta_L \leq p_{1.0} - p_2 \leq \delta_U$$

This composite hypothesis can be reduced to two one-sided hypotheses as follows

$$H_{0L}: p_{1.0} - p_2 \leq \delta_L \quad \text{versus} \quad H_{1L}: \delta_L \leq p_{1.0} - p_2$$

$$H_{0U}: p_{1.0} - p_2 \geq \delta_U \quad \text{versus} \quad H_{1U}: \delta_U \geq p_{1.0} - p_2$$

Equivalence Tests for the Odds Ratio of Two Proportions

There are three common methods of specifying the margin of equivalence. The most direct is to simply give values for p_2 and $p_{1.0}$. However, it is often more meaningful to give p_2 and then specify $p_{1.0}$ implicitly by reporting the difference, ratio, or odds ratio. Mathematically, the definitions of these parameterizations are

Parameter	Computation	Alternative Hypotheses
Difference	$\delta = p_{1.0} - p_2$	$H_1: \delta_L \leq p_{1.0} - p_2 \leq \delta_U$
Ratio	$\phi = p_{1.0} / p_2$	$H_1: \phi_L \leq p_{1.0} / p_2 \leq \phi_U$
Odds Ratio	$\psi = Odds_{1.0} / Odds_2$	$H_1: \psi_L \leq o_{1.0} / o_2 \leq \psi_U$

Odds Ratio

The odds ratio, $\psi = (p_{1.0}/(1 - p_{1.0})) / (p_2/(1 - p_2))$, gives the relative change in the odds (o) of the response. Testing equivalence use the formulation

$$H_0: o_{1.0} / o_2 \leq \psi_L \text{ or } o_{1.0} / o_2 \geq \psi_U \text{ versus } H_1: \psi_L \leq o_{1.0} / o_2 \leq \psi_U$$

The only subtlety is that for equivalence tests $\psi_L < 1$ and $\psi_U > 1$. Usually, $\psi_L = 1 / \psi_U$.

The equivalence test is usually carried out using the Two One-Sided Tests (TOST) method. This procedure computes power and sample size for the TOST equivalence test method.

Power Calculation

The power for a test statistic that is based on the normal approximation can be computed exactly using two binomial distributions. The following steps are taken to compute the power of these tests.

1. Find the critical values using the standard normal distribution. The critical values z_L and z_U are chosen as that value of z that leaves exactly the target value of α in the appropriate tail of the normal distribution.
2. Compute the value of the test statistic z_t for every combination of x_{11} and x_{21} . Note that x_{11} ranges from 0 to n_1 , and x_{21} ranges from 0 to n_2 . A small value (around 0.0001) can be added to the zero-cell counts to avoid numerical problems that occur when the cell value is zero.
3. If $z_t > z_L$ and $z_t < z_U$, the combination is in the rejection region. Call all combinations of x_{11} and x_{21} that lead to a rejection the set A .
4. Compute the power for given values of $p_{1.1}$ and p_2 as

$$1 - \beta = \sum_A \binom{n_1}{x_{11}} p_{1.1}^{x_{11}} q_{1.1}^{n_1 - x_{11}} \binom{n_2}{x_{21}} p_2^{x_{21}} q_2^{n_2 - x_{21}}$$

Equivalence Tests for the Odds Ratio of Two Proportions

5. Compute the actual value of alpha achieved by the design by substituting $p_{1.0L}$ and $p_{1.0U}$ for $p_{1.1}$ to obtain

$$\alpha_L = \sum_A \binom{n_1}{x_{11}} p_{1.0L}^{x_{11}} q_{1.0L}^{n_1-x_{11}} \binom{n_2}{x_{21}} p_2^{x_{21}} q_2^{n_2-x_{21}}$$

and

$$\alpha_U = \sum_A \binom{n_1}{x_{11}} p_{1.0U}^{x_{11}} q_{1.0U}^{n_1-x_{11}} \binom{n_2}{x_{21}} p_2^{x_{21}} q_2^{n_2-x_{21}}$$

The value of alpha is then computed as the maximum of α_L and α_U .

Asymptotic Approximations

When the values of n_1 and n_2 are large (say over 200), these formulas take a long time to evaluate. In this case, a large sample approximation can be used. The large sample approximation is made by replacing the values of \hat{p}_1 and \hat{p}_2 in the z statistic with the corresponding values of $p_{1.1}$ and p_2 and then computing the results based on the normal distribution.

Test Statistics

Two test statistics have been proposed for testing whether the odds ratio is different from a specified value. The main difference between the test statistics is in the formula used to compute the standard error used in the denominator. These tests are both

In power calculations, the values of \hat{p}_1 and \hat{p}_2 are not known. The corresponding values of $p_{1.1}$ and p_2 may be reasonable substitutes.

Following is a list of the test statistics available in **PASS**. The availability of several test statistics begs the question of which test statistic one should use. The answer is simple: one should use the test statistic that will be used to analyze the data. You may choose a method because it is a standard in your industry, because it seems to have better statistical properties, or because your statistical package calculates it. Whatever your reasons for selecting a certain test statistic, you should use the same test statistic when doing the analysis after the data have been collected.

Equivalence Tests for the Odds Ratio of Two Proportions

Miettinen and Nurminen's Likelihood Score Test

Miettinen and Nurminen (1985) proposed a test statistic for testing whether the odds ratio is equal to a specified value, ψ_0 . Because the approach they used with the difference and ratio does not easily extend to the odds ratio, they used a score statistic approach for the odds ratio. The regular MLE's are \hat{p}_1 and \hat{p}_2 . The constrained MLE's are \tilde{p}_1 and \tilde{p}_2 . These estimates are constrained so that $\tilde{\psi} = \psi_0$. A correction factor of $N/(N-1)$ is applied to make the variance estimate less biased. The significance level of the test statistic is based on the asymptotic normality of the score statistic.

The formula for computing the test statistic is

$$z_{MNO} = \frac{\frac{(\hat{p}_1 - \tilde{p}_1)}{\tilde{p}_1 \tilde{q}_1} - \frac{(\hat{p}_2 - \tilde{p}_2)}{\tilde{p}_2 \tilde{q}_2}}{\sqrt{\left(\frac{1}{n_1 \tilde{p}_1 \tilde{q}_1} + \frac{1}{n_2 \tilde{p}_2 \tilde{q}_2}\right) \left(\frac{N}{N-1}\right)}}$$

where

$$\tilde{p}_1 = \frac{\tilde{p}_2 \psi_0}{1 + \tilde{p}_2 (\psi_0 - 1)}$$

$$\tilde{p}_2 = \frac{-B + \sqrt{B^2 - 4AC}}{2A}$$

$$A = n_2(\psi_0 - 1),$$

$$B = n_1 \psi_0 + n_2 - m_1(\psi_0 - 1),$$

$$C = -m_1$$

Farrington and Manning's Likelihood Score Test

Farrington and Manning (1990) indicate that the Miettinen and Nurminen statistic may be modified by removing the factor $N/(N-1)$.

The formula for computing this test statistic is

$$z_{FMO} = \frac{\frac{(\hat{p}_1 - \tilde{p}_1)}{\tilde{p}_1 \tilde{q}_1} - \frac{(\hat{p}_2 - \tilde{p}_2)}{\tilde{p}_2 \tilde{q}_2}}{\sqrt{\left(\frac{1}{n_1 \tilde{p}_1 \tilde{q}_1} + \frac{1}{n_2 \tilde{p}_2 \tilde{q}_2}\right)}}$$

where the estimates, \tilde{p}_1 and \tilde{p}_2 , are computed as in the corresponding test of Miettinen and Nurminen (1985) given above.

Example 1 – Finding Power

A study is being designed to establish the equivalence of a new treatment compared to the current treatment. Historically, the current treatment has enjoyed a 65% cure rate. The new treatment reduces the seriousness of certain side effects that occur with the current treatment. Thus, the new treatment will be adopted even if it is slightly less effective than the current treatment. The researchers will recommend adoption of the new treatment if the odds ratio of treatment to control is between 0.5 and 2.0.

The researchers plan to use the Farrington and Manning likelihood score test statistic to analyze the data. They want to study the power of the Farrington and Manning test at group sample sizes ranging from 50 to 500 for detecting an odds ratio between 0.5 and 2.0 when the actual odds ratio ranges from 1.0 to 1.5. The significance level will be 0.05.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 1** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For	Power
Power Calculation Method	Normal Approximation
Test Type	Likelihood Score (Farr. & Mann.)
Alpha	0.05
Group Allocation	Equal (N1 = N2)
Sample Size Per Group	50 to 500 by 50
OR0.U (Upper Equivalence Odds Ratio)	2
OR0.L (Lower Equivalence Odds Ratio)	1/OR0.U
OR1 (Actual Odds Ratio)	1.0 1.25 1.5
P2 (Group 2 Proportion)	0.65

Equivalence Tests for the Odds Ratio of Two Proportions

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Reports

Numeric Results

Solve For: **Power**
 Groups: 1 = Treatment, 2 = Reference
 Test Statistic: Farrington & Manning Likelihood Score Test
 Hypotheses: $H_0: OR \leq OR_{0.L} \text{ or } OR \geq OR_{0.U}$ vs. $H_1: OR_{0.L} < OR < OR_{0.U}$

Power*	Sample Size			Proportions				Odds Ratio			
				Equivalence		Actual P1.1	Reference P2	Equivalence		Actual OR1	Alpha
	N1	N2	N	Lower P1.0L	Upper P1.0U			Lower OR0.L	Upper OR0.U		
0.0153	50	50	100	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.5295	100	100	200	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.7926	150	150	300	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9137	200	200	400	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9656	250	250	500	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9868	300	300	600	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9950	350	350	700	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9982	400	400	800	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9994	450	450	900	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.9998	500	500	1000	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.0000	50	50	100	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.3913	100	100	200	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.5904	150	150	300	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.7127	200	200	400	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.7977	250	250	500	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.8587	300	300	600	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.9024	350	350	700	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.9333	400	400	800	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.9548	450	450	900	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.9696	500	500	1000	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.0000	50	50	100	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.2126	100	100	200	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.3027	150	150	300	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.3702	200	200	400	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.4314	250	250	500	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.4880	300	300	600	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.5404	350	350	700	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.5884	400	400	800	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.6324	450	450	900	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05
0.6725	500	500	1000	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05

* Power was computed using the normal approximation method.

Power	The probability of rejecting a false null hypothesis when the alternative hypothesis is true.
N1 and N2	The number of items sampled from each population.
N	The total sample size. $N = N1 + N2$.
P1.0L	The smallest treatment-group response rate that still yields an equivalence conclusion.
P1.0U	The largest treatment-group response rate that still yields an equivalence conclusion.
P1.1	The proportion for group 1 assumed by the alternative hypothesis, H_1 . Group 1 is the treatment group. $P1.1 = P1 H1$.
P2	The proportion for group 2. Group 2 is the standard, reference, or control group.
OR0.L	The lowest odds ratio that still results in the conclusion of equivalence.
OR0.U	The highest odds ratio that still results in the conclusion of equivalence.
OR1	The actual odds ratio, $o1 / o2$, at which the power is calculated.
Alpha	The probability of rejecting a true null hypothesis.

Equivalence Tests for the Odds Ratio of Two Proportions

Summary Statements

A parallel two-group design will be used to test whether the Group 1 (treatment) proportion (P1) is equivalent to the Group 2 (reference) proportion (P2), with odds ratio equivalence bounds of 0.5 and 2 ($H_0: OR \leq 0.5$ or $OR \geq 2$ versus $H_1: 0.5 < OR < 2$). The comparison will be made using two one-sided, two-sample likelihood score (Farrington & Manning) tests with an overall Type I error rate (α) of 0.05. The reference group proportion is assumed to be 0.65. To detect an odds ratio (O_1 / O_2) of 1 (or P1 of 0.65) with sample sizes of 50 for Group 1 (treatment) and 50 for Group 2 (reference), the power is 0.0153.

Dropout-Inflated Sample Size

Dropout Rate	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
	N1	N2	N	N1'	N2'	N'	D1	D2	D
20%	50	50	100	63	63	126	13	13	26
20%	100	100	200	125	125	250	25	25	50
20%	150	150	300	188	188	376	38	38	76
20%	200	200	400	250	250	500	50	50	100
20%	250	250	500	313	313	626	63	63	126
20%	300	300	600	375	375	750	75	75	150
20%	350	350	700	438	438	876	88	88	176
20%	400	400	800	500	500	1000	100	100	200
20%	450	450	900	563	563	1126	113	113	226
20%	500	500	1000	625	625	1250	125	125	250

Dropout Rate	The percentage of subjects (or items) that are expected to be lost at random during the course of the study and for whom no response data will be collected (i.e., will be treated as "missing"). Abbreviated as DR.
N1, N2, and N	The evaluable sample sizes at which power is computed (as entered by the user). If N1 and N2 subjects are evaluated out of the N1' and N2' subjects that are enrolled in the study, the design will achieve the stated power.
N1', N2', and N'	The number of subjects that should be enrolled in the study in order to obtain N1, N2, and N evaluable subjects, based on the assumed dropout rate. N1' and N2' are calculated by inflating N1 and N2 using the formulas $N1' = N1 / (1 - DR)$ and $N2' = N2 / (1 - DR)$, with N1' and N2' always rounded up. (See Julious, S.A. (2010) pages 52-53, or Chow, S.C., Shao, J., Wang, H., and Lokhnygina, Y. (2018) pages 32-33.)
D1, D2, and D	The expected number of dropouts. $D1 = N1' - N1$, $D2 = N2' - N2$, and $D = D1 + D2$.

Dropout Summary Statements

Anticipating a 20% dropout rate, 63 subjects should be enrolled in Group 1, and 63 in Group 2, to obtain final group sample sizes of 50 and 50, respectively.

Equivalence Tests for the Odds Ratio of Two Proportions

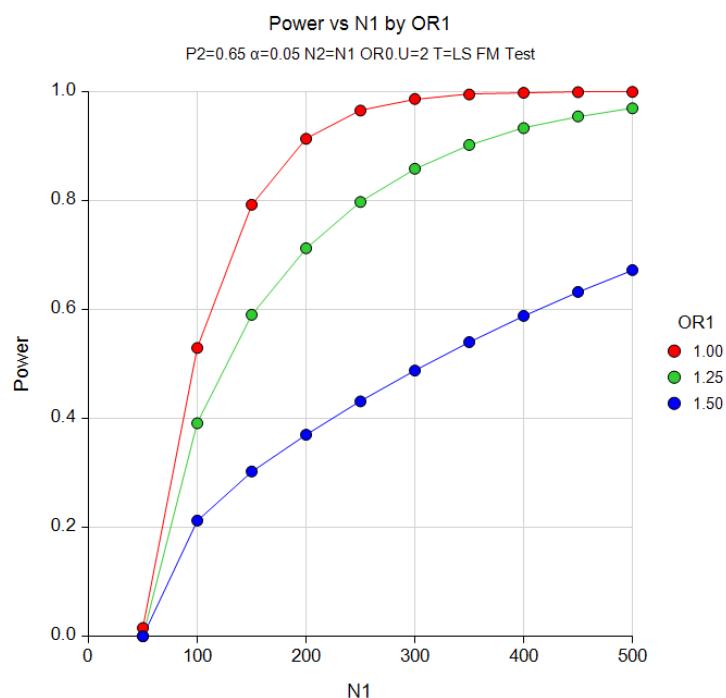
References

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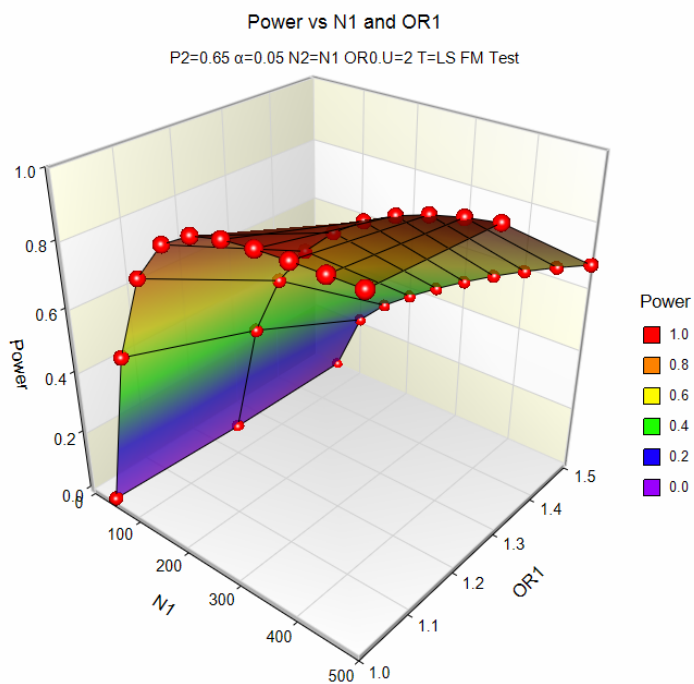
This report shows the values of each of the parameters, one scenario per row.

Plots Section

Plots



Equivalence Tests for the Odds Ratio of Two Proportions



The values from the table are displayed in the above charts. These charts give a quick look at the sample size that will be required for various values of OR1.

Example 2 – Finding the Sample Size

Continuing with the scenario given in Example 1, the researchers want to determine the sample size necessary for each value of OR1 to achieve a power of 0.80.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 2** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For **Sample Size**
 Power Calculation Method **Normal Approximation**
 Test Type **Likelihood Score (Farr. & Mann.)**
 Power **0.80**
 Alpha **0.05**
 Group Allocation **Equal (N1 = N2)**
 OR0.U (Upper Equivalence Odds Ratio) **2**
 OR0.L (Lower Equivalence Odds Ratio) **1/OR0.U**
 OR1 (Actual Odds Ratio) **1.0 1.25 1.5**
 P2 (Group 2 Proportion) **0.65**

Output

Click the Calculate button to perform the calculations and generate the following output.

Numeric Results

Solve For: [Sample Size](#)
 Groups: 1 = Treatment, 2 = Reference
 Test Statistic: Farrington & Manning Likelihood Score Test
 Hypotheses: $H_0: OR \leq OR_{0.L} \text{ or } OR \geq OR_{0.U}$ vs. $H_1: OR_{0.L} < OR < OR_{0.U}$

Power		Sample Size			Proportions				Odds Ratio			
					Equivalence		Actual P1.1	Reference P2	Equivalence		Actual OR1	Alpha
Target	Actual*	N1	N2	N	Lower P1.0L	Upper P1.0U			Lower OR0.L	Upper OR0.U		
0.8	0.8029	153	153	306	0.481	0.788	0.650	0.65	0.5	2	1.00	0.05
0.8	0.8005	252	252	504	0.481	0.788	0.699	0.65	0.5	2	1.25	0.05
0.8	0.8005	705	705	1410	0.481	0.788	0.736	0.65	0.5	2	1.50	0.05

* Power was computed using the normal approximation method.

The required sample size will depend a great deal on the value of OR1. Any effort spent determining an accurate value for OR1 will be worthwhile.

Example 3 – Comparing the Power of the Two Test Statistics

Continuing with Example 2, the researchers want to determine which of the two possible test statistics to adopt by using the comparative reports and charts that **PASS** produces. They decide to compare the powers and actual alphas for various sample sizes between 50 and 200 when OR1 is 1.0.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 3** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For	Power
Power Calculation Method	Binomial Enumeration
Maximum N1 or N2 for Binomial Enumeration	5000
Zero Count Adjustment Method	Add to zero cells only
Zero Count Adjustment Value	0.0001
Test Type	Likelihood Score (Farr. & Mann.)
Alpha	0.05
Group Allocation	Equal (N1 = N2)
Sample Size Per Group	50 to 200 by 50
OR0.U (Upper Equivalence Odds Ratio)	2
OR0.L (Lower Equivalence Odds Ratio)	1/OR0.U
OR1 (Actual Odds Ratio)	1.0
P2 (Group 2 Proportion)	0.65

Reports Tab

Show Comparative Reports	Checked
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Comparative Plots Tab

Show Comparative Plots	Checked
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Equivalence Tests for the Odds Ratio of Two Proportions

Output

Click the Calculate button to perform the calculations and generate the following output.

Power Comparison of Two Different Tests

Hypotheses: $H_0: OR \leq OR_{0.L} \text{ or } OR \geq OR_{0.U}$ vs. $H_1: OR_{0.L} < OR < OR_{0.U}$

Sample Size			P2	OR0.L	OR0.U	OR1	Target Alpha	Power	
N1	N2	N						F.M. Score	M.N. Score
50	50	100	0.65	0.5	2	1	0.05	0.0540	0.0403
100	100	200	0.65	0.5	2	1	0.05	0.5025	0.5025
150	150	300	0.65	0.5	2	1	0.05	0.7715	0.7709
200	200	400	0.65	0.5	2	1	0.05	0.8990	0.8988

Note: Power was computed using binomial enumeration of all possible outcomes.

Actual Alpha Comparison of Two Different Tests

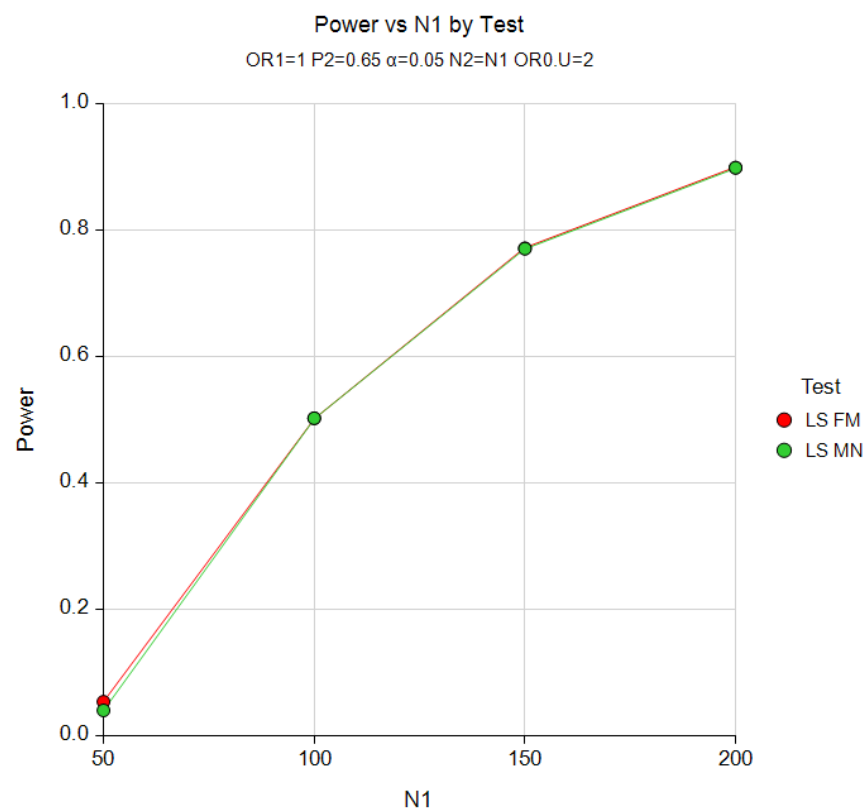
Hypotheses: $H_0: OR \leq OR_{0.L} \text{ or } OR \geq OR_{0.U}$ vs. $H_1: OR_{0.L} < OR < OR_{0.U}$

Sample Size			P2	OR0.L	OR0.U	OR1	Target Alpha	Alpha	
N1	N2	N						F.M. Score	M.N. Score
50	50	100	0.65	0.5	2	1	0.05	0.0527	0.0521
100	100	200	0.65	0.5	2	1	0.05	0.0509	0.0509
150	150	300	0.65	0.5	2	1	0.05	0.0507	0.0504
200	200	400	0.65	0.5	2	1	0.05	0.0497	0.0497

Note: Actual alpha was computed using binomial enumeration of all possible outcomes.

Equivalence Tests for the Odds Ratio of Two Proportions

Plots



Both test statistics have about the same power for all sample sizes studied.

Example 4 – Comparing Power Calculation Methods

Continuing with Example 3, let's see how the results compare if we were to use approximate power calculations instead of power calculations based on binomial enumeration.

Setup

If the procedure window is not already open, use the PASS Home window to open it. The parameters for this example are listed below and are stored in the **Example 4** settings file. To load these settings to the procedure window, click **Open Example Settings File** in the Help Center or File menu.

Design Tab

Solve For **Power**
 Power Calculation Method **Normal Approximation**
 Test Type **Likelihood Score (Farr. & Mann.)**
 Alpha **0.05**
 Group Allocation **Equal (N1 = N2)**
 Sample Size Per Group **50 to 200 by 50**
 OR0.U (Upper Equivalence Odds Ratio) **2**
 OR0.L (Lower Equivalence Odds Ratio) **1/OR0.U**
 OR1 (Actual Odds Ratio) **1.0**
 P2 (Group 2 Proportion) **0.65**

Reports Tab

Show Power Detail Report **Checked**

Output

Click the Calculate button to perform the calculations and generate the following output.

Power Detail Report

Test Statistic: Farrington & Manning Likelihood Score Test
 Hypotheses: $H_0: OR \leq OR_{0.L} \text{ or } OR \geq OR_{0.U}$ vs. $H_1: OR_{0.L} < OR < OR_{0.U}$

Sample Size			P2	OR0.L	OR0.U	OR1	Normal Approximation		Binomial Enumeration	
N1	N2	N					Power	Alpha	Power	Alpha
50	50	100	0.65	0.5	2	1	0.0153	0.05	0.0540	0.0527
100	100	200	0.65	0.5	2	1	0.5295	0.05	0.5025	0.0509
150	150	300	0.65	0.5	2	1	0.7926	0.05	0.7715	0.0507
200	200	400	0.65	0.5	2	1	0.9137	0.05	0.8990	0.0497

Notice that the approximate power values are quite different from the binomial power values, especially for smaller sample sizes.

Example 5 – Validation

We could not find a validation example for an equivalence test for the odds ratio of two proportions. The calculations are basically the same as those for a non-inferiority test of the ratio of two proportions, which has been validated using Blackwelder (1993). We refer you to Example 5 of Chapter 211, “Non-Inferiority Tests for the Ratio of Two Proportions,” for a validation example.