Chapter 437

Tests for the Ratio of Two Poisson Rates (Gu)

Introduction

The Poisson probability law gives the probability distribution of the number of events occurring in a specified interval of time or space. The Poisson distribution is often used to fit count data, such as the number of defects on an item, the number of accidents at an intersection during a year, the number of calls to a call center during an hour, or the number of meteors seen in the evening sky during an hour.

The Poisson distribution is characterized by a single parameter which is the mean number of occurrences during the specified interval.

The procedure documented in this chapter calculates the power or sample size for testing whether the ratio of two Poisson means is different from a specified value (usually one). The test procedure is described in Gu et al. (2008).

Test Procedure

Assume that all subjects in each group are observed for a fixed time period and the number of events, *X*, (outcomes or defects) is recorded. The following table presents the various terms that are used.

Group	**1**	**2**
Fixed time interval	t_1	t_2
Sample Size	N_1	N_2
Number of events	X_1	X_2
Individual event rates	λ_1	λ_2
Distribution of *X*	Poisson$(\lambda_1 t_1)$	Poisson$(\lambda_2 t_2)$

Define the ratio of event rates, *RR*, as

$$RR = \frac{\lambda_2}{\lambda_1}$$

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Gu (2008) considered several test statistics that can be used to test hypotheses about the ratio. For example,

$$H_0 : \frac{\lambda_2}{\lambda_1} = RR_0 \quad \text{versus} \quad H_a : \frac{\lambda_2}{\lambda_1} > RR_0 \,.$$

or equivalently,

$$H_0 : RR = RR_0 \quad \text{versus} \quad H_a : RR > RR_0 \,.$$

where RR_0 is the ratio of event rates under the null hypothesis.

Two test statistics are available in this case. The first is based on unconstrained maximum likelihood estimates

$$W_1 = \frac{X_2 - X_1\left(\frac{\sqrt{RR_0}}{d}\right)}{\sqrt{X_2 + X_1\left(\frac{RR_0}{d}\right)^2}}$$

where

$$d = t_1 N_1 / t_2 N_2.$$

The second test is based on constrained maximum likelihood estimates

$$W_2 = \frac{X_2 - X_1\left(\frac{RR_0}{d}\right)}{\sqrt{(X_2 + X_1)\left(\frac{RR_0}{d}\right)}}$$

An equivalent pair of test statistics are available if logarithms are used. The statistical hypothesis is

$$H_0 : \ln\left(\frac{\lambda_2}{\lambda_1}\right) - \ln(RR_0) = 0 \quad \text{versus} \quad H_a : \ln\left(\frac{\lambda_2}{\lambda_1}\right) - \ln(RR_0) > 0$$

or equivalently,

$$H_0 : \ln(RR) - \ln(RR_0) = 0 \quad \text{versus} \quad H_a : \ln(RR) - \ln(RR_0) > 0$$

Two test statistics are available in this case as well. The first is based on unconstrained maximum likelihood estimates

$$W_3 = \frac{\ln\left(\frac{X_2}{X_1}\right) - \ln\left(\frac{RR_0}{d}\right)}{\sqrt{\frac{1}{X_2} + \frac{1}{X_1}}}$$

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The second test is based on constrained maximum likelihood estimates

$$W_4 = \frac{\ln\left(\frac{X_2}{X_1}\right) - \ln\left(\frac{RR_0}{d}\right)}{\sqrt{\frac{\left(2 + \frac{d}{RR_0} + \frac{RR_0}{d}\right)}{X_1 + X_2}}}$$

After extensive simulation, they recommend the following extension of the variance-stabilized test proposed by Huffman (1984) for the case when $RR_0 \,/\, d > 1$.

$$W_5 = \frac{2\left[\sqrt{X_2 + 3/8} - \sqrt{\frac{RR_0}{d}(X_1 + 3/8)}\right]}{\sqrt{1 + \frac{RR_0}{d}}}$$

Gu et al. (2008) show that all of these test statistics are approximately distributed as a standard normal and thus use the normal distribution as the basis of significance testing and power analysis.

Assumptions

The assumptions of the two-sample *Poisson* test are:

1. The data in each group are counts (discrete) that follow the Poisson distribution.
2. Each sample is a simple random sample from its population. Unlike most designs, in this design the sample size involves a fixed time parameter. That is, instead of specifying the number of people in a study, the number of man-hours is what is important. Hence, a sample size of 10 hours could be achieved by ten people being observed for one hour or two people being observed for five hours.

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Technical Details

Computing Power

If we define RR_a as the ratio of event rates under the alternative hypothesis at which the power is calculated, the power analysis for testing the hypothesis

$$H_0 : RR = RR_0 \quad \text{versus} \quad H_a : RR > RR_0 \,.$$

using the test statistics defined above is completed as follows:

1. **Find the critical value**. Choose the critical value $z_{1-\alpha}$ using the standard normal distribution so that the probability of rejecting H_0 when it is true is α.
2. **Compute the power**. Compute the power for each test as follows.

   For W_1, W_3, and W_4, the power is given by

$$Power(W_i) = 1 - \Phi\left(\frac{z_{1-\alpha}\sigma_i - \mu_i}{\sigma_i}\right)$$

   where

$$\Phi(z) = \int_{-\infty}^{z} \text{Normal}(0,1)$$

$$\mu_1 = \left(\frac{RR_a}{d} - \frac{RR_0}{d}\right) t_1 N_1 \lambda_1$$

$$\mu_3 = \ln\left(\frac{RR_a}{RR_0}\right)$$

$$\mu_4 = \ln\left(\frac{RR_a}{RR_0}\right)$$

$$\sigma_1^2 = \left(\frac{dRR_a + RR_0^2}{d^2}\right) t_1 N_1 \lambda_1$$

$$\sigma_3^2 = \frac{d + RR_a}{t_1 N_1 \lambda_1 RR_a}$$

$$\sigma_4^2 = \frac{\left(2 + \frac{d}{RR_0} + \frac{RR_0}{d}\right)}{t_1 N_1 \lambda_1 \left(1 + \frac{RR_a}{d}\right)}$$

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For W_2, the power is computed using

$$Power(W_2) = 1 - \Phi\left(\frac{Ez_{1-\alpha} - F}{G}\right)$$

where

$$E = \sqrt{\left(\frac{RR_0}{RR_a}\right)^2 + \frac{RR_0^2}{RR_a d}}$$

$$F = \left(1 - \frac{RR_0}{RR_a}\right)\sqrt{\frac{\lambda_1 t_1 N_1 RR_0}{d}}$$

$$G = \sqrt{\frac{RR_0}{RR_a}\left(1 + \frac{RR_0^2}{dRR_a}\right)}$$

For W_5, the power is computed using

$$Power(W_5) = \Phi\left(\frac{|A|\sqrt{B} - z_{1-\alpha}C}{D}\right)$$

where

$$A = 2\left(1 - \sqrt{\frac{RR_0}{RR_a}}\right)$$

$$B = \lambda_1 t_1 N_1 + 3/8$$

$$C = \sqrt{\frac{RR_0 + d}{RR_a}}$$

$$D = \sqrt{\frac{RR_a + d}{RR_a}}$$

Computing Sample Size

The sample size is found using the formula

$$N_1 = \frac{\left(\frac{z_{1-\alpha}C + z_{Power}D}{A}\right)^2 - 3/8}{\lambda_1 t_1}.$$

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Example 1 – Finding the Sample Size

We will use the example of Gu (2008) in which epidemiologists wish to examine the relationship of post-menopausal hormone use and coronary heart disease (CHD). The incidence rate for those not using the hormone is 0.0005 (λ_1= 0.0005). How large of a sample is needed to detect a change in the incidence ratio from RR_0 = 1 to RR_a= 2, 3, 4, 5, or 6. Assume that 90% power is required and α = 0.05. Assume that each subject will be observed for two years and that the design calls for an equal number of subjects in both groups.

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 ..... **Sample Size**
Alternative Hypothesis ..... **One-Sided**
Test Statistic ..... **W5 = Variance Stabilized**
Power..... **0.90**
Alpha..... **0.05**
t1 (Exposure Time of Group 1) **2**
t2 (Exposure Time of Group 2) **2**
Group Allocation ..... **Equal (N1 = N2)**
λ1 (Group 1 Event Rate)..... **0.0005**
RR0 (Ratio of Event Rates under H0)..... **1**
Enter λ2 or Ratio for Group 2..... **RRa (Ratio of Event Rates under H0)**
RRa (Ratio of Event Rates under Ha)..... **2 3 4 5 6**

Design Tab

Decimals for Event Rates **4**

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Output

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

Numeric Reports

Numeric Results

Solve For: Sample Size
Groups: 1 = Control, 2 = Treatment
Alternative Hypothesis: One-Sided (H0: RR ≤ RR0 vs. Ha: RR > RR0)
Test Statistic: W5 = Variance Stabilized

	Sample Size			Exposure Time		Average Event Rate		Event Rate Ratio		
Power	N1	N2	N	t1	t2	λ1	λ2a	Ha RRa	H0 RR0	Alpha
0.90001	29737	29737	59474	2	2	0.0005	0.0010	2	1	0.05
0.90000	10777	10777	21554	2	2	0.0005	0.0015	3	1	0.05
0.90001	6364	6364	12728	2	2	0.0005	0.0020	4	1	0.05
0.90002	4513	4513	9026	2	2	0.0005	0.0025	5	1	0.05
0.90001	3514	3514	7028	2	2	0.0005	0.0030	6	1	0.05

Power The probability of rejecting a false null hypothesis when the alternative hypothesis is true.
N1 and N2 The number of subjects in groups 1 and 2, respectively.
N The total sample size. N = N1 + N2.
t1 and t2 The exposure (observation) times in groups 1 and 2, respectively.
λ1 The mean event rate per time unit in group 1 (control). This is often the baseline event rate.
λ2a The mean event rate per time unit in group 2 (treatment) under the alternative hypothesis, Ha.
RRa The ratio of the two event rates under the alternative hypothesis, Ha. RRa = λ2a/λ1.
RR0 The ratio of the two event rates under the null hypothesis, H0.
Alpha The probability of rejecting a true null hypothesis.

Summary Statements

A parallel two-group design will be used to test whether the Group 2 (treatment) Poisson rate (λ2) is greater than the Group 1 (control) Poisson rate (λ1) (H0: RR ≤ 1 versus Ha: RR > 1, RR = λ2 / λ1). The comparison will be made using a two-sample, one-sided, W5 = Variance Stabilized test statistic, with a Type I error rate (α) of 0.05. The Poisson (event) rate of Group 1 is assumed to be 0.0005. The Group 1 exposure time is assumed to be 2 and the Group 2 exposure time is assumed to be 2. To detect a Group 2 Poisson (event) rate of 0.001 (or a ratio, λ2 / λ1, of 2) with 90% power, the number of subjects needed will be 29737 in Group 1 (control) and 29737 in Group 2 (treatment).

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Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	**N1**	**N2**	**N**	**N1'**	**N2'**	**N'**	**D1**	**D2**	**D**
20%	29737	29737	59474	37172	37172	74344	7435	7435	14870
20%	10777	10777	21554	13472	13472	26944	2695	2695	5390
20%	6364	6364	12728	7955	7955	15910	1591	1591	3182
20%	4513	4513	9026	5642	5642	11284	1129	1129	2258
20%	3514	3514	7028	4393	4393	8786	879	879	1758

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. 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. After solving for N1 and N2, 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, 37172 subjects should be enrolled in Group 1, and 37172 in Group 2, to obtain final group sample sizes of 29737 and 29737, respectively.

References

Gu, K., Ng, H.K.T., Tang, M.L., and Schucany, W. 2008. 'Testing the Ratio of Two Poisson Rates.' Biometrical Journal, 50, 2, 283-298.
Huffman, Michael. 1984. 'An Improved Approximate Two-Sample Poisson Test.' Applied Statistics, 33, 2, 224-226.

This report shows the values of each of the parameters, one scenario per row. The values of power and beta were calculated from the other parameters.

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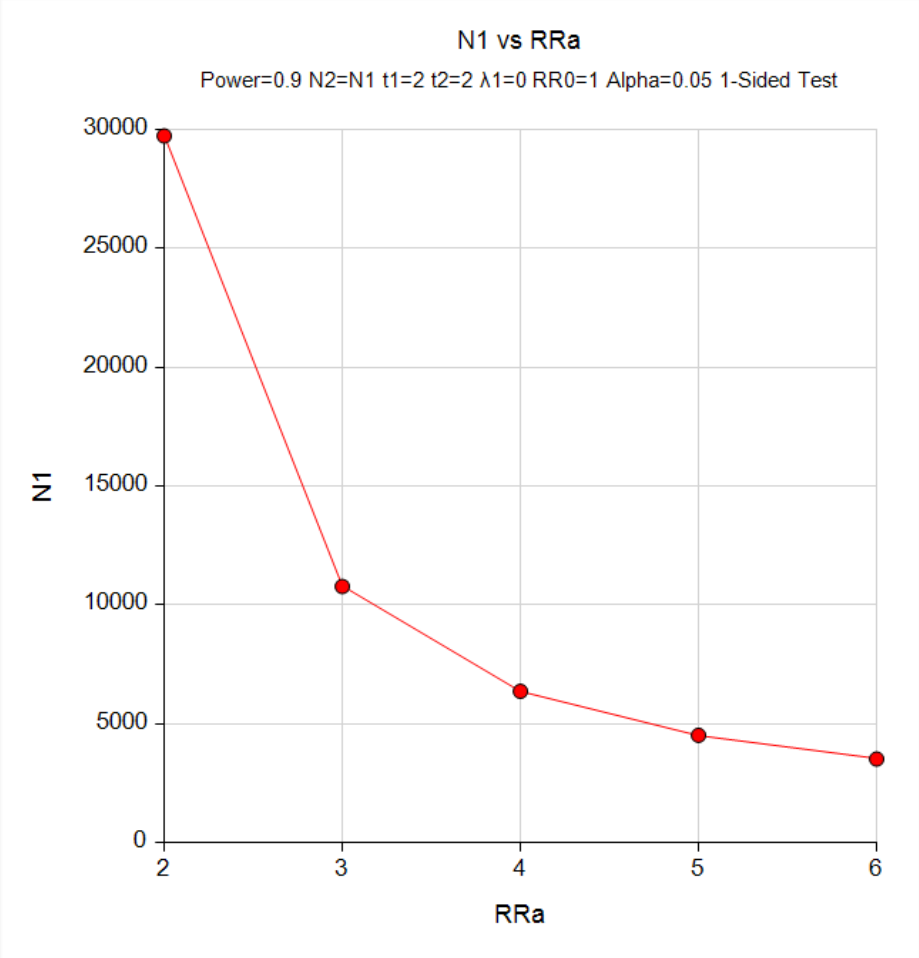
Plots Section

Plots



This plot shows the relationship between group sample size and RRa.

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Example 2 – Validation using Gu et al. (2008)

Gu et al. (2008) present an example that we will use to validate this procedure. Using the scenario cited in Example 1 above, they give a sample size calculation on page 295. In this example, λ_1 = 0.0005, ρ_0 = 1, ρ_a = 4, $t_1 = t_2$ = 2, α = 0.05, R = 0.5, and power = 0.9. In their Table 6, they list the sample size for $p_5^{(A)}$ in this scenario as 8627. However, this number is inaccurate because of the two-decimal place rounding that was done during their calculation. In a private communication, they agreed that the more accurate number is 8590.

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**
Alternative Hypothesis ..... **One-Sided**
Test Statistic ..... **W5 = Variance Stabilized**
Power..... **0.90**
Alpha..... **0.05**
t1 (Exposure Time of Group 1) **2**
t2 (Exposure Time of Group 2) **2**
Group Allocation ..... **Enter R = N2/N1, solve for N1 and N2**
R **0.5**
λ1 (Group 1 Event Rate)..... **0.0005**
RR0 (Ratio of Event Rates under H0)..... **1**
Enter λ2 or Ratio for Group 2..... **RRa (Ratio of Event Rates under H0)**
RRa (Ratio of Event Rates under Ha)..... **4**

Design Tab

Decimals for Event Rates **4**

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Output

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

Numeric Results

Solve For: Sample Size
Groups: 1 = Control, 2 = Treatment
Alternative Hypothesis: One-Sided (H0: RR ≤ RR0 vs. Ha: RR > RR0)
Test Statistic: W5 = Variance Stabilized

	Sample Size			Group Allocation Ratio	Exposure Time		Average Event Rate		Event Rate Ratio		
Power	N1	N2	N	R	t1	t2	λ1	λ2a	Ha RRa	H0 RR0	Alpha
0.90001	8590	4295	12885	0.5	2	2	0.0005	0.002	4	1	0.05

These results match the more accurate value of 8590.

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