

Introduction to Biostatistics (BIOS 4120)  
Breheny

Quiz 4 (Practice)

1. Erectile dysfunction (the persistent inability to achieve or maintain an erection sufficient for satisfactory sexual performance) is estimated to affect up to 30 million American men. Sildenafil (later sold under the brand name Viagra) was developed as an oral therapy for the treatment of erectile dysfunction. The results of the first clinical trial of this drug were published in 1998. In the trial, 155 men were randomized to receive Sildenafil, and 155 men were randomized to receive a placebo. The men remained on the drug/placebo for 12 weeks.

- (a) In the study, the Sildenafil group averaged 5.9 successful attempts at sexual intercourse per month, compared to 1.5 for the placebo group. The pooled standard deviation is 4.5. Is the drug effective at increasing the number of successful attempts at sexual intercourse? In support of your answer, provide (i) an estimate of the effect of Sildenafil on number of successful attempts, (ii) a confidence interval for that effect, and (iii) test the hypothesis that Sildenafil has no effect on the number of successful attempts at successful intercourse.

$$i) \bar{x}_1 - \bar{x}_2 = 5.9 - 1.5 = 4.4$$

Sildenafil increased the number of successful attempts by 4.4/month

$$ii) SE = 4.5 \sqrt{\frac{1}{155} + \frac{1}{155}} = 0.511$$

$$df = 155 + 155 - 2 = 308$$

$$t_{95\%, df=308} = 1.97$$

$$95\% CI: 4.4 \pm 1.97(0.511) = [3.4, 5.4]$$

$$iii) t = \frac{4.4}{0.511} = 8.6 \Rightarrow p < 0.0001$$

conclusion: Sildenafil is effective at increasing the number of successful attempts at sexual intercourse.

- (b) The investigators also recorded the number of men who were able to successfully have sexual intercourse during the trial. In the study, 107 men on Sildenafil were able to successfully have sexual intercourse, compared with 34 in the placebo group. Is the drug effective at increasing the probability of successful intercourse? To answer this question, provide (i) an estimate of the effect of Sildenafil on probability of successful intercourse, (ii) a confidence interval for that effect, and (iii) test the hypothesis that Sildenafil has no effect on probability of successful intercourse.

Able?

i)

|            | Y   | N   |     |
|------------|-----|-----|-----|
| Sildenafil | 107 | 48  | 155 |
| Placebo    | 34  | 121 | 155 |

$$\hat{OR} = \frac{107 \cdot 121}{34 \cdot 48} = 7.93$$

Sildenafil increased the odds of successful intercourse by 693%

ii)  $\log(\hat{OR}) = 2.07$

$$SE_{\log OR} = \sqrt{\frac{1}{107} + \frac{1}{48} + \frac{1}{34} + \frac{1}{121}} = 0.260$$

95% CI for  $\log(OR)$ :  $2.07 \pm 1.96(0.260) = [1.56, 2.58]$

95% CI for OR:  $[e^{1.56}, e^{2.58}] = [4.8, 13.2]$

- iii) If Sildenafil had no effect, we would expect

|   | Y    | N    |
|---|------|------|
| S | 70.5 | 84.5 |
| P | 70.5 | 84.5 |

$$\begin{aligned} \chi^2 = & \frac{(107-70.5)^2}{70.5} + \frac{(34-70.5)^2}{70.5} \\ & + \frac{(48-84.5)^2}{84.5} + \frac{(121-84.5)^2}{84.5} \end{aligned}$$

$$= 69.3 \Rightarrow p < 0.0005$$

Conclusion: Sildenafil is highly effective at increasing the odds of successful intercourse