

A small study investigates the effect oral contraceptives have on blood pressure. Ten female volunteers who are not using oral contraceptives are recruited for the study. Each subject has her baseline blood pressure measured at the beginning of the study at which time she begins to take an oral contraceptive daily. After two months, blood pressure is again measured for each subject. The data (systolic blood pressure in mm Hg) is summarized as R output below.

	[,1]	[,2]	[,3]	[,4]	[,5]	[,6]	[,7]	[,8]	[,9]	[,10]
Subject	1	2	3	4	5	6	7	8	9	10
oralContraceptive	128	115	106	128	122	145	132	109	102	117
noOralContraceptive	115	112	107	119	115	138	126	105	104	115

The mean and SD of the oral contraceptive measurements are 120.4 and 13.2. The mean and SD of the baseline measurements are 115.6 and 10.3. The mean and SD of the pairwise differences (oral contraceptive - baseline) are 4.8 and 4.6. Please use the back of the paper if you need additional space to answer the questions.

- (a) State whether this data should be analyzed using paired sample techniques or two independent sample techniques. Provide a brief justification of your response.

Solution: Paired techniques are appropriate. There are two observations per subject, and these observations are paired. There is a single sample of ten individuals.

- (b) Use a  $t$ -test to test if oral contraceptive use has an effect on blood pressure. If you carry out an independent sample test, you may use the fact there are 17 degrees of freedom. State hypotheses, compute a test statistic, find a  $p$ -value (or a range for the  $p$ -value), and interpret the results of the test in the context of the problem.

Solution: Hypotheses:

$$H_0: \mu_d = 0 \quad H_A: \mu_d \neq 0$$

The  $t$  test statistic is

$$t = \frac{4.8}{4.6/\sqrt{10}} = 3.30.$$

The  $p$ -value is 0.0092 from R. Using your  $t$  table, there are 9 degrees of freedom and the area to the right of 3.30 is between 0.005 and 0.0005. Thus,  $0.001 < p < 0.01$ .

Conclusion. There is fairly strong evidence ( $p < 0.01$ , two-sided paired  $t$ -test) that blood pressure changes on average in the population after women begin taking oral contraceptives.

- (c) What statistical assumptions must you make to conclude that the results in part (b) are valid?

Solution: We assume that the women are equivalent to a random sample from the population of interest. We assume that changes in blood pressure after beginning use of oral contraceptives is normally distributed.

- (d) What further assumptions must you make to conclude that oral contraceptive use have a causal effect on systolic blood pressure?

Solution: We would need to assume that there were no other confounding factors that might have caused a change in blood pressure for the sampled women in the study other than their oral contraceptive use.

- (e) For purely statistical reasons, one might have considered a double blind study with women randomized into a control group who took a placebo and a treatment group who took an oral contraceptive. Explain why this study would not be ethical.

Solution: All women volunteered to participate in the study with the knowledge that they might be taking an oral contraceptive. (It would not be ethical to hide this fact from the volunteers.) More importantly, the women are taking the oral contraceptive to prevent pregnancy (or other medical reasons), not to control blood pressure. The women in the study would need to know if they were protected from becoming pregnant.

- (f) Find the  $p$ -value for a sign test with the alternative hypothesis that the oral contraceptive use results in an increase in systolic blood pressure. You may use the following R output of the binomial distribution for  $n = 10$  and  $p = 0.5$ .

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> round(dbinom(0:10, 10, 0.5), 3)
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[1] 0.001 0.010 0.044 0.117 0.205 0.246 0.205 0.117 0.044 0.010 0.001
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Solution to Exam 6

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Solution: Eight of ten women had increases in blood pressure. The probability of this by chance is the sum of binomial probabilities of eight or more successes when  $n = 10$  and  $p = 0.5$ .

$$0.044 + 0.010 + 0.001 = 0.055$$