

## UNIT 6 HOMEWORK

Read the following abstract before answering the questions that follow:

**Background:** Recent research demonstrated that vitamin D, apart from calcium-related actions, has antiproliferative, prodifferentiative and immunomodulatory activities.

**Objective:** To determine whether actinic keratoses may benefit from the antiproliferative and prodifferentiative effects of topical vitamin D.

**Materials and Methods:** The study was an investigator-blinded, half-side comparison trial. Patients applied calcipotriol cream to one side and Ultrabase cream as placebo to the other side of the scalp and/or face for 12 weeks. The total number of actinic keratoses (AKs), diameters and total scores of the target lesions were determined at each visit.

**Results:** Nineteen patients were included, eighteen of whom completed the treatment. The mean total score of the target lesions reduced significantly at week 12 on calcipotriol side; however, no significant reduction was found on placebo side ( $p=0.017$  vs  $p=0.056$ ). Although side effects were more common on calcipotriol side, the difference was not statistically significant.

**Conclusion:** Topical calcipotriol may show promise in the treatment of actinic keratoses. More studies are needed to confirm its efficacy.

Question 1:

What conclusion(s) might you infer from the results of this study?

1. Topical vitamin D (calcipotriol) was significantly better than the placebo cream at reducing actinic keratoses.
2. Topical vitamin D (calcipotriol) was effective at reducing actinic keratoses, whereas the placebo cream was totally ineffective.
3. You should not infer any conclusions from a study with so few patients.
4. The difference between the creams may not be statistically significant.

Question 2:

What is the unit of observation for this study?

1. a person
2. a side of the face
3. a single actinic keratosis lesion

Question 3:

TRUE or FALSE. This study involves correlated observations.

1. True
2. False

Question 4:

The following tables come from a 2006 study on breast cancer and coffee that appeared in the Journal of Nutrition, entitled: "Consumption of Coffee, but Not Black Tea, Is Associated with Decreased Risk of Premenopausal Breast Cancer." J Nutr 136: 166-171.

TABLE 2. Adjusted Odds Ratios for premenopausal women (n=878) for the association between regular coffee, decaffeinated coffee, or black tea consumption and risk of breast cancer.

Beverage consumption	Adjusted OR (95% CI)
Regular coffee	
None	1.0
<1 cup/d	1.23 (0.73-2.07)
1 cup/d	0.95 (0.52-1.71)
2-3 cups/d	0.94 (0.65-1.39)
4+ cups/d	0.62 (0.39-0.98)
	P for trend = 0.03
Decaffeinated coffee	
None	1.0
<1 cup/d	0.80 (0.54-1.19)
1 cup/d	1.05 (0.67-1.63)
2-3 cups/d	1.12 (0.071-1.76)
4+ cups/d	0.88 (0.51-1.52)
	P for trend = 0.92
Black tea	
None	1.0
<1 cup/d	0.95 (0.68-1.35)
1 cup/d	0.94 (0.61-1.46)
2-3 cups/d	1.08 (0.73-1.65)
4+ cups/d	1.02 (0.56-1.86)
	P for trend = 0.72

TABLE 3. Adjusted Odds Ratios for postmenopausal women (n=2949) for the association between regular coffee, decaffeinated coffee, or black tea consumption and risk of breast cancer.

Beverage consumption	Adjusted OR (95% CI)
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Regular coffee	
None	1.0
<1 cup/d	0.89 (0.69-1.15)
1 cup/d	0.93 (0.73-1.19)
2-3 cups/d	1.11 (0.92-1.34)
4+ cups/d	0.99 (0.79-1.23)
	P for trend = 0.57
Decaffeinated coffee	
None	1.0
<1 cup/d	0.95 (0.76-1.18)
1 cup/d	0.92 (0.73-1.17)
2-3 cups/d	0.83 (0.67-1.01)
4+ cups/d	0.88 (0.65-1.20)
	P for trend = 0.12
Black tea	
None	1.0
<1 cup/d	1.20 (0.97-1.48)
1 cup/d	1.03 (0.80-1.31)
2-3 cups/d	1.17 (0.92-1.49)
4+ cups/d	0.93 (0.67-1.29)
	P for trend = 0.78

The authors also examined associations between coffee, black tea, and decaffeinated coffee within within ductal and lobular histologic subtypes of breast cancer. They write in the text of the paper that: “premenopausal women who consumed  $\leq 1$  cup of coffee/d showed a significant increase in risk of lobular breast cancer (adjusted OR = 3.54, 95% CI 1.17–10.7), although similar elevations were not noted for women who consumed  $\geq 2$  cups/d (OR = 1.84, 95% CI 0.65–5.19). In addition, when consumers of any amount of black tea were compared with nonconsumers of black tea, the observed reduction in risk among premenopausal lobular types was also significant (OR = 0.52, 95% CI 0.28–0.97). In contrast, for postmenopausal women, there were generally no associations between any of the beverages and either ductal (1008 cases) or lobular carcinoma (181 cases; data not shown).”

The authors conclude that coffee consumption is associated with a decreased risk of premenopausal breast cancer.

Do you think that the evidence supports their conclusion? Why or why not?

1. Yes, these data provide strong support that coffee consumption and premenopausal breast cancer are linked.
2. Yes, these data provide modest evidence of a link between coffee consumption and premenopausal breast cancer.
3. No, the significant p-values likely represent chance findings.
4. No, there are no significant p-values so there is no evidence of an effect.

Question 5:

What is the unit of observation in this study?

1. a person.
2. a tumor.
3. a cup of coffee.
4. twin pairs.

Question 6:

TRUE or FALSE. The observations in this study are correlated.

1. True
2. False

The following risk ratios give the increased or decreased risk for various diseases comparing two groups (exposed vs. unexposed).

- a. 2.5 (2.0, 3.0)
- b. 1.03 (1.02, 1.04)
- c. 6.0 (.85, 9.8)
- d. 0.98 (0.88, 1.08)
- e. 0.20 (.05, 1.05)

Question 7:

Which risk ratios are clinically significant? You may choose more than one.

a b c d e

Question 8:

Which risk ratios are statistically significant at the 0.05 level? You may choose more than one.

a b c d e