M.Sc. in Evidence Based Practice

Module: Clinical Biostatistics

Examination, Tuesday 20th June 2006

You have two hours for this examination. You will be given the published papers used in it one week before the examination. The examination is open book and you will be allowed to bring any books or notes you wish into the examination.

Answer all questions. Each question carries equal marks.

Questions 1 to 7 are about the paper 'Randomised placebo controlled multicentre trial to assess short term clarithromycin for patients with stable coronary heart disease: CLARICOR trial'.

1. The authors report (results, paragraph 1) that all tablets were reported taken by 90.0% (1954 patients) in the clarithromycin arm and 93.7% (2061) in the placebo arm, $P < 0.0001$. What do they mean by '$P<0.0001$' and what can we conclude from this?
2. In the second paragraph of the results, the authors say 'The primary outcome (all cause mortality or non-fatal cardiac outcomes) did not differ significantly between the clarithromycin and placebo arms (15.8% *v* 13.8%; hazard ratio 1.15, 95% confidence interval 0.99 to 1.34; $P = 0.08$).' What is meant by 'primary outcome' and why is it important to identify one? When should this be done?
3. What is meant by 'did not differ significantly' and what should we conclude about the risk of the primary outcome following clarithromycin?
4. What is a hazard ratio and how can we interpret a hazard ratio = 1.15?
5. Figure 2 shows a Kaplan Meier estimate What is this? What would you conclude from Figure 2?
6. The authors report that the tertiary outcome was significantly more frequent in the clarithromycin arm than in the placebo arm ($P = 0.03$), the number of non-fatal tertiary outcomes was insignificantly increased by 16% ($P = 0.09$), all cause mortality was significantly higher ($P = 0.03$), as was cardiovascular mortality ($P = 0.01$), and non-cardiovascular mortality and non-classified mortality did not differ significantly between groups. Why should we not conclude from these P values that there is good evidence of increased risk with clarithromycin and what method can we use to examine these P values?

Questions 7 to 12 are about the paper Long term outcomes from the IMPACT randomised trial for depressed elderly patients in primary care

7. In Table 1, what is meant by 'Difference in percentage points between groups'?
8. For any antidepressant medication, 24 month follow-up, what is '(8.69 to 19.14)' and what can we conclude from it?
9. What method would be used for the calculation of the P values in Table 1 and why?
10. In Table 1, what is P = 0.7592 testing for the baseline? Is this a meaningful thing to do?
11. In Table 2, the 24 month follow-up of the overall quality of life score has mean 6.08 and standard deviation 2.22 for the usual care group. What do these numbers mean and how can we interpret them?
12. In Table 2, the 24 month follow-up of the overall quality of life score has a 95% confidence interval for the difference (0.03 to 0.49), P = 0.0296. What method would be used to calculate these and why?