**PBIO 504 Homework RCT**

**Analysis of Randomized Controlled Trials (RCT)**

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***Problem 1***

The Anturane Reinfarction Trial tested a drug called sulfinopyrazone (Anturane) versus a placebo pill in patients who had suffered a myocardial infarction (heart attack). The drug was designed to improve survival in such patients; therefore the primary outcome variable they were trying prevent was mortality (death). A total of 800 patients were randomly assigned to take Anturane, and there were 70 deaths in this group after 6 months of follow up. In the placebo group of 810 patients, 87 deaths occurred during this time period. Place the data into the table below, note the difference in mortality proportions, and then calculate the RR and 95% CI. If you were the director of this RCT, and you had to write a scientific journal article to describe the effect of Anturane in lowering mortality in such patients, what would you write, and why?

**Anturane Reinfarction Trial results.**

|  |  |  |  |
| --- | --- | --- | --- |
| Group | **Dead**  Number (%) | **Alive**  Number (%) | Total Number |
| Anturane | 70 (8.7%) | 730 (91.3%) | 800 |
| Placebo | 87 (10.7%) | 723 (89.3%) | 810 |

a) Results:

RR: (A/(A+B)/(C/C+D) = (70/800)/(87/810) = .814 = 81.4%

95% CI: .604-1.098

b) Your report about the results:

No significant difference in risk of death between the two treatment groups (Anturane and the placebo)

c) If we are informed that in fact only 75% of the people assigned to Anturane took the pill and among those 75% of patients, only 4% died. Will you change your conclusion based on the information provided and why? (You only need to provide calculation if you think it is necessary).

Yes, my conclusion would certainly change because 4% death in the Anturane group is significantly lower than death of 10.7% in the placebo group, and so the risk of death when using Anturane decreases in comparison to the placebo group.

***Problem 2***

The Cancer Education Project was a randomized, controlled trial testing the efficacy of two different cancer education methods to reduce patient anxiety about having a colonoscopy test to screen for colorectal cancer. All patients came to a clinic where they were randomized to one of two methods of health education. The “usual care” (control) method provided a pamphlet (brochure) to the subject, who was instructed to take it home and read it, and then fill in a brief questionnaire to be handed in at the clinic on the day of their test. Those who filled in the questionnaire were considered to have complied with the instructions. The test method consisted of a 10-minute video that the subjects viewed in the clinic; they too were supposed to fill in a questionnaire at home and bring it back later. Each subject was asked on the colonoscopy day whether or not they were anxious. An investigator looked at the data and was convinced that the video was beneficial. He maintained that those patients who saw the video and turned in a questionnaire had the best outcome; he suggested that the appropriate comparison to evaluate the efficacy of the video would be between video compliers and all study participants in the usual care group. Here are the study results.

**Cancer Education Project Results.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
|  | Compliers | | Non-compliers | | Total | |
| Test group | Anxious | Not anxious | Anxious | Not anxious | Anxious | Not anxious |
| Video | 191 | 269 | 409 | 101 | 600 | 370 |
| Pamphlet | 514 | 301 | 315 | 172 | 829 | 473 |

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Determine if there is a significant difference in the occurrence of anxiety between:

(a) video compliers versus all participants who got the pamphlet (the suggested analysis): fill in table 3A

(b) all participants in the video group versus all participants in the pamphlet group: fill in table 3B

Table 3A. Video compliers versus all participants who got the pamphlet

|  |  |  |
| --- | --- | --- |
|  | Anxious | Not anxious |
| Video compliers | 191 | 269 |
| All who received the pamphlet | 829 | 473 |

RR: (A/(A+B)/C/(C+D) = (191/460)/(829/1302) = .65 = 65%

95% confidence interval:​​ .58-.73

Interpretation: There is a significant difference in the occurrence of anxiety between video compliers versus all participants who got the pamphlet and the null hypothesis can be rejected.

Table 3B. All participants in the video group versus all participants in the pamphlet group

|  |  |  |
| --- | --- | --- |
|  | Anxious | Not anxious |
| All video recipients | 600 | 370 |
| All pamphlet recipients | 829 | 473 |

RR: (600/970)/(829/1302) = .971 = 97.1%

95% confidence interval:​​ .97-1.04

Interpretation: there is no significant difference in occurrence of anxiety between all participants in the video group versus all participants in the pamphlet group and the null hypothesis cannot be rejected.

Is it appropriate to use the analysis suggested by the investigator? No

What is the reason for your answer, according to the evidence you see in the data?​​

The problem lies in the questions posed in each randomized trial and the discrepancy in the significance of the results, a more thoughtful proposal would be to check the pamphlet compliers against the video compliers.