# Study Assessment

•••

### **RESEARCH METHODS**

Danu Caus, Massimo Innocentini, Nambiar Shruti Surendrakumar

## STUDY 1

Study of the Therapeutic Effects of Intercessory Prayer (STEP) in cardiac bypass patients

### HYPOTHESES

Study tries to evaluate whether prayer itself or the certainty whether prayer is being provided influences recovery from illness.

H0: Receiving intercessory prayer or being certain of receiving intercessory prayer is associated with complicated recovery after CABG (coronary artery bypass graft) surgery

H1: Receiving intercessory prayer or being certain of receiving intercessory prayer is associated with complication-free recovery after CABG surgery

There are 3 groups of people created <u>using randomization</u>:

Group 1: Received intercessory prayer after being told they may or may not receive it

Group 2: Did NOT receive intercessory prayer after being told they may or may not receive it

Group 3: Received intercessory prayer after being explicitly told they will receive it

The study was *double blind*: people conducting the study were unaware about the group that each patient was assigned to.

In Group 3, there might be confounds like: *psychological factor*, namely: patients may have suffered additional stress from learning they actually needed prayer as it could mean their condition was severe

Group 2 is used as the comparison group, but there is no proper control group

For a more complete outcome, it would have been desirable to have a 4th group with people that did not receive IP and were told explicitly they would not.

There were no eligibility criteria relating to religious belief, patients of any or no religious faith were eligible to participate - this is good since it will allow the study of prayer alone, not the factor of belief itself. Also this variable was controlled through the randomization process.

The prayers were standardized to contain "for a successful surgery with a quick, healthy recovery and no complications" - This makes the experiment reproducible and also removes the "prayer type" variable, which would create another question to answer about the effect of different types of prayers.

The prayers were all christian, although the patients were affiliated to a broad religious spectrum - This removes the factor of GOD or actual religious belief and limits the study to the effect of prayer alone. On the other hand it can be considered as a limitation of the experiment that could not be overcome.

### **ANALYSIS**

Complications for Group 1: 52%

Complications for Group 2: 51%

Complications for Group 3: 59%

Major events and 30-day mortality were similar across all groups

Patients is Group 3 were consistently more likely to have a complication than those in Group 1 - this suggests that IP alone does not have an effect, but also others like - the factor of "knowing" and any psychological effects that derive from this or variation in exposure to non-study prayer from family, friends, self etc.

In the analysis it is mentioned that they would use Chi Square test to compare the baseline and outcome categorical variables (in other words to show if the observations are plausible based on the baseline statistics), but at the end the results are not stated.

### CONCLUSION

The conclusions given were appropriate according to the results and the authors acknowledged the shortcomings of the study.

They compare the results obtained with other studies.

Intercessory prayer had no effect on the recovery from CABG, but certainty of receiving IP was associated with a higher incidence of complications. The authors do not claim why this is the case, but rather give possible reasons. They however do not state an obvious candidate amongst all reasons, which is: the psychological factor.

## STUDY 2

# Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize

### **HYPOTHESES**

The authors try to address multiple questions with regards to toxicity evaluation of herbicides on mammals

- How does the duration of performing rodent feeding studies (short-term vs. long-term) affect the assessment of the toxic effects arising from genetically modified plants and herbicides?
- What are the potential toxic effects of the total chemical formulation rather than just the active constituent?
- They also try to answer whether low doses of R (lower than permitted by authorities) pose a health hazard.

In general it is safe to say they try to address a "lack of information" as they put it, regarding all of the above statements.

### HYPOTHESES 2

They test the following hypotheses in a 2-year long rat feeding study using R-tolerant NK603 maize for the GMO and Roundup as the herbicide -

- H1: Toxic health effects in the rats are caused by the genetic modification in GMOs alone (i.e. the transgene)
- H2: Toxic health effects in the rats can be caused by Roundup-tolerant GMOs and GMOs treated with Roundup herbicide (even below legal levels)
- H3: Toxic health effects in the rats are due to the formulated herbicide mixture used on the Roundup and not the active component (glyphosate) alone

Used rats: virgin albino "Sprague Dawley"

#### There were 4 scenarios:

- 1. Administer diets with 11% 22% 33% GM corn (NK603) NOT treated with Roundup pesticide
- 2. Administer diets with 11% 22% 33% GM corn (NK603) treated with Roundup pesticide
- 3. Administer diets with GM corn NOT treated with pesticide, but using the Roundup in water
- 4. Administer normal corn (not genetically modified) to the control group.

Control treatment of the rest of the diet is not documented and unclear (Could some of the non-treated food consumed have had any affect? Was the diet balanced?)

The study assessed 200 rats: 100 males + 100 females split in 20 groups of 10 rats separated by gender (Major disobedience: For study of tumours, the protocol suggests 50 rats per group! At least 30 rats would be enough for statistical purposes. The protocol states 50 for a reason... The authors do not give arguments as to why they disregarded guidelines, suggesting that they somehow compensate with longer study time and regular measurements, which is not an argument)

The length of the experiment was also appropriate for the study since toxicity can manifest after a long time. On the other hand, tumours are more likely to appear at old age, and they do not state the age when tumours appear.

Control groups were present but not all treatment groups had corresponding control groups - for eg. the groups with different doses of Roundup lacked control group comparisons

### **ANALYSIS**

As only 10 rats were used per group (instead of the protocol suggested 50), gathered results are not enough for statistical significance.

Effects were tested on only one kind of rat, but analysis seems generalized

Some tumours may actually not be cancerous. The authors do not say if they are benign or not.

The authors do not address the cases where the control rats also have tumours (they also do not show pictures of the control rats with tumours, that are said to exist in the presented graphs. Not showing control rat images might be biased and misleading)

### CONCLUSION

The conclusion of the authors is that GMOs do cause tumours according to their results and that they can be explained by:

- Roundup pesticide disrupts the endocrine system and hence causes severe hormonal imbalance.
- The GMO overexpressed transgene has metabolic consequences on the body ingesting the GMO.

Authors claim that GMOs cause in particular kidney and liver damage for all rats and in the case of females: mammary tissue tumours.