

Assignment

1. Complete article citation
2. Provide the basic goals of the study: background, motivation, results, conclusion. (3-4 sentences total)
3. Describe the treatment arms: details of what the treatment groups underwent
4. Experimental Design: who, how they were recruited, how many individuals, experiment vs. observational study, funding, blindness, randomization
5. Who was removed from the study and why (to the extent they tell you)
6. A description of the variables in our dataset (you don't have to give info on all variables in the entire manuscript). Remember to include units and any coding (e.g., 1=male 0=female).
7. Optional: anything interesting you want to tell us from the manuscript.

Example

1. Bernard, G. R., A. P. Wheeler, et al. (1997). "The effects of ibuprofen on the physiology and survival of patients with sepsis. The Ibuprofen in Sepsis Study Group." *N Engl J Med* 336: 912-8.
2. The goal of the study is to determine whether taking ibuprofen will increase survival and improve health of patients with sepsis (blood poisoning). The ibuprofen group showed improvements in some areas (urinary levels of prostacyclin and thromboxane, temperature, heart rate, oxygen consumption, and lactic acidosis), but they showed no statistically significant improvement in other areas (duration of shock, acute respiratory distress syndrome, overall survival at 30 days). Ibuprofen has some beneficial effects, though it does not improve survival significantly (note: the ibuprofen group, however, did have a lower mortality rate).
3. This study had only two treatment arms, an ibuprofen group and a placebo group:
 - **Ibuprofen:** given intravenously in a dose of 10mg / kg over a period of 30 to 60 minutes every 6 hours for eight doses
 - **Placebo:** same as ibuprofen, but a glycine-buffer was given instead (same volume, same times)
4.
 - Seven medical centers in the US and Canada participated. Patients were recruited if they had known or suspected serious infection (if they met criteria for sepsis as described by Bone et al. 1987). Patient must have also met various clinical variables including: core temp between 38.3°C and 35.5°C, heart rate of at least 90 beats per min, and a respiratory rate of 20 breaths per minute. Patient must also have had symptoms related to at least one additional organ system: heart, renal-system, respiratory-system, pulmonary-system, or central nervous system.
 - 455 patients were enrolled, 224 in the treatment arm, 231 in the control arm

- The study was a double blind randomized experiment.
 - The study was supported by grants from the National Heart, Lung, and Blood Institute and by the Bernard Werthan, Sr., Fund for Pulmonary Research. The Upjohn Company provided the ibuprofen (Motrin).
5. Patients were excluded if they were pregnant, under 18 years old, has suspected hypersensitivity to cyclooxygenase (COX) inhibitors (aspirin, ibuprofen), had received a COX inhibitor in the last 12 hours, were enrolled in another study, or if consent could not be obtained. Patients were also excluded if they were thought to have less than six hours to live (see paper for more complete details).

6. Variables

- id; patient ID, presumably made up for the textbook
 - treat; treatment: treat=1 is ibuprofen, treat = 0 is placebo
 - race; patient's race: race=0 is white, race=1 is black, race=2 is other
 - apache; patient's APACHE score: a measure of the severity of disease, integer between 0 and 71, higher scores imply a more severe disease and a higher risk of death
 - o2del; patient's oxygen delivery at baseline measure in ml per minute per m² of body surface area
 - fate; patient's survival at end of study: fate=1 died, fate =0 survived
 - followup; hours from randomization (baseline) until death; all follow-up times are censored at 30 days (720 hours). Note: death after 30 days are rarely due to patient's systemic infection.
 - temp0; patient's baseline temperature in Fahrenheit
 - temp1; temp at 2 hours post baseline
 - temp2; temp at 4 hours post baseline
 - temp3; temp at 8 hours post baseline
 - temp4; temp at 12 hours post baseline
 - temp5; temp at 16 hours post baseline
 - temp6; temp at 20 hours post baseline
 - temp7; temp at 24 hours post baseline
 - temp8; temp at 28 hours post baseline
 - temp9; temp at 32 hours post baseline
 - temp10; temp at 36 hours post baseline
 - temp11; temp at 40 hours post baseline
 - temp12; temp at 44 hours post baseline
 - temp13; temp at 72 hours post baseline
 - temp14; temp at 96 hours post baseline
 - temp15; temp at 120 hours post baseline
7. When I downloaded the paper online, there was a correction in the form of a note from a peer researcher. His point was that taking ibuprofen can be quite risky for patients with sepsis. He felt the risks were overlooked in the NEJM paper (citing research with opposite conclusions). Bernard et al. respond that the benefits outweigh the risks.