

Cholangitis data

STAT 131A (Fall 2022)

Description of data

The data are from a randomized, double-blinded, placebo-controlled clinical trial of the immunosuppressive drug D-penicillamine at the Mayo Clinic. Patients living with primary biliary cholangitis, a fatal chronic autoimmune disease of unknown cause affecting the liver, were referred to the Mayo Clinic. Of these, 312 were enrolled in the study and randomized to receive the drug or placebo. An additional 106 patients were enrolled, but did not consent to randomization so they received neither the drug nor the placebo. The resulting data thus includes observations from 418 patients. Of these 418, 25 patients received a liver transplant and were dropped from the study because they were in effect “cured” of primary biliary cholangitis. Note that the data related to the variables listed after **drug** were collected from each patient at the beginning of the study, prior to randomization to either drug or placebo.

Table 1: Description of variables.

| Variable | Description |
|---------------------|---|
| id | Unique identifier |
| n_days | Number of days between registration and the earlier of: death, transplantation, or end of study |
| status | Status of the patient at end of study: C (not dead), CL (received liver transplant), or D (died) |
| drug | Drug received: D-penicillamine or placebo |
| age | Age at enrollment [days] |
| sex | M (male) or F (female) |
| ascites | Presence of ascites: N (No) or Y (Yes) |
| hepatomegaly | Presence of hepatomegaly: N (No) or Y (Yes) |
| spiders | Presence of spider angiomas: N (No) or Y (Yes) |
| edema | Presence of edema: N (no edema and no diuretic therapy for edema), S (edema present without diuretics, or edema resolved by diuretics), or Y (edema despite diuretic therapy) |
| bilirubin | Serum bilirubin in [mg/dl] |
| cholesterol | Serum cholesterol in [mg/dl] |
| albumin | Albumin in [gm/dl] |
| copper | Urine copper in [ug/day] |
| alk_phos | Alkaline phosphatase in [U/liter] |
| sgot | Serum glutamic-oxaloacetic transaminase in [U/ml] |

| Variable | Description |
|----------------------|--|
| triglycerides | Triglycerides in [mg/dl] |
| platelets | Platelets per cubic [ml/1000] |
| prothrombin | Prothrombin time in seconds [s] |
| stage | Histologic stage of disease: 1, 2, 3, or 4 |

Table 2: First 8 columns and a random selection of rows from the data.

| id | n_days | status | drug | age | sex | ascites | hepatomegaly |
|-----|--------|--------|-----------------|-------|-----|---------|--------------|
| 218 | 2170 | C | D-penicillamine | 12636 | F | N | N |
| 276 | 1481 | C | D-penicillamine | 18302 | F | N | N |
| 52 | 2386 | D | D-penicillamine | 18460 | M | N | N |
| 171 | 2574 | C | D-penicillamine | 19237 | F | N | N |
| 378 | 1168 | D | NA | 21915 | F | N | Y |
| 197 | 2365 | C | D-penicillamine | 16300 | F | N | N |