

Analysis Data Set from the EDIC Eight Year Nephropathy Paper*

(*DCCT/EDIC Research Group. Sustained effect of intensive treatment of type 1 diabetes mellitus on development and progression of diabetic nephropathy. American Medical Association 2003.)

FORMAT: The data set is named “EDICREN8”, and is stored in a **SAS** export library.

STRUCTURE: One record per patient per EDIC year (1349 patients, EDIC year 0-8, 11745 observations in total) containing both outcome variables and covariates from DCCT closeout (EDICYEAR=0) to EDIC year 8.

CONTENTS: A complete SAS contents listing is attached separately.

Summary Statistics: A complete summary statistics (mean/std for continuous variables, frequency for categorical variables) is attached separately.

Data Collection: Renal data and lipid data are collected every other year during EDIC. So every year there is one half of the cohort having renal or lipid data. No medication data was collected during DCCT, therefore, medication data is missing when EDICYEAR=0.

Naming Conventions:

1. P_XX: Indicator of prevalence of an event at a particular EDIC year: 1:yes/ 0:no.
2. CI_XX: Indicator of cumulative incidence of an event by a particular EDIC year: 1:yes/0:no.
3. NEW_XX: Indicator of the first incidence of an event at a particular EDIC year: 1:yes/0:no.
4. XXX00: 00 refers to DCCT baseline visit
5. XXX99: 99 refers to DCCT closeout visit, which is EDICYEAR=0.
6. EDXXX: latest EDIC status (DEAD/ACTIVE) through EDIC year 8 or status change date for every patient.

Definition of Main Outcome and Covariates:

1. **Albumin Excretion Rate (AER).** Four-hour timed collection at every other year during EDIC.

The **AER** data are presented as the unit of ug / min. They can be transformed to mg/24 hrs.

The formula is:

$$\begin{aligned} &(\text{mg}/24\text{hrs}) * (1000 \text{ ug}/\text{mg} / (60\text{min}/\text{hour} * 24\text{hrs})) = (\text{ug} / \text{min}) \\ &\text{or } (\text{mg}/24\text{hrs})/ 1.44 = (\text{ug}/ \text{min}) \end{aligned}$$

Example:

AER = 40 mg/ 24hrs equals **AER** = 28 ug/ min. (rounded up to the closest integer)

2. **Microalbuminuria:** AER > 28 ug/min or if a patient had dialysis or kidney transplant.
3. **Albuminuria:** AER > 208 ug/min or if a patient had dialysis or kidney transplant.
4. **Serum Creatinine** (mg/dl): collected annually during EDIC.

5. **Iothalamate Clearance (GFR)**, an I-125 iothalamate clearance was done simultaneously with **AER** at DCCT study termination. **GFR** adjusted of the baseline body surface area: presented as ml/min/1.73m²

6. **Blood Pressure (mm Hg)**, measured annually during EDIC, only used annual data in this paper

- a. Diastolic blood pressure
- b. Systolic blood pressure
- c. Mean blood pressure: (2/3 diastolic blood pressure + 1/3 systolic blood pressure)

7. Hypertension:

Two definitions were used in the hypertension:

- a. >140/90, confirmed: systolic blood pressure > 90 mm Hg or diastolic blood pressure > 140 mm Hg or form reported hypertension, or on anti-hypertensive medication.
- b. > 130/80, unconfirmed: systolic blood pressure > 80 mm Hg or diastolic blood pressure > 130 mm Hg or form reported hypertension.

De-identification:

1. Replaced Patient ID with MASK Patient ID.
2. Stripped obvious identifier, like CLINIC, INITIALS, RACE, DOB, etc.
3. Shifted all the dates to days since DCCT randomization date.