

Analysis Data Set from the EDIC Eight Year Neuropathy Paper

Martin, CL, Albers J, Herman BH, Cleary P, Waberski B, Greene DA, Stevens MJ, Feldman EL: Neuropathy among the Diabetes Control and Complications Trial cohort 8 years after trial completion. *Diabetes Care* 29:340-344, 2006.

Format:

The data set name is “EDICNEU8”, and is stored in a SAS export library.

Structure:

One record per patient per EDIC year (1,398 patients, EDIC years 1-8, 10,543 observations in total).

Contents: A complete SAS contents listing is attached separately.

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

Data Collection:

DCCT: Data was collected through the following three sources:

1. Tests of the autonomic nervous system (ANS), administered biennially.
1. Nerve conduction testing, administered at baseline, five years, and study end. Testing was carried out on each of four peripheral nerves (median motor, median sensory, peroneal, and sural).
2. Physical examination and neurological histories, administered at baseline, five years, and study end by DCCT neurologists.

EDIC: Data was collected annually using the MNSI (Michigan Neuropathy Screening Instrument).

Naming Conventions:

1. **XX_HIGH:** Indicator variable of a clinical examination or questionnaire score corresponding to the presence of neuropathy (1=yes/0=no).
2. **SUMXXX:** Variable indicating the total number of amputations, foot/leg ulcers through EDIC year 8 for every patient.

Definition of Main Outcomes:

1. DCCT Neuropathy was defined as follows:
 - a. A finding of definite neuropathy unattributable to other causes on the history and physical examination, confirmed by unequivocal abnormality of autonomic function, abnormal conduction results in at least two anatomically distinct peripheral nerves, or both (DCCT_DN).
2. EDIC Neuropathy was defined as follows:
 - a. Seven or more positive responses on the MNSI questionnaire (PT_HIGH).

OR

- b. Score of <2.0 on the MNSI examination (C_HIGH).
3. Scoring variables:
 - a. PT_SCORE is the MNSI questionnaire score calculated by summing the first fifteen variables (EOB1-EOB15), and then subtracting the number of non-missing responses (variables taken from the neuropathy history section of the MNSI).
 - b. C_SCORE is the MNSI examination score calculated by the following algorithm (variables taken from the neuropathy screening instrument section of the MNSI):
$$C_SCORE = \text{sum}((EOCAL = 1), (EOCAR = 1), (EOC2L = 2), (EOC2R = 2), (0.5 * (EOC3L = 2) + (EOC3L = 3)), (0.5 * (EOC3R = 2) + (EOC3R = 3)), (0.5 * (EOC4L = 2) + (EOC4L = 3)), (0.5 * (EOC4R = 2) + (EOC4R = 3)))$$
 4. Lower-extremity events include a history or presence of lower-extremity ulcers requiring medical or surgical treatment and surgical or traumatic amputations.

De-identification:

1. Replace Patient ID with MASK Patient ID.
2. Strip obvious identifiers, such as CLINIC, INITIALS, RACE, etc.
3. Shift all the dates to days since DCCT randomization date.

NOTE. The dataset available for distribution to authorized users has been de-identified in this manner.