

March 30, 2004

Matching Results for Ancillary Study #132 Part 2:
A Prospective Study of Genetic and Biochemical Predictors of Type 2 Diabetes Mellitus

Case Selection:

All locally adjudicated cases of incident Diabetes Mellitus (DM) among Black, Hispanic, and Asian participants that were not involved in the first phase of case/control selection were selected as cases from the February 28, 2004 database from the WHI Observational Study. Both self report and medication use was used to classify a participant as having incident diabetes. The following mixes of these report methods determined eligibility:

Medication Use	Self - Report		
	<i>Yes</i>	<i>No</i>	<i>Missing</i>
<i>Yes</i>	Eligible Case	Eligible Case	Eligible Case
<i>No</i>	Not Eligible	Not Eligible	Not Eligible
<i>Missing</i>	Eligible Case	Not Eligible	Not Eligible

A potential case was then excluded if they possessed any of the following characteristics:

Baseline Glucose ≥ 126 mg / dl (only available for about 1% of the participants)
Inadequate Baseline Blood and DNA Supply
Baseline CVD (Defined as having a MI, Angina, Stroke, or CHF)
Refusal to participate in a genetic study
Confirmed No Antidiabetics Usage at AV-3 (for those participants who report incidence diabetes prior to AV-3)
Baseline Diabetes

Out of an original 396 minority cases of DM occurring after baseline, a total of 177 cases were excluded from the case set using the above criteria, leaving a total of 219.

Control Selection:

A potential control was excluded if they possessed any of the following characteristics:

Baseline Glucose ≥ 126 mg / dl (only available for about 1% of participants)
Inadequate Baseline Blood and DNA Supply
Baseline CVD (Defined as having a MI, Angina, Stroke, or CHF)
Refusal to participate in a genetic study
Antidiabetics Usage at AV-3
Baseline or Incident Diabetes

Selection of the remaining controls was done in a time-forward manner, selecting two controls for a minority case from the risk set at the time of the case's event.

The final control set used for matching consisted of 6,877 minority participants.

Matching criteria:

Matching is done on age at screening, blood draw time of day, ethnicity, and randomization clinic. Ethnicity and randomization clinic (the categorical variables) were matched exactly, and the continuous matching variables were selected based on a criteria to minimize an overall distance measure (Bergstralh EJ, Kosanke JL. Computerized matching of cases to controls. Technical Report #56, Department of Health Sciences Research, Mayo Clinic, Rochester, MN. April 1995). SAS code is available to implement this matching scheme.

Matching summary:

A total of 219 incident cases of DM and 6,877 controls were put into the matching process. 164 minority cases were successfully matched with two controls each (55 unmatchable cases). Three minority cases who were positive for AV-3 Diabetic Medications was initially selected for the study. An additional 130 cases were then selected via simple random sample from the remaining set of matched cases to give a total of 133 minority case / control sets. The final ethnic distribution of matched cases is as follows:

Ethnicity	Cases	Controls	Total
Black	76	152	228
Hispanic	38	76	114
Asian	19	38	57

Specific matching summaries are given in the table below. Each row summarizes the matching performance for a specific variable or overall criteria. For example, the mean case-control absolute difference in age is 0.55 years (just over 6 months), with a maximum of three years difference. The mean age for both the case and control groups is around 60. The mean case-control absolute difference in blood draw time (hours since midnight) is 0.49 hours. The 'overall' measurement represents the total of absolute deviations for all matching components. Thus, an overall average weight of 0.11 means that the total difference in age plus the total difference in blood draw time averages to 0.11. The weighting equates a deviation of one year in age to one hour in blood draw time. Ethnicity and Randomization Clinic are matched exactly for all subjects.

Balance on each covariate individually and overall is sufficient.

A. Minority Cases / Controls

Matching Factor	Sum (weighted) of Absolute Differences	Cases	Controls
	Mean (min, max)	Mean	Mean
Overall	1.04 (0, 4.08)	-	-
Ethnicity	0	-	-
Randomization Clinic	0	-	-
Age (years)	0.55 (0, 3.00)	59.96	60.06
Baseline Blood Draw Time (hours)	0.49 (0, 2.00)	9.89	9.84