

Integrity Check DCCT-EDIC Diabetic Nephropathy Analysis File

As a partial check of the integrity of the DCCT-EDIC datasets archived in the NIDDK data repository, a set of analyses were performed to verify that selected published results from the DCCT-EDIC study can be reproduced using archived datasets. A small number of analyses were performed to duplicate published results on diabetic nephropathy reported by the DCCT-EDIC Research Group in 2003 in the *Journal of the American Medical Association (JAMA, [290(16)])*. Results of the data integrity check are described below.

The intent of this integrity check is to provide confidence that the data distributed by the NIDDK repository is a true copy of the study data. Our intent is *not* to assess the integrity of the statistical analyses reported by study investigators. As with all statistical analyses of complex datasets, complete replication of a set of statistical results should not be expected on a first (or second) exercise in secondary analysis. This occurs for a number of reasons including differences in the handling of missing data, restrictions on cases included in samples for a particular analysis, software coding used to define complex variables, etc. Experience suggests that most discrepancies can ordinarily be resolved by consultation with the study DCC, however this process is labor-intensive for both DCC and Repository staff. It is thus not our policy to resolve every discrepancy that is observed in an integrity check. Thus, we do not attempt to resolve minor or inconsequential discrepancies with published results or discrepancies that involve complex analyses unless staff of the NIDDK Repository suspect that the observed discrepancy suggests that the dataset may have been corrupted in storage, transmission, or processing by repository staff. We do, however, document in footnotes to the integrity check those instances in which our secondary analyses produced results that were not fully consistent with those reported in the target publication.

DCCT-EDIC Nephropathy Analysis. The DCCT-EDIC Research Group reports results for 1349 participants who completed the DCCT study and were recruited into EDIC. Of these 1349, 676 were originally assigned to “intensive treatment”, and the remaining 673 were assigned “conventional treatment.” Table 1 compares the published breakdown to results obtained from the dataset extracted from the archived dataset. The table published by the study group in *JAMA* breaks down the EDIC study sample by original DCCT treatment allocation. Table 1 compares this published breakdown to results obtained from the dataset extracted from the archived SAS CIMPORT file *edicREN8.xpt*. As Table 1 shows, the counts, percentages, means, and standard deviations obtained from analyses of the archived data closely match the published tabulations. The limited number of small discrepancies may be due to differences in rounding conventions. With one exception¹, *P*-values for tests of differences between treatment groups calculated from archived data exactly match the published results; see Table 1.

¹ In determining statistical significance of differences in group means or percentages, Wilcoxon rank-sum tests were used for continuous variables, and chi-square tests were used for categorical variables -- except for analyses with small cell sizes (<5 subjects in any cell) when Fisher exact tests were used. There was one substantively unimportant discrepant result. Testing of the difference across groups in diabetes duration yielded a *P*-value of 0.15 while the corresponding published *P*-value is “>0.99”. Archived data had means (SDs) of: 12.24 (4.89) for the intensive treatment condition and 11.87 (4.85) for the conventional treatment condition. Table 1 of the published results reports that both conditions have means of 12 years with SDs of 5 years.

TABLE 1. Participant Characteristics at Study Baseline: Top panel is calculated from Archived Data; Bottom panel contains published results.

Label	Variable	Intensive (n=676)		Conventional (n=673)		P-Value
Attained age, mean (SD), y	ATT_AGE	34	(7)	33	(7)	0.11
Women, No (%)	SEX	330	(49)	313	(47)	0.40
Attained Duration at DCCT Closeout, mean (SD), y	ATT_DU99	12	(5)	12	(5)	0.15
HbA _{1c} , mean (SD), %	HBA1C	7.4	(1.1)	9.1	(1.6)	<0.0001
Body mass index, mean (SD), kg/m ²	BMI	26.5	(4)	25.0	(3)	<0.0001
Smoking, No. (%)	SMOKE99	155	(23)	145	(22)	0.54
LDL, mean (SD), mg/dL	LDL	113	(27)	115	(32)	0.39
Albumin excretion rate, mg/day						
Median (IQR)	AER	8.6	5.8-14.4	10.1	5.8-20.2	<0.0001
>28 mg/min, No. (%)	CLOSE_40	50	(7.4)	87	(12.9)	0.0008
>208 mg/min, No. (%)	CLOSE300	10	(1.5)	20	(3.0)	0.06
Serum creatinine, mean (SD)	SERUMCR	0.85	(0.15)	0.84	(0.17)	0.12
GFR at DCCT Closeout, mean (SD)	GFRXB99	125	(20)	126	(21)	0.26
<70 mL/min per 1.73 m ² , No. (%)	GFRXB70	2	(0.4)	3	(0.6)	0.68
Standard creatinine clearance, mean (SD)	STDCLR	122	(26)	122	(26)	0.57
<70 mL/min per 1.73 m ² , No. (%)	CLR_70	10	(1.5)	10	(1.5)	0.99
Blood pressure, mm Hg						
>140/90, confirmed, No. (%)	HT	74	(11)	71	(11)	0.81
>130/80, unconfirmed, No. (%)	F2_HT130	260	(39)	242	(36)	0.35
MAP, mean (SD), [2/3 DBP + 1/3 SBP]	MAP	89	(9)	88	(9)	0.26
Heart rate, mean (SD), bpm	PULSE	75	(10)	75	(11)	0.19

Table 1. Participant Characteristics at EDIC Study Baseline

Characteristic	Original DCCT Treatment Group		P Value*
	Intensive (n = 676)	Conventional (n = 673)	
Age, mean (SD), y	34 (7)	33 (7)	.11
Women, No. (%)	330 (49)	313 (46)	.40
Diabetes duration, mean (SD), y	12 (5)	12 (5)	>.99
HbA _{1c} , mean (SD), %	7.4 (1.1)	9.1 (1.6)	<.001
Body mass index, mean (SD)†	26.5 (4)	25.0 (3)	<.001
Smoking, No. (%)	155 (23)	145 (22)	.54
LDL-C, mean (SD), mg/dL	113 (27)	115 (32)	.39
Albumin excretion rate‡			
Median (IQR), mg/24 h	8.6 (5.8-14.4)	10.1 (5.8-20.2)	<.001
>28 µg/min, No. (%)	50 (7.4)	87 (12.9)	<.001
>208 µg/min, No. (%)	10 (1.5)	20 (3.0)	.06
Serum creatinine, mean (SD), mg/dL	0.85 (0.17)	0.84 (0.15)	.12
GFR by ¹²⁵ I-iothalamate clearance, mean (SD), mL/min per 1.73 m ²	125 (20)	126 (21)	.26
<70 mL/min per 1.73 m ² , No. (%)	2 (0.4)	3 (0.6)	.68
Standard creatinine clearance, mean (SD), mL/min per 1.73 m ²	122 (26)	122 (26)	.57
<70 mL/min per 1.73 m ² , No. (%)	10 (1.5)	10 (1.5)	.99
Blood pressure, mm Hg			
>140/90, confirmed, No. (%)	74 (11)	71 (11)	.81
>130/80, unconfirmed, No. (%)	260 (39)	242 (36)	.35
Arterial pressure, mean (SD), mm Hg§	89 (9)	88 (9)	.26
Heart rate, mean (SD), beats/min	75 (10)	75 (10)	.19

Abbreviations: DCCT, Diabetes Control and Complications Trial; EDIC, Epidemiology of Diabetes Interventions and Complications; GFR, glomerular filtration rate; HbA_{1c}, glycosylated hemoglobin; IQR, interquartile range; LDL-C, low-density lipoprotein cholesterol.

SI conversion factors: To convert LDL-C to mmol/L, multiply mg/dL values by 0.0259; to convert serum creatinine to µmol/L, multiply mg/dL values by 88.4; to convert GFR and standard creatinine clearance to mL/s, multiply mL/min values by 0.0167.

*From Wilcoxon rank-sum test (continuous variables) and χ^2 or Fisher exact test (categorical variables).

†Calculated as weight in kilograms divided by the square of height in meters.

‡Based on 4-hour collection of urine.

§Mean arterial pressure = 2/3 diastolic pressure + 1/3 systolic pressure.

HbA_{1c} Level. Figure 1 compares the published distribution of HbA_{1c} concentration by treatment group at DCCT closeout and each year of the EDIC study to corresponding distributions calculated from archived data. Visual comparison of box-and-whisker plots show no obvious differences between published results and results from analysis of archived data (Figure 1). In addition, published results of statistical comparisons of average HbA_{1c} concentration between groups at each time point exactly match the results of analyses using archived data. Finally, the text published by the study group states that the “mean values of HbA_{1c} throughout the 8-year period of the EDIC study were 8.0% in the group that received intensive treatment during the DCCT and 8.2% in the group that received conventional treatment ($P=0.002$ by Wilcoxon rank-sum test)”. Group comparisons of individual subject-means calculated on archived data yielded an average HbA_{1c} concentration of 8.0% in the intensive treatment group, and of 8.3% in the group that received conventional treatment. This slight difference could be due to rounding error.

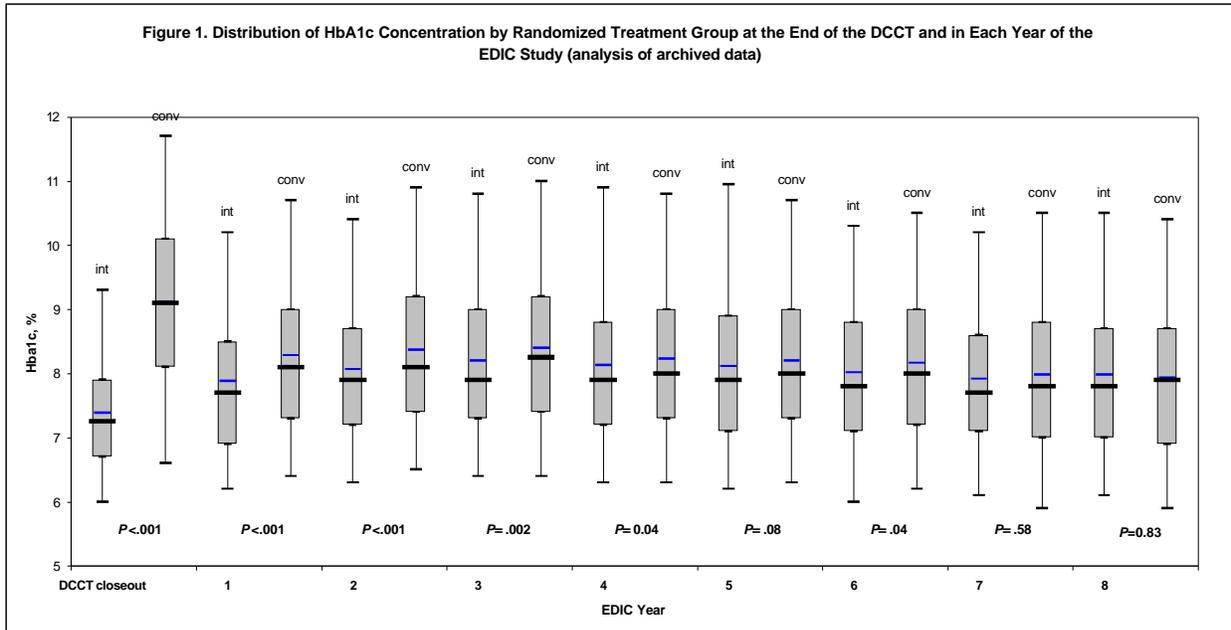
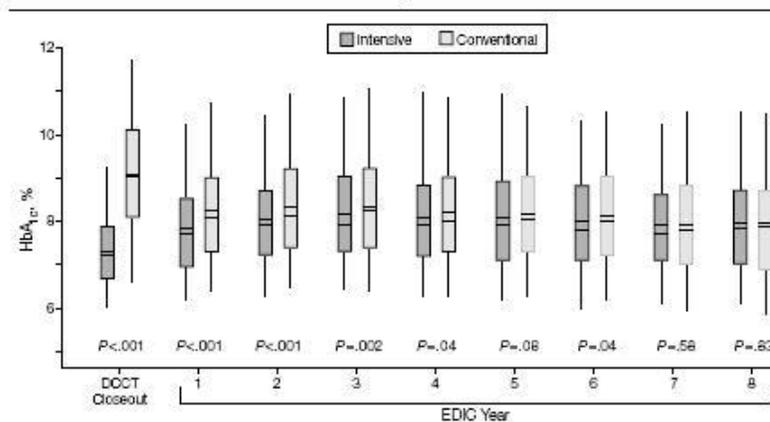


Figure 1. Distribution of HbA_{1c} Concentration by Randomized Treatment Group at the End of the DCCT and in Each Year of the EDIC Study



DCCT indicates Diabetes Control and Complications Trial; EDIC, Epidemiology of Diabetes Interventions and Complications; HbA_{1c}, glycosylated hemoglobin. Boxes indicate 25th and 75th percentiles of HbA_{1c} level; whiskers, 5th and 95th percentiles; heavy horizontal lines, medians; thin horizontal lines, means.

Microalbuminuria. The text published by the study group states there were 572 participants originally assigned to receive intensive treatment for diabetes whose AERs were normal (<28 mg/min) at both the beginning and at the end of the DCCT. Of this risk group, 39 (6.8%) exhibited microalbuminuria at the EDIC year 7 or year 8 examination. Analyses of study data confirmed these numbers, after restricting the baseline risk set to those with non-missing AER data at the year 7 or year 8 evaluation.²

Clinical Albuminuria The published text reported that there were 632 participants originally assigned to receive intensive treatment for diabetes who did not exhibit clinical albuminuria at the end of the DCCT. Of this risk group, 9 (1.4%) exhibited clinical albuminuria at the EDIC year 7 or year 8 examinations. Analyses of archived data confirmed these numbers, after restricting the baseline risk set to those with AER data at the year 7 or year 8 evaluation. Our analysis for the group receiving conventional treatment replicated the published result with a minor discrepancy.³

Other Kidney Outcomes. The published text states that twenty-seven patients doubled their serum creatinine concentration since DCCT baseline (published Table 2). Of these 27, 10 (1.5%) were formerly in the intensive treatment group, and 17 (2.5%) were formerly undergoing conventional treatment. Analyses of study data confirmed that 27 patients had doubled their serum creatinine concentration since DCCT baseline; however, from our analysis it appeared that 9 were formerly undergoing intensive treatment, while 18 were undergoing conventional treatment.⁴

Blood Pressure/Hypertension. Exactly as reported in the published text (p.2164), analyses of archived data demonstrated that the prevalence of hypertension did not differ between treatment groups at the end of the DCCT (11% in both groups, $P=0.81$, from both Wald's and Chi-square tests). The text also states that more participants in the original conventional-treatment group developed hypertension over time, with the difference becoming significant during years 3 through 8 of the EDIC study. Analyses of archived data demonstrated the same result.] Exactly as stated in the text, analyses of archived data showed the prevalence of hypertension in the conventional-treatment group was 40.3%, as compared to 29.9% in the intensive treatment group, in year 8 of the study ($P<0.001$, by both Wald's and Chi-square tests). Lastly, visual comparisons of the prevalence of hypertension at each year of the EDIC study (figure 4) with unadjusted analyses of archived data show no major differences. Any slight differences could be due to the effect of adjusting for baseline covariates in the published results.

² The published analysis also reported that: "Of 550 participants originally assigned to conventional treatment with normoalbuminuria at both the beginning and at the end of the DCCT, 87 (15.8%) of those at risk had microalbuminuria at the year 7 or 8 evaluation." Our preliminary analyses found 84 (15.4%) of 527 at risk participants in conventional therapy with microalbuminuria at the year 7 or 8 evaluation.

³ The published analysis reported for the comparable group receiving conventional therapy that 59 (9.4%) of 630 developed clinical albuminuria. Our analysis found 55 (8.8%) of 626 with clinical albuminuria.

⁴ We obtained the published numerator ($n=27$) after restricting the risk group to those with nonmissing serum creatinine data at each year of the EDIC study, resulting in a denominator of $N=1038$ not 1349.

**Figure 4. Prevalence of Hypertension at Each Year of the EDIC Study
(analysis of archived data)**

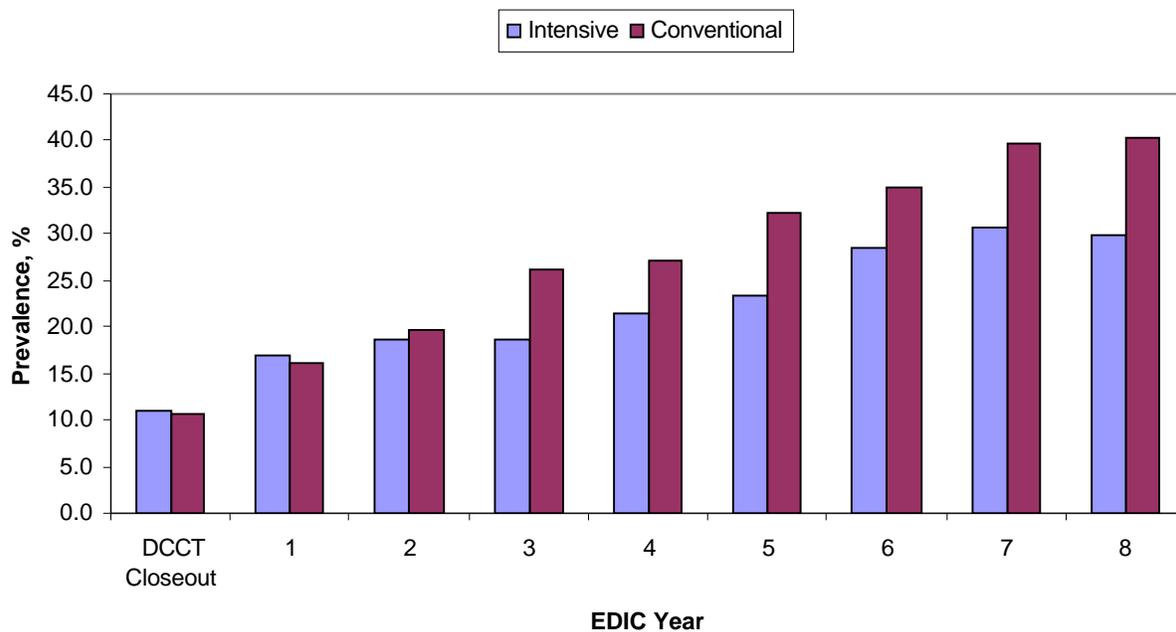
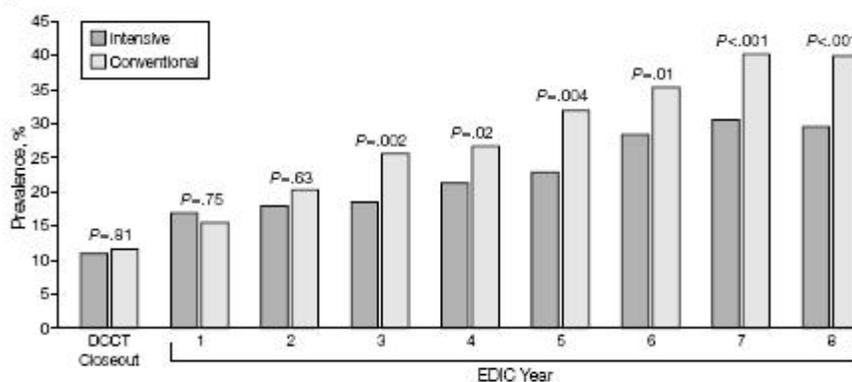


Figure 4. Prevalence of Hypertension at Each Year of the EDIC Study



Prevalence of hypertension (defined as blood pressure >140/90 mm Hg) at the end of the Diabetes Control and Complications Trial (DCCT) and during the Epidemiology of Diabetes Interventions and Complications (EDIC) study for participants in the intensive- vs conventional-treatment groups. The aggregate odds reduction with intensive vs conventional therapy of emergent hypertension during the EDIC study, adjusted for DCCT mean arterial pressure, was 40.4% (95% confidence interval, 33.7%-46.5%; $P < .001$).

APPENDIX A

Writing Team for the DCCT-EDIC Research Group. (2003) Sustained Effect of Intensive Treatment of Type 1 Diabetes mellitus on Development and Progression of Diabetic Nephropathy: The Epidemiology of Diabetes Interventions and Complications (EDIC) Study. Journal of the American Medical Association, 290(16):2159-2167.

The full text of the article referenced will be provided to approved requestors along with the data archive.

APPENDIX B

**SAS 9.1 Code and Output for Replication of Table 1:
Participant Characteristics at EDIC Study Baseline, from
EDIC Nephropathy Dataset in NIDDK Repository**

The SAS System: Baseline Characteristics (Table 1)

SAS Log file for Data read-in and Baseline Characteristics Comparison

```
.
:007
The SAS System 12:57 Monday, February 12,

NOTE: Copyright (c) 2002-2003 by SAS Institute Inc., Cary, NC, USA.
NOTE: SAS (r) 9.1 (TS1M3)
      Licensed to RESEARCH TRIANGLE INSTITUTE, Site 0047670011.
NOTE: This session is executing on the XP_PRO platform.

NOTE: SAS 9.1.3 Service Pack 3

NOTE: SAS initialization used:
      real time          1.59 seconds
      cpu time           0.28 seconds

      * Filename:  NephInteg.SAS
      Location:   \\Rtints23\niddk2\05_Users\Sylvia\DCCT_EDIC\IntegCheck\Neph_JAMA
      Project:   NIDDK Data Repository Integrity Checks (0208866.000.001)
      By:       Sylvia Tan
      Purpose:   Analysis of integrity of EDIC Nephropathy archived dataset in the NIDDK
! Data Repository
      Compare results to tables/text/selected figures in paper published by
      DCCT-EDIC Research Group in 2003 (JAMA, [290(16)])
      Last updated: 1/24/07 *;

.0      options ps=55 ls=75 nonumber formchar='|----|+\----+=|~^<>*' mprint
orientation=portrait
.0      ! ;
.1
.2      libname niddk "C:\DATA\NIDDK\New-Data\NEPH";
NOTE: Libref NIDDK was successfully assigned as follows:
      Engine:          V9
      Physical Name:  C:\DATA\NIDDK\New-Data\NEPH
.3      * (SAS dataset edicREN8.sas7bdat, same as edicREN8.xpt file:);
.4      libname niddkx xport "C:\DATA\NIDDK\New-Data\NEPH\edicREN8.xpt";
NOTE: Libref NIDDKX was successfully assigned as follows:
      Engine:          XPORT
      Physical Name:  C:\DATA\NIDDK\New-Data\NEPH\edicREN8.xpt
.5
.6      * both datasets were copied on 12/20/2006 from the NIDDK server
.7      \\Rtints23\niddk2\03_Data_And_Tools\Database\Databases\DCCT-EDIC\EDIC\New-Data
.8      and are exactly the same, comparison run using SAS Proc Compare, ID=Mask_Pat
.8      ! edicyear *;
.9
.10     * proc cimport data=niddk.edicREN8 infile=niddkx; run;
.11     proc contents position data=niddk.neph_8yr; run;

NOTE: PROCEDURE CONTENTS used (Total process time):
      real time          0.20 seconds
      cpu time           0.01 seconds

NOTE: The PROCEDURE CONTENTS printed pages 1-4.

.12
.13     proc format;
.14     value YESNO 0=No 1=Yes;
```

The SAS System: Baseline Characteristics (Table 1)

SAS Log file for Data read-in and Baseline Characteristics Comparison

The SAS System

12:57 Monday, February 12,

:007

NOTE: Format YESNO has been output.

```
:5 value $GPFMT "EXPERIMENTAL"=Intensive Treatment "STANDARD"=Conventional Treatment;
```

NOTE: Format \$GPFMT has been output.

```
:6 value $RETBASF "PRIM"=Primary Prevention "SCND"=Secondary Intervention;
```

NOTE: Format \$RETBASF has been output.

```
:7 value $GENDERF "F"=Female "M"=Male;
```

NOTE: Format \$GENDERF has been output.

:8

```
:9 ods rtf file="C:\DATA\NIDDK\Neph\nephinteg_out.rtf" style=sasdocprinter;
```

NOTE: Writing RTF Body file: C:\DATA\NIDDK\Neph\nephinteg_out.rtf

:10

NOTE: PROCEDURE FORMAT used (Total process time):

real time	1.01 seconds
cpu time	0.29 seconds

```
:11 data NEPH_8YR; set niddk.neph_8yr;
```

```
:12 if group='EXPERIMENTAL' then IntensTx=1;
```

```
:13 else if group='STANDARD' then IntensTx=0;
```

NOTE: There were 11745 observations read from the data set NIDDK.NEPH_8YR.

NOTE: The data set WORK.NEPH_8YR has 11745 observations and 54 variables.

NOTE: DATA statement used (Total process time):

real time	0.07 seconds
cpu time	0.01 seconds

```
:14 proc sort; by mask_pat; * deidentified patient id *;
```

:15

```
:16 * check our means with the means file (included with the XPT file) *;
```

```
:17 *ods html file="c:\temp\neph_means.xls" style=minimal;
```

:18

```
:19 /*  
:19 proc means n mean std min max data=neph_8yr;
```

```
:20 var aer aer00 att_age att_du99 bmi clr00 dbp eddate fsasdate gfrxb99 hbalc
```

```
:21 hdl height lab_date ldl map pulse sbp scr00 serumcr stdclr tchol trig weight; run;
```

```
:22 proc freq data=neph_8yr;
```

```
:23 tables ace base_40 ci_300 ci_40 close_40 close300 clr_70 combined dialysis double
```

```
:23 ! edicyear
```

```
:24 edstat f2_ht130 gfrxb70 group ht hyperten lipid new_300 new_40 other_ht p_300 p_40
```

```
:24 ! ren_insf
```

```
:25 retbase sex smoke99 trans/missing nocum; run;
```

:26

```
:26 */
```

```
:27 *ods html close; run;
```

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.

NOTE: The data set WORK.NEPH_8YR has 11745 observations and 54 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time	0.04 seconds
cpu time	0.04 seconds

```
:28 * everything matches * ;
```

The SAS System: Baseline Characteristics (Table 1)

SAS Log file for Data read-in and Baseline Characteristics Comparison

The SAS System

12:57 Monday, February 12,

007

```
9
10      data NEPH_BASE; set neph_8yr;
11      if edicyear=0;
```

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The data set WORK.NEPH_BASE has 1349 observations and 54 variables.
NOTE: DATA statement used (Total process time):
real time 0.01 seconds
cpu time 0.01 seconds

```
12      proc freq; tables group; run;
```

NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.
NOTE: The PROCEDURE FREQ printed page 5.
NOTE: PROCEDURE FREQ used (Total process time):
real time 0.03 seconds
cpu time 0.01 seconds

```
13
14      *****;
15      * EDIC Baseline: Table 1 *;
16      *****;
17      *ods html file="c:\temp\neph_Baselinegrpmeans.xls" style=minimal;
18      proc means mean std data=neph_base; class group;
19      var att_age att_du99 hbalc bmi ldl aer serumcr gfrxb99 stdclr map pulse; run;
```

NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.
NOTE: The PROCEDURE MEANS printed pages 6-7.
NOTE: PROCEDURE MEANS used (Total process time):
real time 0.03 seconds
cpu time 0.03 seconds

```
20      proc univariate data=neph_base plot normal; class group;
21      var aer; run;
```

NOTE: Non-portable document will be produced. The current settings of FORMCHAR use non-standard line-drawing characters and the resultant output file will not render correctly unless all readers of the document have the SAS Monospace font installed. To make your document portable, issue the following command:
OPTIONS FORMCHAR="|----|+|----+=|/\<>*";

NOTE: The PROCEDURE UNIVARIATE printed pages 8-14.
NOTE: PROCEDURE UNIVARIATE used (Total process time):
real time 0.10 seconds
cpu time 0.04 seconds

```
22      proc nparlway wilcoxon ; class group;
23      var att_age att_du99 hbalc bmi ldl aer serumcr gfrxb99 stdclr map pulse; run;
```

The SAS System: Baseline Characteristics (Table 1)

SAS Log file for Data read-in and Baseline Characteristics Comparison

The SAS System

12:57 Monday, February 12,

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NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.

NOTE: The PROCEDURE NPAR1WAY printed pages 15-25.

NOTE: PROCEDURE NPAR1WAY used (Total process time):

real time 0.12 seconds

cpu time 0.09 seconds

```
14 *ods html file="c:\temp\Baseline diab dur ttest.xls" style=minimal;
```

```
15 proc ttest data=neph_base; class group;
```

```
16 var att_du99; run;
```

NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.

NOTE: The PROCEDURE TTEST printed page 26.

NOTE: PROCEDURE TTEST used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

```
17 *ods html close; run;
```

```
18
```

```
19 proc freq data=neph_base;
```

```
20 tables group*(sex smoke99 close_40 close300 gfrxb70 clr_70 ht f2_ht130)/chisq exact;
```

```
20 ! run;
```

NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.

NOTE: The PROCEDURE FREQ printed pages 27-36.

NOTE: PROCEDURE FREQ used (Total process time):

real time 0.09 seconds

cpu time 0.06 seconds

```
21 * results are close to published, except for diabetes duration (ATT_DU99)
```

```
22 where p-value is 0.15 instead of >0.99)... other slight diffs are noted in text *;
```

```
23 *ods html close; run;
```

```
24
```

The SAS System: Output for Baseline Characteristics (Table 1)

TREATMENT GROUP				
GROUP	Frequency	Percent	Cumulative Frequency	Cumulative Percent
Intensive Treatment	676	50.11	676	50.11
Conventional Treatment	673	49.89	1349	100.00

The SAS System: Output for Baseline Characteristics (Table 1)

The MEANS Procedure

TREATMENT GROUP	N		Variable	Label	Mean	Std Dev
	Obs					
Intensive Treatment	676		ATT_AGE	Attained age (years)	33.7240356	6.9246283
			ATT_DU99	Attained Duration at DCCT Closeout (yr)	12.2363996	4.8914142
			HBA1C	HbA1c (percent)	7.3775964	1.0846160
			BMI	Body mass index (kg/m**2)	26.5429766	4.0306340
			LDL	LDL (mg/dL)	112.7604167	27.0421768
			AER	Albumin excretion rate (mg/day)	30.4846498	201.0585870
			SERUMCR	Serum creatinine (mg/dL)	0.8521545	0.1459746
			GFRXB99	GFR at DCCT Closeout	124.7738380	20.3328328
			STDCLR	Standard creatinine clearance	121.8837556	26.1359515
			MAP	2/3 DBP + 1/3 SBP	88.7555887	8.7382544
		PULSE	Pulse (bpm)	74.5014925	9.9695724	
Conventional Treatment	673		ATT_AGE	Attained age (years)	33.0973054	6.9641054
			ATT_DU99	Attained Duration at DCCT Closeout (yr)	11.8685130	4.8504721
			HBA1C	HbA1c (percent)	9.1208644	1.5547174
			BMI	Body mass index (kg/m**2)	25.0094789	3.0395205
			LDL	LDL (mg/dL)	114.8026906	32.0953378
			AER	Albumin excretion rate (mg/day)	73.3405405	440.7897448
			SERUMCR	Serum creatinine (mg/dL)	0.8428786	0.1729174
			GFRXB99	GFR at DCCT Closeout	126.0559043	21.4775395
			STDCLR	Standard creatinine clearance	122.2237237	26.3318231
			MAP	2/3 DBP + 1/3 SBP	88.3483258	8.8157904
		PULSE	Pulse (bpm)	75.2485030	10.5841915	

The SAS System: Output for Baseline Characteristics (Table 1)

The UNIVARIATE Procedure
Variable: AER (Albumin excretion rate (mg/day))
GROUP = Intensive Treatment

Moments			
N	671	Sum Weights	671
Mean	30.4846498	Sum Observations	20455.2
Std Deviation	201.058587	Variance	40424.5554
Skewness	19.5255457	Kurtosis	436.240541
Uncorrected SS	27708021.7	Corrected SS	27084452.1
Coeff Variation	659.540419	Std Error Mean	7.76178066

Basic Statistical Measures			
Location		Variability	
Mean	30.48465	Std Deviation	201.05859
Median	8.64000	Variance	40425
Mode	5.76000	Range	4689
		Interquartile Range	8.64000

Tests for Location: $\mu_0=0$				
Test		Statistic		p Value
Student's t	t	3.927533	Pr > t 	<.0001
Sign	M	335.5	Pr >= M 	<.0001
Signed Rank	S	112728	Pr >= S 	<.0001

Tests for Normality				
Test		Statistic		p Value
Shapiro-Wilk	W	0.086328	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.442569	Pr > D	<0.0100
Cramer-von Mises	W-Sq	45.65077	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	214.9495	Pr > A-Sq	<0.0050

The SAS System: Output for Baseline Characteristics (Table 1)

The UNIVARIATE Procedure
 Variable: AER (Albumin excretion rate (mg/day))
 GROUP = Intensive Treatment

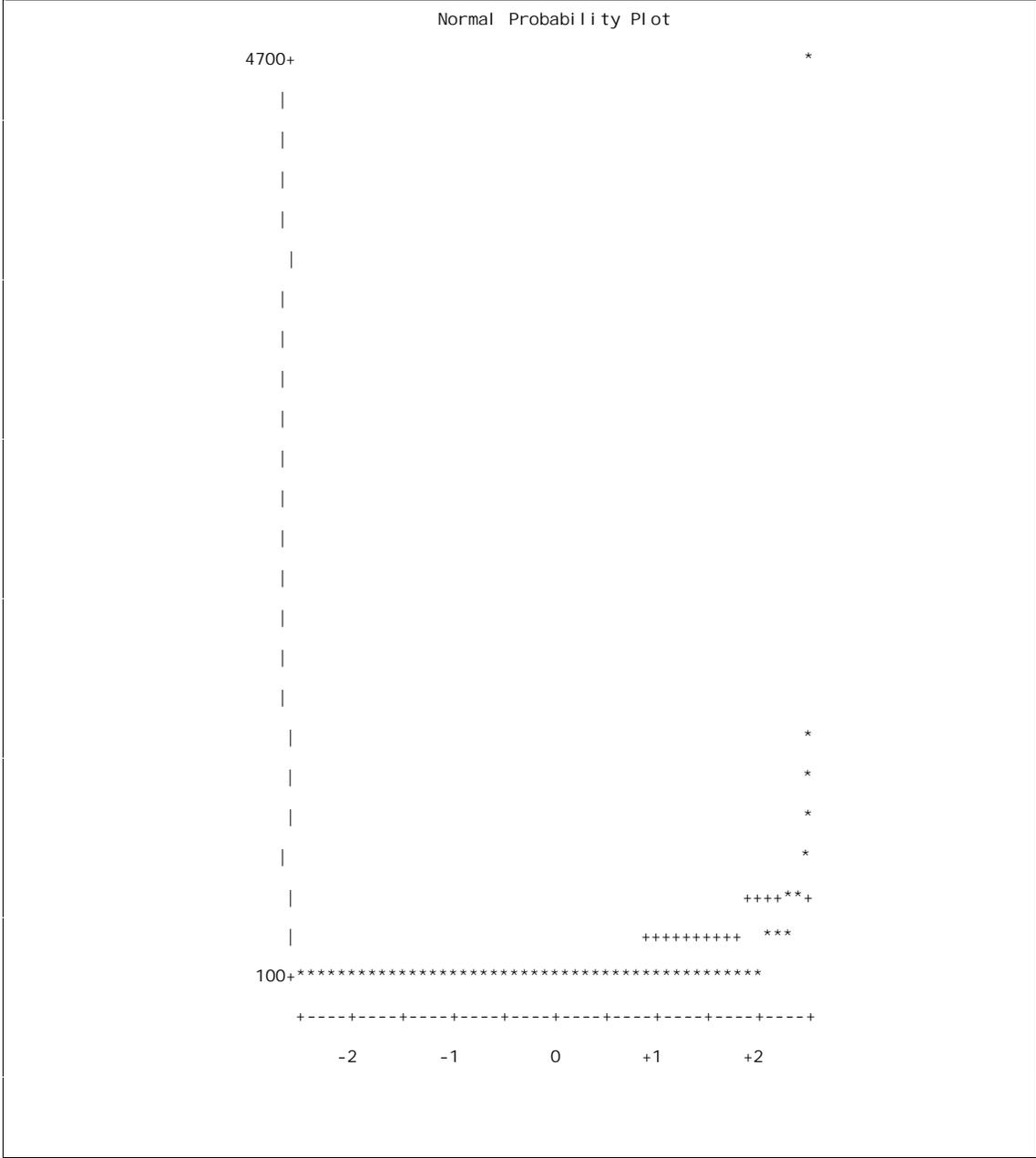
Quantiles (Definition 5)	
Quantile	Estimate
100% Max	4690.08
99%	439.20
95%	48.96
90%	31.68
75% Q3	14.40
50% Median	8.64
25% Q1	5.76
10%	2.88
5%	2.88
1%	1.44
0% Min	1.44

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
1.44	1345	760.32	409
1.44	1278	889.92	28
1.44	1275	1110.24	1106
1.44	1241	1336.32	885
1.44	1034	4690.08	253

Missing Values			
Percent Of			
Missing Value	Count	All Obs	Missing Obs
.	5	0.74	100.00

The SAS System: Output for Baseline Characteristics (Table 1)

The UNIVARIATE Procedure
Variable: AER (Albumin excretion rate (mg/day))
GROUP = Intensive Treatment



The SAS System: Output for Baseline Characteristics (Table 1)

The UNIVARIATE Procedure
Variable: AER (Albumin excretion rate (mg/day))
GROUP = Conventional Treatment

Moments			
N	666	Sum Weights	666
Mean	73.3405405	Sum Observations	48844.8
Std Deviation	440.789745	Variance	194295.599
Skewness	13.1320505	Kurtosis	206.517009
Uncorrected SS	132788877	Corrected SS	129206573
Coeff Variation	601.017857	Std Error Mean	17.0802557

Basic Statistical Measures			
Location		Variability	
Mean	73.34054	Std Deviation	440.78974
Median	10.08000	Variance	194296
Mode	7.20000	Range	8182
		Interquartile Range	14.40000

Tests for Location: $\mu_0=0$				
Test		Statistic		p Value
Student's t	t	4.293878	Pr > t 	<.0001
Sign	M	333	Pr >= M 	<.0001
Signed Rank	S	111055.5	Pr >= S 	<.0001

Tests for Normality				
Test		Statistic		p Value
Shapiro-Wilk	W	0.128351	Pr < W	<0.0001
Kolmogorov-Smirnov	D	0.435213	Pr > D	<0.0100
Cramer-von Mises	W-Sq	45.00993	Pr > W-Sq	<0.0050
Anderson-Darling	A-Sq	210.9362	Pr > A-Sq	<0.0050

The SAS System: Output for Baseline Characteristics (Table 1)

The UNIVARIATE Procedure
 Variable: AER (Albumin excretion rate (mg/day))
 GROUP = Conventional Treatment

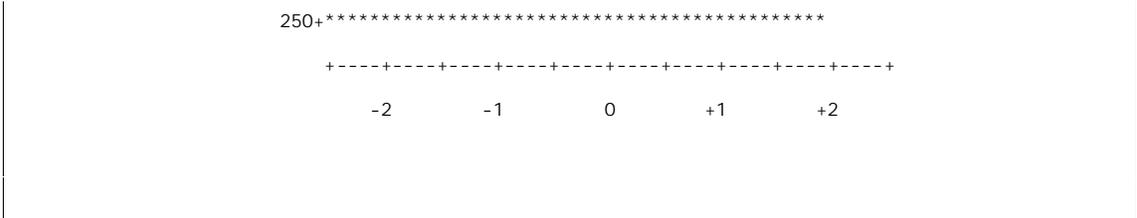
Quantiles (Definition 5)	
Quantile	Estimate
100% Max	8183.52
99%	1360.80
95%	180.00
90%	59.04
75% Q3	20.16
50% Median	10.08
25% Q1	5.76
10%	4.32
5%	2.88
1%	1.44
0% Min	1.44

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
1.44	1293	2060.64	13
1.44	1261	2534.40	442
1.44	1254	3628.80	176
1.44	1183	5126.40	14
1.44	1110	8183.52	893

Missing Values			
Percent Of			
Missing Value	Count	All Obs	Missing Obs
.	7	1.04	100.00

The SAS System: Output for Baseline Characteristics (Table 1)

The UNIVARIATE Procedure
Variable: AER (Albumin excretion rate (mg/day))
GROUP = Conventional Treatment



The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable ATT_AGE Classified by Variable GROUP					
GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	674	463835.0	452591.0	7092.28860	688.182493
Conventional Treatment	668	437318.0	448562.0	7092.28860	654.667665

Average scores were used for ties.

Wilcoxon Two-Sample Test	
Statistic	437318.0000
Normal Approximation	
Z	-1.5853
One-Sided Pr < Z	0.0564
Two-Sided Pr > Z	0.1129
t Approximation	
One-Sided Pr < Z	0.0566
Two-Sided Pr > Z	0.1131

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test	
Chi-Square	2.5134
DF	1
Pr > Chi-Square	0.1129

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable ATT_DU99
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	674	462791.50	452591.0	7098.31947	686.634273
Conventional Treatment	668	438361.50	448562.0	7098.31947	656.229790

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	438361.5000
------------------	-------------

Normal Approximation

Z	-1.4370
One-Sided Pr < Z	0.0754
Two-Sided Pr > Z 	0.1507

t Approximation

One-Sided Pr < Z	0.0755
Two-Sided Pr > Z 	0.1510

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	2.0651
DF	1
Pr > Chi-Square	0.1507

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	674	302322.0	453602.0	7120.70245	448.548961
Conventional Treatment	671	602863.0	451583.0	7120.70245	898.454545

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	602863.0000
------------------	-------------

Normal Approximation

Z	21.2450
One-Sided Pr > Z	<.0001
Two-Sided Pr > Z 	<.0001

t Approximation

One-Sided Pr > Z	<.0001
Two-Sided Pr > Z 	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	451.3541
DF	1
Pr > Chi-Square	<.0001

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable BMI Classified by Variable GROUP					
GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	657	475863.50	430992.0	6854.05909	724.297565
Conventional Treatment	654	384152.50	429024.0	6854.05909	587.389144

Average scores were used for ties.

Wilcoxon Two-Sample Test	
Statistic	384152.5000
Normal Approximation	
Z	-6.5466
One-Sided Pr < Z	<.0001
Two-Sided Pr > Z	<.0001
t Approximation	
One-Sided Pr < Z	<.0001
Two-Sided Pr > Z	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test	
Chi-Square	42.8593
DF	1
Pr > Chi-Square	<.0001

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable LDL Classified by Variable GROUP					
GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	672	444801.0	450912.0	7090.12196	661.906250
Conventional Treatment	669	455010.0	448899.0	7090.12196	680.134529

Average scores were used for ties.

Wilcoxon Two-Sample Test	
Statistic	455010.0000
Normal Approximation	
Z	0.8618
One-Sided Pr > Z	0.1944
Two-Sided Pr > Z	0.3888
t Approximation	
One-Sided Pr > Z	0.1945
Two-Sided Pr > Z	0.3889

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test	
Chi-Square	0.7429
DF	1
Pr > Chi-Square	0.3887

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable AER
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	671	419629.0	448899.0	7040.84248	625.378539
Conventional Treatment	666	474824.0	445554.0	7040.84248	712.948949

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	474824.0000
------------------	-------------

Normal Approximation

Z	4.1571
One-Sided Pr > Z	<.0001
Two-Sided Pr > Z 	<.0001

t Approximation

One-Sided Pr > Z	<.0001
Two-Sided Pr > Z 	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	17.2821
DF	1
Pr > Chi-Square	<.0001

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable SERUMCR Classified by Variable GROUP					
GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	673	462030.50	451246.50	6940.25103	686.523774
Conventional Treatment	667	436439.50	447223.50	6940.25103	654.332084

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic 436439.5000

Normal Approximation

Z -1.5538

One-Sided Pr < Z 0.0601

Two-Sided Pr > |Z| 0.1202

t Approximation

One-Sided Pr < Z 0.0602

Two-Sided Pr > |Z| 0.1205

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square 2.4144

DF 1

Pr > Chi-Square 0.1202

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable GFRXB99
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	542	278005.0	283466.0	4874.82304	512.924354
Conventional Treatment	503	268530.0	263069.0	4874.82304	533.856859

Wilcoxon Two-Sample Test

Statistic 268530.0000

Normal Approximation

Z 1.1201

One-Sided Pr > Z 0.1313

Two-Sided Pr > |Z| 0.2627

t Approximation

One-Sided Pr > Z 0.1315

Two-Sided Pr > |Z| 0.2629

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square 1.2550

DF 1

Pr > Chi-Square 0.2626

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable STDCLR
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	671	444884.50	448899.0	7058.10409	663.017139
Conventional Treatment	666	449568.50	445554.0	7058.10409	675.027778

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	449568.5000
------------------	-------------

Normal Approximation

Z	0.5687
One-Sided Pr > Z	0.2848
Two-Sided Pr > Z 	0.5696

t Approximation

One-Sided Pr > Z	0.2848
Two-Sided Pr > Z 	0.5696

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	0.3235
DF	1
Pr > Chi-Square	0.5695

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable MAP
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	671	457159.50	449234.50	7064.74325	681.310730
Conventional Treatment	667	438631.50	446556.50	7064.74325	657.618441

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	438631.5000
------------------	-------------

Normal Approximation

Z	-1.1217
One-Sided Pr < Z	0.1310
Two-Sided Pr > Z 	0.2620

t Approximation

One-Sided Pr < Z	0.1311
Two-Sided Pr > Z 	0.2622

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	1.2584
DF	1
Pr > Chi-Square	0.2620

The SAS System: Output for Baseline Characteristics (Table 1)

The NPAR1WAY Procedure

**Wilcoxon Scores (Rank Sums) for Variable PULSE
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	670	439362.50	448565.0	7036.14944	655.764925
Conventional Treatment	668	456428.50	447226.0	7036.14944	683.276198

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	456428.5000
------------------	-------------

Normal Approximation

Z	1.3078
One-Sided Pr > Z	0.0955
Two-Sided Pr > Z 	0.1909

t Approximation

One-Sided Pr > Z	0.0956
Two-Sided Pr > Z 	0.1912

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	1.7106
DF	1
Pr > Chi-Square	0.1909

The SAS System: Output for Baseline Characteristics (Table 1)

The TTEST Procedure

Statistics										
Variable	GROUP	N	Lower CL Mean	Mean	Upper CL Mean	Lower CL Std Dev	Std Dev	Upper CL Std Dev	Std Err	Minimum
ATT_DU99	Conventional Treatment	668	11.5	11.869	12.237	4.6036	4.8505	5.1256	0.1877	4.8333
ATT_DU99	Intensive Treatment	674	11.866	12.236	12.606	4.6435	4.8914	5.1675	0.1884	4.75
ATT_DU99	Diff (1-2)		-0.89	-0.368	0.1538	4.6935	4.8711	5.0628	0.2659	

Statistics		
Variable	GROUP	Maximum
ATT_DU99	Conventional Treatment	24
ATT_DU99	Intensive Treatment	24.333
ATT_DU99	Diff (1-2)	

T-Tests					
Variable	Method	Variances	DF	t Value	Pr > t
ATT_DU99	Pooled	Equal	1340	-1.38	0.1668
ATT_DU99	Satterthwaite	Unequal	1340	-1.38	0.1668

Equality of Variances					
Variable	Method	Num DF	Den DF	F Value	Pr > F
ATT_DU99	Folded F	673	667	1.02	0.8279

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Table of GROUP by SEX			
GROUP(TREATMENT GROUP)	SEX(Gender)		
Frequency	Female	Male	Total
Percent			
Row Pct			
Col Pct			
Intensive Treatment	330	346	676
	24.46	25.65	50.11
	48.82	51.18	
	51.32	49.01	
Conventional Treatment	313	360	673
	23.20	26.69	49.89
	46.51	53.49	
	48.68	50.99	
Total	643	706	1349
	47.66	52.34	100.00

Statistics for Table of GROUP by SEX

Statistic	DF	Value	Prob
Chi-Square	1	0.7204	0.3960
Likelihood Ratio Chi-Square	1	0.7205	0.3960
Continuity Adj. Chi-Square	1	0.6308	0.4270
Mantel-Haenszel Chi-Square	1	0.7199	0.3962
Phi Coefficient		0.0231	
Contingency Coefficient		0.0231	
Cramer's V		0.0231	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	330
Left-sided Pr <= F	0.8168
Right-sided Pr >= F	0.2135
Table Probability (P)	0.0303
Two-sided Pr <= P	0.4137

Sample Size = 1349

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Table of GROUP by SMOKE99

GROUP(TREATMENT GROUP)	SMOKE99(Smoking DCCT Closeout)		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	519	155	674
	38.59	11.52	50.11
	77.00	23.00	
	49.67	51.67	
Conventional Treatment	526	145	671
	39.11	10.78	49.89
	78.39	21.61	
	50.33	48.33	
Total	1045	300	1345
	77.70	22.30	100.00

Frequency Missing = 4

Statistics for Table of GROUP by SMOKE99

Statistic	DF	Value	Prob
Chi-Square	1	0.3735	0.5411
Likelihood Ratio Chi-Square	1	0.3736	0.5411
Continuity Adj. Chi-Square	1	0.2978	0.5853
Mantel-Haenszel Chi-Square	1	0.3733	0.5412
Phi Coefficient		-0.0167	
Contingency Coefficient		0.0167	
Cramer's V		-0.0167	

Fisher's Exact Test

Cell (1,1) Frequency (F)	519
Left-sided Pr <= F	0.2927
Right-sided Pr >= F	0.7507
Table Probability (P)	0.0433
Two-sided Pr <= P	0.5559

Effective Sample Size = 1345
Frequency Missing = 4

The FREQ Procedure

Table of GROUP by CLOSE_40

GROUP(TREATMENT GROUP)	CLOSE_40(AER > 40 at DCCT close-out)		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	626	50	676
	46.40	3.71	50.11
	92.60	7.40	
	51.65	36.50	
Conventional Treatment	586	87	673
	43.44	6.45	49.89
	87.07	12.93	
	48.35	63.50	
Total	1212	137	1349
	89.84	10.16	100.00

Statistics for Table of GROUP by CLOSE_40

Statistic	DF	Value	Prob
Chi-Square	1	11.3062	0.0008
Likelihood Ratio Chi-Square	1	11.4316	0.0007
Continuity Adj. Chi-Square	1	10.7082	0.0011
Mantel-Haenszel Chi-Square	1	11.2978	0.0008
Phi Coefficient		0.0915	
Contingency Coefficient		0.0912	
Cramer's V		0.0915	

Fisher's Exact Test

Cell (1,1) Frequency (F)	626
Left-sided Pr <= F	0.9997
Right-sided Pr >= F	5.048E-04
Table Probability (P)	2.456E-04
Two-sided Pr <= P	8.221E-04

Sample Size = 1349

The FREQ Procedure

Table of GROUP by CLOSE300

GROUP(TREATMENT GROUP)	CLOSE300(AER > 300 at DCCT close-out)		
	No	Yes	Total
Intensive Treatment	666	10	676
	49.37	0.74	50.11
	98.52	1.48	
	50.49	33.33	
Conventional Treatment	653	20	673
	48.41	1.48	49.89
	97.03	2.97	
	49.51	66.67	
Total	1319	30	1349
	97.78	2.22	100.00

Statistics for Table of GROUP by CLOSE300

Statistic	DF	Value	Prob
Chi-Square	1	3.4548	0.0631
Likelihood Ratio Chi-Square	1	3.5194	0.0607
Continuity Adj. Chi-Square	1	2.8025	0.0941
Mantel-Haenszel Chi-Square	1	3.4522	0.0632
Phi Coefficient		0.0506	
Contingency Coefficient		0.0505	
Cramer's V		0.0506	

Fisher's Exact Test

Cell (1,1) Frequency (F)	666
Left-sided Pr <= F	0.9803
Right-sided Pr >= F	0.0463
Table Probability (P)	0.0266
Two-sided Pr <= P	0.0672

Sample Size = 1349

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Table of GROUP by GFRXB70

GROUP(TREATMENT GROUP)	GFRXB70(GFR < 70 DCCT Closeout)		Total
	No	Yes	
Intensive Treatment	540	2	542
	51.67	0.19	51.87
	99.63	0.37	
	51.92	40.00	
Conventional Treatment	500	3	503
	47.85	0.29	48.13
	99.40	0.60	
	48.08	60.00	
Total	1040	5	1045
	99.52	0.48	100.00

Frequency Missing = 304

Statistics for Table of GROUP by GFRXB70

Statistic	DF	Value	Prob
Chi-Square	1	0.2834	0.5945
Likelihood Ratio Chi-Square	1	0.2844	0.5939
Continuity Adj. Chi-Square	1	0.0070	0.9333
Mantel-Haenszel Chi-Square	1	0.2831	0.5947
Phi Coefficient		0.0165	
Contingency Coefficient		0.0165	
Cramer's V		0.0165	

WARNING: 50% of the cells have expected counts less than 5. Chi-Square may not be a valid test.

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Statistics for Table of GROUP by GFRXB70

Fisher's Exact Test	
Cell (1,1) Frequency (F)	540
Left-sided Pr <= F	0.8356
Right-sided Pr >= F	0.4650
Table Probability (P)	0.3005
Two-sided Pr <= P	0.6761

Effective Sample Size = 1045
Frequency Missing = 304

WARNING: 23% of the data are missing.

Table of GROUP by CLR_70

GROUP(TREATMENT GROUP)	CLR_70(Standard clearance < 70)		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	661 49.44 98.51 50.19	10 0.75 1.49 50.00	671 50.19
Conventional Treatment	656 49.07 98.50 49.81	10 0.75 1.50 50.00	666 49.81
Total	1317 98.50	20 1.50	1337 100.00

Frequency Missing = 12

Statistics for Table of GROUP by CLR_70

Statistic	DF	Value	Prob
Chi-Square	1	0.0003	0.9866
Likelihood Ratio Chi-Square	1	0.0003	0.9866
Continuity Adj. Chi-Square	1	0.0000	1.0000
Mantel-Haenszel Chi-Square	1	0.0003	0.9866

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Statistics for Table of GROUP by CLR_70

Statistic	DF	Value	Prob
Phi Coefficient		0.0005	
Contingency Coefficient		0.0005	
Cramer's V		0.0005	

Fisher's Exact Test

Cell (1,1) Frequency (F)	661
Left-sided Pr <= F	0.5954
Right-sided Pr >= F	0.5821
Table Probability (P)	0.1775
Two-sided Pr <= P	1.0000

Effective Sample Size = 1337
Frequency Missing = 12

Table of GROUP by HT

GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	602	74	676
	44.63	5.49	50.11
	89.05	10.95	
	50.00	51.03	
Conventional Treatment	602	71	673
	44.63	5.26	49.89
	89.45	10.55	
	50.00	48.97	
Total	1204	145	1349
	89.25	10.75	100.00

Statistics for Table of GROUP by HT

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Statistics for Table of GROUP by HT

Statistic	DF	Value	Prob
Chi-Square	1	0.0554	0.8139
Likelihood Ratio Chi-Square	1	0.0554	0.8139
Continuity Adj. Chi-Square	1	0.0217	0.8828
Mantel-Haenszel Chi-Square	1	0.0554	0.8140
Phi Coefficient		-0.0064	
Contingency Coefficient		0.0064	
Cramer's V		-0.0064	

Fisher's Exact Test

Cell (1,1) Frequency (F)	602
Left-sided Pr <= F	0.4414
Right-sided Pr >= F	0.6267
Table Probability (P)	0.0681
Two-sided Pr <= P	0.8606

Sample Size = 1349

Table of GROUP by F2_HT130

GROUP(TREATMENT GROUP)	F2_HT130(Hypertension >=130/80)		
	No	Yes	Total
Intensive Treatment	411 30.72 61.25 49.16	260 19.43 38.75 51.79	671 50.15
Conventional Treatment	425 31.76 63.72 50.84	242 18.09 36.28 48.21	667 49.85
Total	836 62.48	502 37.52	1338 100.00

Frequency Missing = 11

The SAS System: Output for Baseline Characteristics (Table 1)

The FREQ Procedure

Statistics for Table of GROUP by F2_HT130

Statistic	DF	Value	Prob
Chi-Square	1	0.8679	0.3515
Likelihood Ratio Chi-Square	1	0.8681	0.3515
Continuity Adj. Chi-Square	1	0.7659	0.3815
Mantel-Haenszel Chi-Square	1	0.8673	0.3517
Phi Coefficient		-0.0255	
Contingency Coefficient		0.0255	
Cramer's V		-0.0255	

Fisher's Exact Test

Cell (1,1) Frequency (F)	411
Left-sided Pr <= F	0.1907
Right-sided Pr >= F	0.8384
Table Probability (P)	0.0292
Two-sided Pr <= P	0.3665

Effective Sample Size = 1338
Frequency Missing = 11

APPENDIX C

SAS 9.1 Code and Output for Replication of Selected Analyses in Results: HbA_{1c} Level and in Figure 1: Distribution of HbA_{1c} Concentration by Randomized Treatment Group at the End of the DCCT and in Each Year of the EDIC Study, from EDIC Nephropathy Dataset in NIDDK Repository

The SAS System: HbA1c analyses – SAS log file

03:07 Friday, June 19, 2009

```
72
73      *****;
74      * HbA1c Level *;
75      *****;
76
77      ** Figure 1 and next-to-last sentence pg.2161 **;
78      proc sort data=neph_8yr; by edicyear;
```

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.

NOTE: The data set WORK.NEPH_8YR has 11745 observations and 54 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time	0.04 seconds
cpu time	0.03 seconds

```
79      proc univariate data=neph_8yr noprint; by edicyear;
80      var hba1c; class group; output out=hbameans mean=meanhba0-
meanhba8
81      median=medhba0-medhba8 q1=q1hba0-q1hba8 q3=q3hba0-q3hba8
p5=p5hba0-p5hba8
82      p95=p95hba0-p95hba8; run;
```

NOTE: The data set WORK.HBAMEANS has 18 observations and 8 variables.

NOTE: PROCEDURE UNIVARIATE used (Total process time):

The SAS System: Output for HbA1c analyses
Mean and Median Hba1c at each year of EDIC (Compare to Figure 1, p.2162 JAMA)

Obs	EDICYEAR	GROUP	meanhba0	p95hba0	q3hba0	medhba0	q1hba0	p5hba0
1	00	Intensive Treatment	7.37760	9.30	7.9	7.25	6.7	6.0
2	00	Conventional Treatment	9.12086	11.70	10.1	9.10	8.1	6.6
3	01	Intensive Treatment	7.88563	10.20	8.5	7.70	6.9	6.2
4	01	Conventional Treatment	8.28279	10.70	9.0	8.10	7.3	6.4
5	02	Intensive Treatment	8.06615	10.40	8.7	7.90	7.2	6.3
6	02	Conventional Treatment	8.36677	10.90	9.2	8.10	7.4	6.5
7	03	Intensive Treatment	8.20109	10.80	9.0	7.90	7.3	6.4
8	03	Conventional Treatment	8.39766	11.00	9.2	8.25	7.4	6.4
9	04	Intensive Treatment	8.12703	10.90	8.8	7.90	7.2	6.3
10	04	Conventional Treatment	8.23818	10.80	9.0	8.00	7.3	6.3
11	05	Intensive Treatment	8.10859	10.95	8.9	7.90	7.1	6.2
12	05	Conventional Treatment	8.20548	10.70	9.0	8.00	7.3	6.3
13	06	Intensive Treatment	8.00964	10.30	8.8	7.80	7.1	6.0
14	06	Conventional Treatment	8.15917	10.50	9.0	8.00	7.2	6.2
15	07	Intensive Treatment	7.92374	10.20	8.6	7.70	7.1	6.1
16	07	Conventional Treatment	7.98622	10.50	8.8	7.80	7.0	5.9
17	08	Intensive Treatment	7.98137	10.50	8.7	7.80	7.0	6.1
18	08	Conventional Treatment	7.93783	10.40	8.7	7.90	6.9	5.9

The SAS System: Output for HbA1c analyses

The MEANS Procedure

Analysis Variable : HBA1C HbA1c (percent)

EDIC FOLLOWUP YEAR	TREATMENT GROUP	N Obs	Mean
0	Intensive Treatment	676	7.3775964
	Conventional Treatment	673	9.1208644
1	Intensive Treatment	652	7.8856260
	Conventional Treatment	648	8.2827907
2	Intensive Treatment	651	8.0661515
	Conventional Treatment	647	8.3667707
3	Intensive Treatment	651	8.2010853
	Conventional Treatment	652	8.3976636
4	Intensive Treatment	646	8.1270312
	Conventional Treatment	645	8.2381847
5	Intensive Treatment	647	8.1085937
	Conventional Treatment	646	8.2054773
6	Intensive Treatment	653	8.0096423
	Conventional Treatment	654	8.1591680
7	Intensive Treatment	653	7.9237366
	Conventional Treatment	652	7.9862229
8	Intensive Treatment	652	7.9813665
	Conventional Treatment	647	7.9378336

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=00

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	674	302322.0	453602.0	7120.70245	448.548961
Conventional Treatment	671	602863.0	451583.0	7120.70245	898.454545

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	602863.0000
-----------	-------------

Normal Approximation

Z	21.2450
One-Sided Pr > Z	<.0001
Two-Sided Pr > Z	<.0001

t Approximation

One-Sided Pr > Z	<.0001
Two-Sided Pr > Z	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	451.3541
DF	1
Pr > Chi-Square	<.0001

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=01

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	647	378872.50	418285.50	6703.24767	585.583462
Conventional Treatment	645	456405.50	416992.50	6703.24767	707.605426

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	456405.5000
-----------	-------------

Normal Approximation

Z	5.8796
One-Sided Pr > Z	<.0001
Two-Sided Pr > Z	<.0001

t Approximation

One-Sided Pr > Z	<.0001
Two-Sided Pr > Z	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	34.5707
DF	1
Pr > Chi-Square	<.0001

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=02

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	647	389220.0	416991.50	6672.21233	601.576507
Conventional Treatment	641	440896.0	413124.50	6672.21233	687.825273

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	440896.0000
-----------	-------------

Normal Approximation

Z	4.1622
One-Sided Pr > Z	<.0001
Two-Sided Pr > Z	<.0001

t Approximation

One-Sided Pr > Z	<.0001
Two-Sided Pr > Z	<.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	17.3244
DF	1
Pr > Chi-Square	<.0001

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=03

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	645	394568.0	415380.0	6664.61982	611.733333
Conventional Treatment	642	434260.0	413448.0	6664.61982	676.417445

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	434260.0000
-----------	-------------

Normal Approximation

Z	3.1227
One-Sided Pr > Z	0.0009
Two-Sided Pr > Z	0.0018

t Approximation

One-Sided Pr > Z	0.0009
Two-Sided Pr > Z	0.0018

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	9.7516
DF	1
Pr > Chi-Square	0.0018

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=04

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	640	395999.50	409600.0	6602.46314	618.749219
Conventional Treatment	639	422560.50	408960.0	6602.46314	661.284038

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	422560.5000
-----------	-------------

Normal Approximation

Z	2.0598
One-Sided Pr > Z	0.0197
Two-Sided Pr > Z	0.0394

t Approximation

One-Sided Pr > Z	0.0198
Two-Sided Pr > Z	0.0396

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	4.2432
DF	1
Pr > Chi-Square	0.0394

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=05

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	640	397935.0	409600.0	6602.70666	621.773438
Conventional Treatment	639	420625.0	408960.0	6602.70666	658.255086

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	420625.0000
-----------	-------------

Normal Approximation

Z	1.7666
One-Sided Pr > Z	0.0386
Two-Sided Pr > Z	0.0773

t Approximation

One-Sided Pr > Z	0.0388
Two-Sided Pr > Z	0.0775

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	3.1212
DF	1
Pr > Chi-Square	0.0773

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=06

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	643	401658.0	415699.50	6703.45475	624.662519
Conventional Treatment	649	433620.0	419578.50	6703.45475	668.135593

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	401658.0000
-----------	-------------

Normal Approximation

Z	-2.0946
One-Sided Pr < Z	0.0181
Two-Sided Pr > Z	0.0362

t Approximation

One-Sided Pr < Z	0.0182
Two-Sided Pr > Z	0.0364

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	4.3876
DF	1
Pr > Chi-Square	0.0362

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=07

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	653	420712.0	424450.0	6757.76830	644.275651
Conventional Treatment	646	423638.0	419900.0	6757.76830	655.786378

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	423638.0000
-----------	-------------

Normal Approximation

Z	0.5531
One-Sided Pr > Z	0.2901
Two-Sided Pr > Z	0.5802

t Approximation

One-Sided Pr > Z	0.2902
Two-Sided Pr > Z	0.5803

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	0.3060
DF	1
Pr > Chi-Square	0.5802

The SAS System: Output for HbA1c analyses
Compare to P-values for Figure 1 (group differences in Hba1c levels at each year of EDIC)
The NPAR1WAY Procedure

EDIC FOLLOWUP YEAR=08

Wilcoxon Scores (Rank Sums) for Variable HBA1C
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	644	414241.50	412804.0	6618.00052	643.232143
Conventional Treatment	637	406879.50	408317.0	6618.00052	638.743328

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	406879.5000
-----------	-------------

Normal Approximation

Z	-0.2171
One-Sided Pr < Z	0.4141
Two-Sided Pr > Z	0.8281

t Approximation

One-Sided Pr < Z	0.4141
Two-Sided Pr > Z	0.8281

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	0.0472
DF	1
Pr > Chi-Square	0.8280

The SAS System: Output for HbA1c analyses
Compare to results in last sentence, p. 2161 (JAMA) – Mean values of HbA1c throughout 8-yea
period

The UNIVARIATE Procedure
Variable: meanhba (HbA1c (percent))
GROUP = Intensive Treatment

Moments			
N	677	Sum Weights	677
Mean	7.98187226	Sum Observations	5403.72752
Std Deviation	1.15302597	Variance	1.32946888
Skewness	0.84713399	Kurtosis	1.01563315
Uncorrected SS	44030.5837	Corrected SS	898.720963
Coeff Variation	14.4455578	Std Error Mean	0.04431439

Basic Statistical Measures			
Location		Variability	
Mean	7.981872	Std Deviation	1.15303
Median	7.855556	Variance	1.32947
Mode	7.600000	Range	7.20833
		Interquartile Range	1.47222

Note: The mode displayed is the smallest of 3 modes with a count of 5.

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	180.1192	Pr > t 	<.0001
Sign	M	338.5	Pr >= M 	<.0001
Signed Rank	S	114751.5	Pr >= S 	<.0001

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	12.97500
99%	11.43333
95%	10.23333
90%	9.53333
75% Q3	8.62222
50% Median	7.85556

The SAS System: Output for HbA1c analyses
Compare to results in last sentence, p. 2161 (JAMA) – Mean values of HbA1c throughout 8-year period

The UNIVARIATE Procedure
Variable: meanhba (HbA1c (percent))
GROUP = Intensive Treatment

Quantiles (Definition 5)	
Quantile	Estimate
25% Q1	7.15000
10%	6.62222
5%	6.37778
1%	5.98889
0% Min	5.76667

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
5.76667	1823	11.6833	1551
5.76667	1500	11.6875	1835
5.82222	1518	12.0800	1667
5.84444	2006	12.4556	1895
5.87778	1570	12.9750	1617

The SAS System: Output for HbA1c analyses
Compare to results in last sentence, p. 2161 (JAMA) – Mean values of HbA1c throughout 8-yea
period

The UNIVARIATE Procedure
Variable: meanhba (HbA1c (percent))
GROUP = Conventional Treatment

Moments			
N	674	Sum Weights	674
Mean	8.32192872	Sum Observations	5608.97996
Std Deviation	1.15275308	Variance	1.32883967
Skewness	0.51070504	Kurtosis	0.16933616
Uncorrected SS	47571.8405	Corrected SS	894.309101
Coeff Variation	13.8519942	Std Error Mean	0.04440239

Basic Statistical Measures			
Location		Variability	
Mean	8.321929	Std Deviation	1.15275
Median	8.177778	Variance	1.32884
Mode	7.366667	Range	7.11111
		Interquartile Range	1.53333

Note: The mode displayed is the smallest of 3 modes with a count of 6.

Tests for Location: Mu0=0				
Test	Statistic		p Value	
Student's t	t	187.4207	Pr > t 	<.0001
Sign	M	337	Pr >= M 	<.0001
Signed Rank	S	113737.5	Pr >= S 	<.0001

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	12.68889
99%	11.24444
95%	10.42222
90%	9.91667
75% Q3	9.05556
50% Median	8.17778

The SAS System: Output for HbA1c analyses

Compare to results in last sentence, p. 2161 (JAMA) – Mean values of HbA1c throughout 8-year period

The UNIVARIATE Procedure

Variable: meanhba (HbA1c (percent))

GROUP = Conventional Treatment

Quantiles (Definition 5)	
Quantile	Estimate
25% Q1	7.52222
10%	7.00000
5%	6.65556
1%	6.01111
0% Min	5.57778

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
5.57778	2227	11.7111	2050
5.62222	2099	11.7333	2217
5.77778	2373	11.9889	2266
5.77778	2697	12.0000	2543
5.81111	2140	12.6889	2573

**Wilcoxon Scores (Rank Sums) for Variable meanhba
Classified by Variable GROUP**

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	677	415896.0	457652.0	7170.02854	614.322009
Conventional Treatment	674	497380.0	455624.0	7170.02854	737.952522

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic 497380.0000

Normal Approximation

Z 5.8236

One-Sided Pr > Z <.0001

Two-Sided Pr > |Z| <.0001

t Approximation

One-Sided Pr > Z <.0001

Two-Sided Pr > |Z| <.0001

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square 33.9153

DF 1

Pr > Chi-Square <.0001

APPENDIX D

**SAS 9.1 Code and Output for Replication of Selected
Analyses in Results: Development of Microalbuminuria and
in Results: Development of Clinical Albuminuria, from EDIC
Nephropathy Dataset in NIDDK Repository**

The SAS System: Log file for Microalbuminuria Analyses

```
97
98 *****;
99 * Development of Microalbuminuria *;
100 *****;
101
102 * Figure 2 *;
103 data atrisk1(keep=mask_pat); set neph_8yr;
104     where base_40=0 and close_40=0 and IntensTx=1 and edicyear=0;
105     run;
```

NOTE: There were 603 observations read from the data set WORK.NEPH_8YR.
WHERE (base_40=0) and (close_40=0) and (IntensTx=1) and (edicyear=0);

NOTE: The data set WORK.ATRISK1 has 603 observations and 1 variables.

NOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.00 seconds

```
106     data NEPH_7(keep=mask_pat p_40); set neph_8yr; where edicyear=7
and p_40^=.;
```

NOTE: There were 629 observations read from the data set WORK.NEPH_8YR.
WHERE (edicyear=7) and (p_40 not = .);

NOTE: The data set WORK.NEPH_7 has 629 observations and 2 variables.

NOTE: DATA statement used (Total process time):

real time	0.03 seconds
cpu time	0.01 seconds

```
107     proc sort; by mask_pat;
```

NOTE: There were 629 observations read from the data set WORK.NEPH_7.

NOTE: The data set WORK.NEPH_7 has 629 observations and 2 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

```
108     data NEPH_8(keep=mask_pat p_40); set neph_8yr; where edicyear=8
and p_40^=.;
```

NOTE: There were 663 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=8) and (p_40 not = .);

The SAS System: Log file for Microalbuminuria Analyses

The SAS System

14:46

Friday, February 9, 2007

NOTE: The data set WORK.NEPH_8 has 663 observations and 2 variables.

NOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

```
109          proc sort; by mask_pat;
```

NOTE: There were 663 observations read from the data set WORK.NEPH_8.

NOTE: The data set WORK.NEPH_8 has 663 observations and 2 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time	0.00 seconds
cpu time	0.00 seconds

```
110          data atrisk1; merge atrisk1(in=in1) neph_7(in=in7)
111                                neph_8(in=in8);
112          by mask_pat;
113          if in1 and (in7 or in8);
114          * n=572 as stated in the text *;
115          run;
```

NOTE: There were 603 observations read from the data set WORK.ATRISK1.

NOTE: There were 629 observations read from the data set WORK.NEPH_7.

NOTE: There were 663 observations read from the data set WORK.NEPH_8.

NOTE: The data set WORK.ATRISK1 has 572 observations and 2 variables.

NOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

```
116          proc freq; tables p_40; run;
```

NOTE: There were 572 observations read from the data set WORK.ATRISK1.

NOTE: The PROCEDURE FREQ printed page 53.

NOTE: PROCEDURE FREQ used (Total process time):

real time	0.03 seconds
cpu time	0.01 seconds

```
117
118          data atrisk0(keep=mask_pat); set neph_8yr;
119          where base_40=0 and close_40=0 and IntensTx=0 and edicyear=0;
120          run;
```

NOTE: There were 567 observations read from the data set WORK.NEPH_8YR.

WHERE (base_40=0) and (close_40=0) and (IntensTx=0) and (edicyear=0);

NOTE: The data set WORK.ATRISK0 has 567 observations and 1 variables.

NOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

The SAS System: Log file for Microalbuminuria Analyses

The SAS System

14:46

Friday, February 9, 2007

```
121      data atrisk0; merge atrisk0(in=in1) neph_7(in=in7)
122                               neph_8(in=in8);
123      by mask_pat;
124      if in1 and (in7 or in8);
125      * n=547, as opposed to n=550 as stated in the text *;
126      run;
```

NOTE: There were 567 observations read from the data set WORK.ATRISK0.

NOTE: There were 629 observations read from the data set WORK.NEPH_7.

NOTE: There were 663 observations read from the data set WORK.NEPH_8.

NOTE: The data set WORK.ATRISK0 has 547 observations and 2 variables.

NOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.00 seconds

```
127      proc freq; tables p_40; run;
```

NOTE: There were 547 observations read from the data set WORK.ATRISK0.

NOTE: The PROCEDURE FREQ printed page 54.

NOTE: PROCEDURE FREQ used (Total process time):

real time	0.03 seconds
cpu time	0.01 seconds

128

The SAS System: Output for Microalbuminuria Analyses
Compare to results in First sentence under “Development of Microalbuminuria”, p.2162
(JAMA)
The FREQ Procedure

Prevalence indicator of current AER > 40

P_40	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	533	93.18	533	93.18
Yes	39	6.82	572	100.00

The SAS System: Output for Microalbuminuria Analyses
Compare to results in Second sentence under “Development of Microalbuminuria”, p.2162
(JAMA)

Prevalence indicator of current AER > 40

P_40	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	463	84.64	463	84.64
Yes	84	15.36	547	100.00

The SAS System: Log file for Clinical Albuminuria Analyses

```
.28
.29 *****;
.30 * Development of Clinical Albuminuria *;
.31 *****;
.32
.33 * Figure 2 *;
.34 data atrisk1b(keep=mask_pat); set neph_8yr;
.35     where close300=0 and IntensTx=1 and edicyear=0;
.36     run;

NOTE: There were 666 observations read from the data set WORK.NEPH_8YR.
      WHERE (close300=0) and (IntensTx=1) and (edicyear=0);
NOTE: The data set WORK.ATRISK1B has 666 observations and 1 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds

.37     data NEPH_7b(keep=mask_pat p_300); set neph_8yr; where edicyear=7 and p_300^=.;

NOTE: There were 629 observations read from the data set WORK.NEPH_8YR.
      WHERE (edicyear=7) and (p_300 not = .);
NOTE: The data set WORK.NEPH_7B has 629 observations and 2 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds
```

The SAS System: Log file for Clinical Albuminuria Analyses

The SAS System

14:46 Friday, February 9,

:007

```
.38      proc sort; by mask_pat;
```

[NOTE: There were 629 observations read from the data set WORK.NEPH_7B.

[NOTE: The data set WORK.NEPH_7B has 629 observations and 2 variables.

[NOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

```
.39      data NEPH_8b(keep=mask_pat p_300); set neph_8yr; where edicyear=8 and p_300^=.;
```

[NOTE: There were 663 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=8) and (p_300 not = .);

[NOTE: The data set WORK.NEPH_8B has 663 observations and 2 variables.

[NOTE: DATA statement used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

```
.40      proc sort; by mask_pat;
```

[NOTE: There were 663 observations read from the data set WORK.NEPH_8B.

[NOTE: The data set WORK.NEPH_8B has 663 observations and 2 variables.

[NOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

```
.41      data atrisk1b; merge atrisk1b(in=in1) neph_7b(in=in7)
```

```
.42                        neph_8b(in=in8);
```

```
.43      by mask_pat;
```

```
.44      if in1 and (in7 or in8);
```

```
.45      * n=572 as stated in the text *;
```

```
.46      run;
```

[NOTE: There were 666 observations read from the data set WORK.ATRISK1B.

[NOTE: There were 629 observations read from the data set WORK.NEPH_7B.

[NOTE: There were 663 observations read from the data set WORK.NEPH_8B.

[NOTE: The data set WORK.ATRISK1B has 632 observations and 2 variables.

[NOTE: DATA statement used (Total process time):

real time 0.00 seconds

cpu time 0.00 seconds

```
.47      proc freq; tables p_300; run;
```

[NOTE: There were 632 observations read from the data set WORK.ATRISK1B.

[NOTE: The PROCEDURE FREQ printed page 55.

[NOTE: PROCEDURE FREQ used (Total process time):

real time 0.03 seconds

cpu time 0.01 seconds

The SAS System: Log file for Clinical Albuminuria Analyses

The SAS System

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.007

```
.48  
.49     data atrisk0b(keep=mask_pat); set neph_8yr;  
.50         where close300=0 and IntensTx=0 and edicyear=0;  
.51         run;
```

NOTE: There were 653 observations read from the data set WORK.NEPH_8YR.
WHERE (close300=0) and (IntensTx=0) and (edicyear=0);

NOTE: The data set WORK.ATRISK0B has 653 observations and 1 variables.

NOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

```
.52     data atrisk0b; merge atrisk0b(in=in1) neph_7b(in=in7)  
.53                             neph_8b(in=in8);  
.54     by mask_pat;  
.55     if in1 and (in7 or in8);  
.56     * n=626, as opposed to n=630 stated in the text *;  
.57     run;
```

NOTE: There were 653 observations read from the data set WORK.ATRISK0B.

NOTE: There were 629 observations read from the data set WORK.NEPH_7B.

NOTE: There were 663 observations read from the data set WORK.NEPH_8B.

NOTE: The data set WORK.ATRISK0B has 626 observations and 2 variables.

NOTE: DATA statement used (Total process time):

real time	0.00 seconds
cpu time	0.00 seconds

```
.58     proc freq; tables p_300; run;
```

NOTE: There were 626 observations read from the data set WORK.ATRISK0B.

NOTE: The PROCEDURE FREQ printed page 56.

NOTE: PROCEDURE FREQ used (Total process time):

real time	0.03 seconds
cpu time	0.00 seconds

.59

The SAS System: Output for Clinical Albuminuria Analyses
Compare to results in first sentence under “Development of Clinical Albuminuria”

The FREQ Procedure

Prevalence indicator of current AER > 300

P_300	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	623	98.58	623	98.58
Yes	9	1.42	632	100.00

The SAS System

Compare to results in first sentence under “Development of Clinical Albuminuria”

Prevalence indicator of current AER > 300				
P_300	Frequency	Percent	Cumulative Frequency	Cumulative Percent
No	571	91.21	571	91.21
Yes	55	8.79	626	100.00

APPENDIX E

SAS 9.1 Code and Output for Replication of Selected Analyses in Results: Other Kidney Outcomes and in Table 2: Patients With Kidney Outcomes through Year 8 in the EDIC Study, from EDIC Nephropathy Dataset in NIDDK Repository

The SAS System: Log for analyses of Other Kidney Outcomes

```
.59  
.60 *****;  
.61 * other kidney outcomes *;  
.62 *****;  
.63 ** pg.2163, attempt to replicate results in last sentence of first paragraph under  
.63 ! Other Kidney Outcomes **;  
.64 proc means data=neph_8yr noprint; class group mask_pat; var serumcr;  
.65 output out=meancreat mean=meancreat; run;
```

The SAS System: Log for analyses of Other Kidney Outcomes

The SAS System

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:007

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.

NOTE: The data set WORK.MEANCREAT has 2701 observations and 5 variables.

NOTE: PROCEDURE MEANS used (Total process time):

real time 0.06 seconds

cpu time 0.04 seconds

.66 proc univariate data=meancreat; class group; var meancreat; run;

NOTE: The PROCEDURE UNIVARIATE printed pages 57-60.

NOTE: PROCEDURE UNIVARIATE used (Total process time):

real time 0.03 seconds

cpu time 0.01 seconds

.67 proc nparlway wilcoxon data=meancreat; class group; var meancreat; run;

NOTE: There were 2701 observations read from the data set WORK.MEANCREAT.

NOTE: The PROCEDURE NPARIWAY printed page 61.

NOTE: PROCEDURE NPARIWAY used (Total process time):

real time 0.15 seconds

cpu time 0.00 seconds

.68 ** very close to published **;

.69

.70 ** pg.2163, attempt to replicate results in last sentence of second paragraph under

.70 ! Other Kidney Outcomes **;

.71 proc freq data=neph_8yr; where edicyear=7;

.72 tables group*clr_70/chisq exact; run;

NOTE: There were 1305 observations read from the data set WORK.NEPH_8YR.

WHERE edicyear=7;

NOTE: The PROCEDURE FREQ printed pages 62-63.

NOTE: PROCEDURE FREQ used (Total process time):

real time 0.04 seconds

cpu time 0.00 seconds

.73

.74 * table 2 *;

.75 data neph_8yr; set neph_8yr;

.76 creat_elev=.;

.77 if serumcr>=2 then creat_elev=1;

.78 else if .<serumcr<2 then creat_elev=0;

.79

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.

NOTE: The data set WORK.NEPH_8YR has 11745 observations and 55 variables.

NOTE: DATA statement used (Total process time):

real time 0.04 seconds

cpu time 0.03 seconds

The SAS System: Log for analyses of Other Kidney Outcomes

The SAS System

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007

```
.80      data doubles; set neph_8yr; if double=1;
.81          * double = doubling of serum creatinine level from DCCT baseline *
.82          * i checked this variable against indicator[serumcr >= 2*scr00], data match *;
```

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.

NOTE: The data set WORK.DOUBLES has 154 observations and 55 variables.

NOTE: DATA statement used (Total process time):

```
real time          0.03 seconds
cpu time           0.01 seconds
```

```
.83      proc sort; by mask_pat edicyear;
.84      /*
.85      proc print data=doubles; by mask_pat;
.86          var edicyear group serumcr scr00 double dialysis trans; run;
.87      */
.88          * get year when creatinine level was first doubled from DCCT bsln *;
```

NOTE: There were 154 observations read from the data set WORK.DOUBLES.

NOTE: The data set WORK.DOUBLES has 154 observations and 55 variables.

NOTE: PROCEDURE SORT used (Total process time):

```
real time          0.01 seconds
cpu time           0.01 seconds
```

```
.189      data firstdoub; set doubles; by mask_pat edicyear;
.90      if first.mask_pat; keep mask_pat edicyear scr00 group; run;
```

NOTE: There were 154 observations read from the data set WORK.DOUBLES.

NOTE: The data set WORK.FIRSTDOUB has 52 observations and 4 variables.

NOTE: DATA statement used (Total process time):

```
real time          0.01 seconds
cpu time           0.00 seconds
```

```
.91      proc freq; tables edicyear*group;
.92      title The first year EDIC subjects doubled their serum creatinine levels from DCCT
>sln
.92      ! (N=52); run;
```

NOTE: There were 52 observations read from the data set WORK.FIRSTDOUB.

NOTE: The PROCEDURE FREQ printed pages 64-65.

NOTE: PROCEDURE FREQ used (Total process time):

```
real time          0.03 seconds
cpu time           0.00 seconds
```

```
.93          * we get n=52 subjects who doubled their serum creatinine concentration since DCCT
.93      ! bsln,
.94          not n=27 as stated in the text and in Table 2.
.95          Even if we limit the sample to those who doubled their s.creatinine after DCCT
.95      ! closeout,
```

The SAS System: Log for analyses of Other Kidney Outcomes

The SAS System

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:007

```
.96         we still get n=45. *;  
.97  
.98         * Try limiting dataset to patients with complete serum creatinine data at each year  
.98 ! of EDIC,  
.99         as stated in the Title of Table 2: Patients with kidney outcomes Through Year 8 in  
.99 ! the EDIC Study *;  
:00         title;  
:01         data NEPH_at1(keep=mask_pat); set neph_8yr; where edicyear=1 and double^=.;
```

IOTE: There were 1280 observations read from the data set WORK.NEPH_8YR.
WHERE (edicyear=1) and (double not = .);

IOTE: The data set WORK.NEPH_AT1 has 1280 observations and 1 variables.

IOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.00 seconds

```
:02         proc sort; by mask_pat;
```

IOTE: There were 1280 observations read from the data set WORK.NEPH_AT1.

IOTE: The data set WORK.NEPH_AT1 has 1280 observations and 1 variables.

IOTE: PROCEDURE SORT used (Total process time):

real time	0.00 seconds
cpu time	0.00 seconds

```
:03         data NEPH_at2(keep=mask_pat); set neph_8yr; where edicyear=2 and double^=.;
```

IOTE: There were 1263 observations read from the data set WORK.NEPH_8YR.
WHERE (edicyear=2) and (double not = .);

IOTE: The data set WORK.NEPH_AT2 has 1263 observations and 1 variables.

IOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

```
:04         proc sort; by mask_pat;
```

IOTE: There were 1263 observations read from the data set WORK.NEPH_AT2.

IOTE: The data set WORK.NEPH_AT2 has 1263 observations and 1 variables.

IOTE: PROCEDURE SORT used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

```
:05         data NEPH_at3(keep=mask_pat); set neph_8yr; where edicyear=3 and double^=.;
```

IOTE: There were 1268 observations read from the data set WORK.NEPH_8YR.
WHERE (edicyear=3) and (double not = .);

IOTE: The data set WORK.NEPH_AT3 has 1268 observations and 1 variables.

IOTE: DATA statement used (Total process time):

real time	0.01 seconds
cpu time	0.01 seconds

The SAS System: Log for analyses of Other Kidney Outcomes

The SAS System

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:06 proc sort; by mask_pat;

IOTE: There were 1268 observations read from the data set WORK.NEPH_AT3.

IOTE: The data set WORK.NEPH_AT3 has 1268 observations and 1 variables.

IOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.00 seconds

:07 data NEPH_at4(keep=mask_pat); set neph_8yr; where edicyear=4 and double^=.;

IOTE: There were 1257 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=4) and (double not = .);

IOTE: The data set WORK.NEPH_AT4 has 1257 observations and 1 variables.

IOTE: DATA statement used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

:08 proc sort; by mask_pat;

IOTE: There were 1257 observations read from the data set WORK.NEPH_AT4.

IOTE: The data set WORK.NEPH_AT4 has 1257 observations and 1 variables.

IOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.00 seconds

:09 data NEPH_at5(keep=mask_pat); set neph_8yr; where edicyear=5 and double^=.;

IOTE: There were 1262 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=5) and (double not = .);

IOTE: The data set WORK.NEPH_AT5 has 1262 observations and 1 variables.

IOTE: DATA statement used (Total process time):

real time 0.03 seconds

cpu time 0.01 seconds

:10 proc sort; by mask_pat;

IOTE: There were 1262 observations read from the data set WORK.NEPH_AT5.

IOTE: The data set WORK.NEPH_AT5 has 1262 observations and 1 variables.

IOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

:11 data NEPH_at6(keep=mask_pat); set neph_8yr; where edicyear=6 and double^=.;

IOTE: There were 1270 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=6) and (double not = .);

The SAS System: Log for analyses of Other Kidney Outcomes

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NOTE: The data set WORK.NEPH_AT6 has 1270 observations and 1 variables.

NOTE: DATA statement used (Total process time):

real time 0.03 seconds

cpu time 0.01 seconds

:12 proc sort; by mask_pat;

NOTE: There were 1270 observations read from the data set WORK.NEPH_AT6.

NOTE: The data set WORK.NEPH_AT6 has 1270 observations and 1 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time 0.00 seconds

cpu time 0.00 seconds

:13 data NEPH_at7(keep=mask_pat); set neph_8yr; where edicyear=7 and double^=.;

NOTE: There were 1277 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=7) and (double not = .);

NOTE: The data set WORK.NEPH_AT7 has 1277 observations and 1 variables.

NOTE: DATA statement used (Total process time):

real time 0.03 seconds

cpu time 0.01 seconds

:14 proc sort; by mask_pat;

NOTE: There were 1277 observations read from the data set WORK.NEPH_AT7.

NOTE: The data set WORK.NEPH_AT7 has 1277 observations and 1 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

:15 data NEPH_at8(keep=mask_pat); set neph_8yr; where edicyear=8 and double^=.;

NOTE: There were 1250 observations read from the data set WORK.NEPH_8YR.

WHERE (edicyear=8) and (double not = .);

NOTE: The data set WORK.NEPH_AT8 has 1250 observations and 1 variables.

NOTE: DATA statement used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

:16 proc sort; by mask_pat;

:17

NOTE: There were 1250 observations read from the data set WORK.NEPH_AT8.

NOTE: The data set WORK.NEPH_AT8 has 1250 observations and 1 variables.

NOTE: PROCEDURE SORT used (Total process time):

real time 0.01 seconds

cpu time 0.01 seconds

The SAS System: Log for analyses of Other Kidney Outcomes

The SAS System

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```
:18      data neph_base_doub; merge neph_base firstdoub(in=in0 rename=(edicyear=firstyear))
:19          neph_at1(in=in1) neph_at2(in=in2) neph_at3(in=in3) neph_at4(in=in4)
:20          neph_at5(in=in5) neph_at6(in=in6) neph_at7(in=in7) neph_at8(in=in8);
:21      by mask_pat;
:22      if in0 then firstdoub=1;
:23      else do; firstdoub=0; firstyear=-1; end; *serum creatinine not doubled from DCCT
:sln
:24                      during the followup period *;
:25      if in1 and in2 and in3 and in4 and in5 and in6 and in7 and in8;
:26      run;
```

```
NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.
NOTE: There were 52 observations read from the data set WORK.FIRSTDOUB.
NOTE: There were 1280 observations read from the data set WORK.NEPH_AT1.
NOTE: There were 1263 observations read from the data set WORK.NEPH_AT2.
NOTE: There were 1268 observations read from the data set WORK.NEPH_AT3.
NOTE: There were 1257 observations read from the data set WORK.NEPH_AT4.
NOTE: There were 1262 observations read from the data set WORK.NEPH_AT5.
NOTE: There were 1270 observations read from the data set WORK.NEPH_AT6.
NOTE: There were 1277 observations read from the data set WORK.NEPH_AT7.
NOTE: There were 1250 observations read from the data set WORK.NEPH_AT8.
NOTE: The data set WORK.NEPH_BASE_DOUB has 1038 observations and 56 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds
```

```
:27      proc freq data=neph_base_doub; tables firstdoub*group/chisq exact; run;
```

```
NOTE: There were 1038 observations read from the data set WORK.NEPH_BASE_DOUB.
NOTE: The PROCEDURE FREQ printed page 66.
NOTE: PROCEDURE FREQ used (Total process time):
      real time           0.15 seconds
      cpu time            0.01 seconds
```

```
:28      * now we get the published numerator (n=27),
:29      * but denominators are still different... after restricting the sample to those with
:29      ! complete
:30      creat data at each year of EDIC,
:31      i have an N of 1038, but published N in Table 2 is 1349 *;
:32
:33      *****;
:34
```

The SAS System: Output for analyses of Other Kidney Outcomes
Compare to results in last sentence of first paragraph of section, JAMA p. 2163
The UNIVARIATE Procedure
Variable: meancreat (Serum creatinine (mg/dL))
GROUP = Intensive Treatment

Moments			
N	677	Sum Weights	677
Mean	0.88906941	Sum Observations	601.899991
Std Deviation	0.18524657	Variance	0.03431629
Skewness	6.05081285	Kurtosis	74.0773246
Uncorrected SS	558.328684	Corrected SS	23.1978141
Coeff Variation	20.836008	Std Error Mean	0.0071196

Basic Statistical Measures			
Location		Variability	
Mean	0.889069	Std Deviation	0.18525
Median	0.875000	Variance	0.03432
Mode	0.800000	Range	2.97143
		Interquartile Range	0.19206

Tests for Location: $\mu_0=0$				
Test	Statistic		p Value	
Student's t	t	124.8762	Pr > t 	<.0001
Sign	M	338.5	Pr >= M 	<.0001
Signed Rank	S	114751.5	Pr >= S 	<.0001

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	3.571429
99%	1.366667
95%	1.100000
90%	1.044444
75% Q3	0.977778
50% Median	0.875000
25% Q1	0.785714
10%	0.722222
5%	0.683333

**The SAS System: Output for analyses of Other Kidney Outcomes
 Compare to results in last sentence of first paragraph of section, JAMA p. 2163**

The UNIVARIATE Procedure

Variable: meancreat (Serum creatinine (mg/dL))

GROUP = Intensive Treatment

Quantiles (Definition 5)

Quantile	Estimate
1%	0.622222
0% Min	0.600000

Extreme Observations

Lowest		Highest	
Value	Obs	Value	Obs
0.600000	1976	1.50000	1365
0.600000	1748	1.93333	1796
0.600000	1405	2.07500	1419
0.611111	1922	2.40000	1811
0.611111	1465	3.57143	1861

The SAS System: Output for analyses of Other Kidney Outcomes
Compare to results in last sentence of first paragraph of section, JAMA p. 2163
The UNIVARIATE Procedure
Variable: meancreat (Serum creatinine (mg/dL))
GROUP = Conventional Treatment

Moments			
N	674	Sum Weights	674
Mean	0.90651462	Sum Observations	610.990851
Std Deviation	0.1960986	Variance	0.03845466
Skewness	2.7580103	Kurtosis	14.1929654
Uncorrected SS	579.752124	Corrected SS	25.8799875
Coeff Variation	21.6321501	Std Error Mean	0.00755344

Basic Statistical Measures			
Location		Variability	
Mean	0.906515	Std Deviation	0.19610
Median	0.886607	Variance	0.03845
Mode	0.888889	Range	1.87778
		Interquartile Range	0.20000

Tests for Location: $\mu_0=0$				
Test	Statistic		p Value	
Student's t	t	120.0135	Pr > t 	<.0001
Sign	M	337	Pr >= M 	<.0001
Signed Rank	S	113737.5	Pr >= S 	<.0001

Quantiles (Definition 5)	
Quantile	Estimate
100% Max	2.400000
99%	1.737500
95%	1.188889
90%	1.077778
75% Q3	0.988889
50% Median	0.886607
25% Q1	0.788889
10%	0.711111
5%	0.677778

The SAS System: Output for analyses of Other Kidney Outcomes
Compare to results in last sentence of first paragraph of section, JAMA p. 2163
The UNIVARIATE Procedure
Variable: meancreat (Serum creatinine (mg/dL))
GROUP = Conventional Treatment

Quantiles (Definition 5)	
Quantile	Estimate
1%	0.633333
0% Min	0.522222

Extreme Observations			
Lowest		Highest	
Value	Obs	Value	Obs
0.522222	2685	1.88571	2037
0.600000	2368	1.98750	2207
0.622222	2251	2.15000	2098
0.633333	2543	2.30000	2346
0.633333	2274	2.40000	2111

The SAS System: Output for analyses of Other Kidney Outcomes
Compare to results in last sentence of first paragraph of section, JAMA p. 2163
The NPAR1WAY Procedure

Wilcoxon Scores (Rank Sums) for Variable meancreat
Classified by Variable GROUP

GROUP	N	Sum of Scores	Expected Under H0	Std Dev Under H0	Mean Score
Intensive Treatment	677	449706.0	457652.0	7169.51988	664.262925
Conventional Treatment	674	463570.0	455624.0	7169.51988	687.789318

Average scores were used for ties.

Wilcoxon Two-Sample Test

Statistic	463570.0000
-----------	-------------

Normal Approximation

Z	1.1082
One-Sided Pr > Z	0.1339
Two-Sided Pr > Z	0.2678

t Approximation

One-Sided Pr > Z	0.1340
Two-Sided Pr > Z	0.2680

Z includes a continuity correction of 0.5.

Kruskal-Wallis Test

Chi-Square	1.2283
DF	1
Pr > Chi-Square	0.2677

**The SAS System: Output for analyses of Other Kidney Outcomes
 Compare to results in last sentence of second paragraph of section, JAMA p. 2163
 The FREQ Procedure**

Table of GROUP by CLR_70

GROUP(TREATMENT GROUP)	CLR_70(Standard clearance < 70)		Total
	No	Yes	
Intensive Treatment	320	2	322
	50.87	0.32	51.19
	99.38	0.62	
	51.86	16.67	
Conventional Treatment	297	10	307
	47.22	1.59	48.81
	96.74	3.26	
	48.14	83.33	
Total	617	12	629
	98.09	1.91	100.00

Frequency Missing = 676

Statistics for Table of GROUP by CLR_70

Statistic	DF	Value	Prob
Chi-Square	1	5.8363	0.0157
Likelihood Ratio Chi-Square	1	6.3219	0.0119
Continuity Adj. Chi-Square	1	4.5126	0.0336
Mantel-Haenszel Chi-Square	1	5.8270	0.0158
Phi Coefficient		0.0963	
Contingency Coefficient		0.0959	
Cramer's V		0.0963	

Fisher's Exact Test

Cell (1,1) Frequency (F)	320
Left-sided Pr <= F	0.9977
Right-sided Pr >= F	0.0150
Table Probability (P)	0.0127
Two-sided Pr <= P	0.0187

**Effective Sample Size = 629
 Frequency Missing = 676**

The SAS System: Output for analyses of Other Kidney Outcomes

The FREQ Procedure

Statistics for Table of GROUP by CLR_70

WARNING: 52% of the data are missing.

The SAS System: Output for analyses of Other Kidney Outcomes
First year during EDIC subjects doubled their serum creatinine levels from DCCT bsln, by
treatment group, (Total n=52)
Compare to (Total n=27), Table 2, line 1, JAMA p. 2163
The FREQ Procedure

Table of EDICYEAR by GROUP			
EDICYEAR(EDIC FOLLOWUP YEAR)	GROUP(TREATMENT GROUP)		
Frequency Percent Row Pct Col Pct	Intensive Treatment	Conventional Treatment	Total
00	4 7.69 57.14 26.67	3 5.77 42.86 8.11	7 13.46
01	1 1.92 14.29 6.67	6 11.54 85.71 16.22	7 13.46
02	3 5.77 37.50 20.00	5 9.62 62.50 13.51	8 15.38
03	1 1.92 25.00 6.67	3 5.77 75.00 8.11	4 7.69
04	0 0.00 0.00 0.00	3 5.77 100.00 8.11	3 5.77
05	2 3.85 25.00 13.33	6 11.54 75.00 16.22	8 15.38
06	2 3.85 50.00 13.33	2 3.85 50.00 5.41	4 7.69
07	0 0.00 0.00 0.00	5 9.62 100.00 13.51	5 9.62
08	2 3.85 33.33 13.33	4 7.69 66.67 10.81	6 11.54
Total	15 28.85	37 71.15	52 100.00

The SAS System: Output for analyses of Other Kidney Outcomes
EDIC subjects who doubled their serum creatinine levels from DCCT bsln, by treatment group,
with serum creatinine data at each year of EDIC (Total n=27, out of N=1038)
Compare to (Total n=27, out of N=1349), Table 2, line 1, JAMA p. 2163
The FREQ Procedure

Table of firstdoub by GROUP			
firstdoub	GROUP(TREATMENT GROUP)		
	Intensive Treatment	Conventional Treatment	Total
Frequency			
Percent			
Row Pct			
Col Pct			
0	511 49.23 50.54 98.27	500 48.17 49.46 96.53	1011 97.40
1	9 0.87 33.33 1.73	18 1.73 66.67 3.47	27 2.60
Total	520 50.10	518 49.90	1038 100.00

Statistics for Table of firstdoub by GROUP

Statistic	DF	Value	Prob
Chi-Square	1	3.1158	0.0775
Likelihood Ratio Chi-Square	1	3.1740	0.0748
Continuity Adj. Chi-Square	1	2.4654	0.1164
Mantel-Haenszel Chi-Square	1	3.1128	0.0777
Phi Coefficient		0.0548	
Contingency Coefficient		0.0547	
Cramer's V		0.0548	

Fisher's Exact Test

Cell (1,1) Frequency (F)	511
Left-sided Pr <= F	0.9760
Right-sided Pr >= F	0.0574
Table Probability (P)	0.0334
Two-sided Pr <= P	0.0826

Sample Size = 1038

The SAS System: Output for analyses of Other Kidney Outcomes

The FREQ Procedure

APPENDIX F

SAS 9.1 Code and Output for Replication of Selected Analyses in Results: Blood Pressure/Hypertension and in Figure 4: Prevalence of Hypertension at Each Year of the EDIC Study, from EDIC Nephropathy Dataset in NIDDK Repository

The SAS System: Log for analyses of Blood Pressure/Hypertension

```
!35 *****;  
!36 * Blood pressure / hypertension (HT) *;  
!37 *****;  
!38 * Figure 4 *;  
!39 proc sort data=NEPH_BASE; by mask_pat;
```

NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.
NOTE: The data set WORK.NEPH_BASE has 1349 observations and 54 variables.
NOTE: PROCEDURE SORT used (Total process time):

The SAS System: Log for analyses of Blood Pressure/Hypertension

The SAS System

12:13 Monday, February 12,

:007

```
real time          0.01 seconds
cpu time           0.01 seconds
```

```
:40      proc sort data=neph_8yr; by mask_pat;
```

```
NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The data set WORK.NEPH_8YR has 11745 observations and 55 variables.
NOTE: PROCEDURE SORT used (Total process time):
real time          0.06 seconds
cpu time           0.06 seconds
```

```
:41      data neph_8yr; merge neph_8yr neph_base(keep=mask_pat map rename=(map=map0));
:42      by mask_pat; run;
```

```
NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: There were 1349 observations read from the data set WORK.NEPH_BASE.
NOTE: The data set WORK.NEPH_8YR has 11745 observations and 56 variables.
NOTE: DATA statement used (Total process time):
real time          0.06 seconds
cpu time           0.06 seconds
```

```
:43      * dont have average map from DCCT, which was adjusted for in the figure...
:44      so use DCCT closeout map instead *;
```

```
:45
:46      proc sort data=neph_8yr; by edicyear group;
```

```
NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The data set WORK.NEPH_8YR has 11745 observations and 56 variables.
NOTE: PROCEDURE SORT used (Total process time):
real time          0.07 seconds
cpu time           0.06 seconds
```

```
:47      proc freq data=neph_8yr; by edicyear;
:48      tables group*ht/chisq exact; run;
```

```
NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The PROCEDURE FREQ printed pages 67-75.
NOTE: PROCEDURE FREQ used (Total process time):
real time          0.10 seconds
cpu time           0.06 seconds
```

```
:49      proc freq data=neph_8yr noprint; by edicyear group;
:50      tables ht/out=htprevs; run;
```

```
NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The data set WORK.HTPREVS has 36 observations and 5 variables.
NOTE: PROCEDURE FREQ used (Total process time):
real time          0.01 seconds
```

The SAS System: Log for analyses of Blood Pressure/Hypertension

The SAS System

12:13 Monday, February 12,

:007

cpu time 0.01 seconds

```
:51 * to replicate figure 4 *;  
:52 *ods html file="C:\DATA\NIDDK\Neph\htprevs2.xls" style=minimal;  
:53 proc print data=htprevs; where ht=1; run;
```

NOTE: There were 18 observations read from the data set WORK.HTPREVS.
WHERE ht=1;

NOTE: The PROCEDURE PRINT printed page 76.

NOTE: PROCEDURE PRINT used (Total process time):
real time 0.06 seconds
cpu time 0.00 seconds

```
:54 *ods html close;  
:55 * check with logistic regression, adjusting for DCCT closeout map instead of DCCT  
:55 ! average map which was not available *;  
:56 proc logistic data=neph_8yr descending;  
:57 by edickeyear;  
:58 model ht=intenstx map0/risklimits; run;
```

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=00

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=01

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=02

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=03

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=04

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=05

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:
EDIC FOLLOWUP YEAR=06

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:

The SAS System: Log for analyses of Blood Pressure/Hypertension

The SAS System

12:13 Monday, February 12,

:007

EDIC FOLLOWUP YEAR=07

NOTE: PROC LOGISTIC is modeling the probability that HT='Yes'.

NOTE: Convergence criterion (GCONV=1E-8) satisfied.

NOTE: The above message was for the following by-group:

EDIC FOLLOWUP YEAR=08

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.

NOTE: The PROCEDURE LOGISTIC printed pages 77-94.

NOTE: PROCEDURE LOGISTIC used (Total process time):

real time 0.39 seconds

cpu time 0.25 seconds

:59 * either way, results are close to published p-values *;

:60

:61 ods rtf close; run;

:62

The SAS System: Output for analyses of Blood Pressure/Hypertension
The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164

EDIC FOLLOWUP YEAR=00

Table of GROUP by HT

GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	602	74	676
	44.63	5.49	50.11
	89.05	10.95	
	50.00	51.03	
Conventional Treatment	602	71	673
	44.63	5.26	49.89
	89.45	10.55	
	50.00	48.97	
Total	1204	145	1349
	89.25	10.75	100.00

Statistics for Table of GROUP by HT

Statistic	DF	Value	Prob
Chi-Square	1	0.0554	0.8139
Likelihood Ratio Chi-Square	1	0.0554	0.8139
Continuity Adj. Chi-Square	1	0.0217	0.8828
Mantel-Haenszel Chi-Square	1	0.0554	0.8140
Phi Coefficient		-0.0064	
Contingency Coefficient		0.0064	
Cramer's V		-0.0064	

Fisher's Exact Test

Cell (1,1) Frequency (F)	602
Left-sided Pr <= F	0.4414
Right-sided Pr >= F	0.6267
Table Probability (P)	0.0681
Two-sided Pr <= P	0.8606

Sample Size = 1349

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=01

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	542	110	652
	41.69	8.46	50.15
	83.13	16.87	
	49.91	51.40	
Conventional Treatment	544	104	648
	41.85	8.00	49.85
	83.95	16.05	
	50.09	48.60	
Total	1086	214	1300
	83.54	16.46	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	0.1596	0.6895
Likelihood Ratio Chi-Square	1	0.1596	0.6895
Continuity Adj. Chi-Square	1	0.1054	0.7454
Mantel-Haenszel Chi-Square	1	0.1595	0.6896
Phi Coefficient		-0.0111	
Contingency Coefficient		0.0111	
Cramer's V		-0.0111	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	542
Left-sided Pr <= F	0.3727
Right-sided Pr >= F	0.6823
Table Probability (P)	0.0551
Two-sided Pr <= P	0.7088

Sample Size = 1300

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=02

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	530	121	651
	40.83	9.32	50.15
	81.41	18.59	
	50.48	48.79	
Conventional Treatment	520	127	647
	40.06	9.78	49.85
	80.37	19.63	
	49.52	51.21	
Total	1050	248	1298
	80.89	19.11	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	0.2281	0.6330
Likelihood Ratio Chi-Square	1	0.2281	0.6329
Continuity Adj. Chi-Square	1	0.1656	0.6840
Mantel-Haenszel Chi-Square	1	0.2279	0.6331
Phi Coefficient		0.0133	
Contingency Coefficient		0.0133	
Cramer's V		0.0133	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	530
Left-sided Pr <= F	0.7082
Right-sided Pr >= F	0.3420
Table Probability (P)	0.0502
Two-sided Pr <= P	0.6719

Sample Size = 1298

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=03

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	529	122	651
	40.60	9.36	49.96
	81.26	18.74	
	52.32	41.78	
Conventional Treatment	482	170	652
	36.99	13.05	50.04
	73.93	26.07	
	47.68	58.22	
Total	1011	292	1303
	77.59	22.41	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	10.0746	0.0015
Likelihood Ratio Chi-Square	1	10.1113	0.0015
Continuity Adj. Chi-Square	1	9.6573	0.0019
Mantel-Haenszel Chi-Square	1	10.0669	0.0015
Phi Coefficient		0.0879	
Contingency Coefficient		0.0876	
Cramer's V		0.0879	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	529
Left-sided Pr <= F	0.9994
Right-sided Pr >= F	9.276E-04
Table Probability (P)	3.425E-04
Two-sided Pr <= P	0.0018

Sample Size = 1303

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=04

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	508	138	646
	39.35	10.69	50.04
	78.64	21.36	
	51.94	44.09	
Conventional Treatment	470	175	645
	36.41	13.56	49.96
	72.87	27.13	
	48.06	55.91	
Total	978	313	1291
	75.76	24.24	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	5.8495	0.0156
Likelihood Ratio Chi-Square	1	5.8601	0.0155
Continuity Adj. Chi-Square	1	5.5396	0.0186
Mantel-Haenszel Chi-Square	1	5.8450	0.0156
Phi Coefficient		0.0673	
Contingency Coefficient		0.0672	
Cramer's V		0.0673	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	508
Left-sided Pr <= F	0.9935
Right-sided Pr >= F	0.0093
Table Probability (P)	0.0028
Two-sided Pr <= P	0.0163

Sample Size = 1291

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=05

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	496	151	647
	38.36	11.68	50.04
	76.66	23.34	
	53.10	42.06	
Conventional Treatment	438	208	646
	33.87	16.09	49.96
	67.80	32.20	
	46.90	57.94	
Total	934	359	1293
	72.24	27.76	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	12.6511	0.0004
Likelihood Ratio Chi-Square	1	12.6918	0.0004
Continuity Adj. Chi-Square	1	12.2132	0.0005
Mantel-Haenszel Chi-Square	1	12.6413	0.0004
Phi Coefficient		0.0989	
Contingency Coefficient		0.0984	
Cramer's V		0.0989	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	496
Left-sided Pr <= F	0.9999
Right-sided Pr >= F	2.329E-04
Table Probability (P)	8.812E-05
Two-sided Pr <= P	3.982E-04

Sample Size = 1293

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=06

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	467	186	653
	35.73	14.23	49.96
	71.52	28.48	
	52.35	44.82	
Conventional Treatment	425	229	654
	32.52	17.52	50.04
	64.98	35.02	
	47.65	55.18	
Total	892	415	1307
	68.25	31.75	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	6.4322	0.0112
Likelihood Ratio Chi-Square	1	6.4410	0.0112
Continuity Adj. Chi-Square	1	6.1344	0.0133
Mantel-Haenszel Chi-Square	1	6.4273	0.0112
Phi Coefficient		0.0702	
Contingency Coefficient		0.0700	
Cramer's V		0.0702	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	467
Left-sided Pr <= F	0.9953
Right-sided Pr >= F	0.0066
Table Probability (P)	0.0019
Two-sided Pr <= P	0.0125

Sample Size = 1307

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=07

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	453	200	653
	34.71	15.33	50.04
	69.37	30.63	
	53.55	43.57	
Conventional Treatment	393	259	652
	30.11	19.85	49.96
	60.28	39.72	
	46.45	56.43	
Total	846	459	1305
	64.83	35.17	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	11.8384	0.0006
Likelihood Ratio Chi-Square	1	11.8630	0.0006
Continuity Adj. Chi-Square	1	11.4429	0.0007
Mantel-Haenszel Chi-Square	1	11.8294	0.0006
Phi Coefficient		0.0952	
Contingency Coefficient		0.0948	
Cramer's V		0.0952	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	453
Left-sided Pr <= F	0.9998
Right-sided Pr >= F	3.548E-04
Table Probability (P)	1.240E-04
Two-sided Pr <= P	6.236E-04

Sample Size = 1305

The FREQ Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164
EDIC FOLLOWUP YEAR=08

Table of GROUP by HT			
GROUP(TREATMENT GROUP)	HT(Current Hypertension (>=140/90))		
	No	Yes	Total
Intensive Treatment	457	195	652
	35.18	15.01	50.19
	70.09	29.91	
	54.21	42.76	
Conventional Treatment	386	261	647
	29.72	20.09	49.81
	59.66	40.34	
	45.79	57.24	
Total	843	456	1299
	64.90	35.10	100.00

Statistics for Table of GROUP by HT			
Statistic	DF	Value	Prob
Chi-Square	1	15.5134	<.0001
Likelihood Ratio Chi-Square	1	15.5539	<.0001
Continuity Adj. Chi-Square	1	15.0589	0.0001
Mantel-Haenszel Chi-Square	1	15.5015	<.0001
Phi Coefficient		0.1093	
Contingency Coefficient		0.1086	
Cramer's V		0.1093	

Fisher's Exact Test	
Cell (1,1) Frequency (F)	457
Left-sided Pr <= F	1.0000
Right-sided Pr >= F	5.113E-05
Table Probability (P)	1.971E-05
Two-sided Pr <= P	9.645E-05

Sample Size = 1299

The PRINT Procedure
Compare to results in first paragraph in section and Figure 4, JAMA p. 2164

Obs	EDICYEAR	GROUP	HT	COUNT	PERCENT
2	00	Intensive Treatment	Yes	74	10.9467
4	00	Conventional Treatment	Yes	71	10.5498
6	01	Intensive Treatment	Yes	110	16.8712
8	01	Conventional Treatment	Yes	104	16.0494
10	02	Intensive Treatment	Yes	121	18.5868
12	02	Conventional Treatment	Yes	127	19.6291
14	03	Intensive Treatment	Yes	122	18.7404
16	03	Conventional Treatment	Yes	170	26.0736
18	04	Intensive Treatment	Yes	138	21.3622
20	04	Conventional Treatment	Yes	175	27.1318
22	05	Intensive Treatment	Yes	151	23.3385
24	05	Conventional Treatment	Yes	208	32.1981
26	06	Intensive Treatment	Yes	186	28.4839
28	06	Conventional Treatment	Yes	229	35.0153
30	07	Intensive Treatment	Yes	200	30.6279
32	07	Conventional Treatment	Yes	259	39.7239
34	08	Intensive Treatment	Yes	195	29.9080
36	08	Conventional Treatment	Yes	261	40.3400