S. Tan
NIDDK Repository
February 28, 2007

DCCT-EDIC Diabetic Nephropathy Analysis File
Dataset Integrity Check

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 dataset integrity check are described below.

The intent of this dataset integrity check is to provide confidence that the dataset 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 a dataset 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 dataset 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 exception[1], *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.

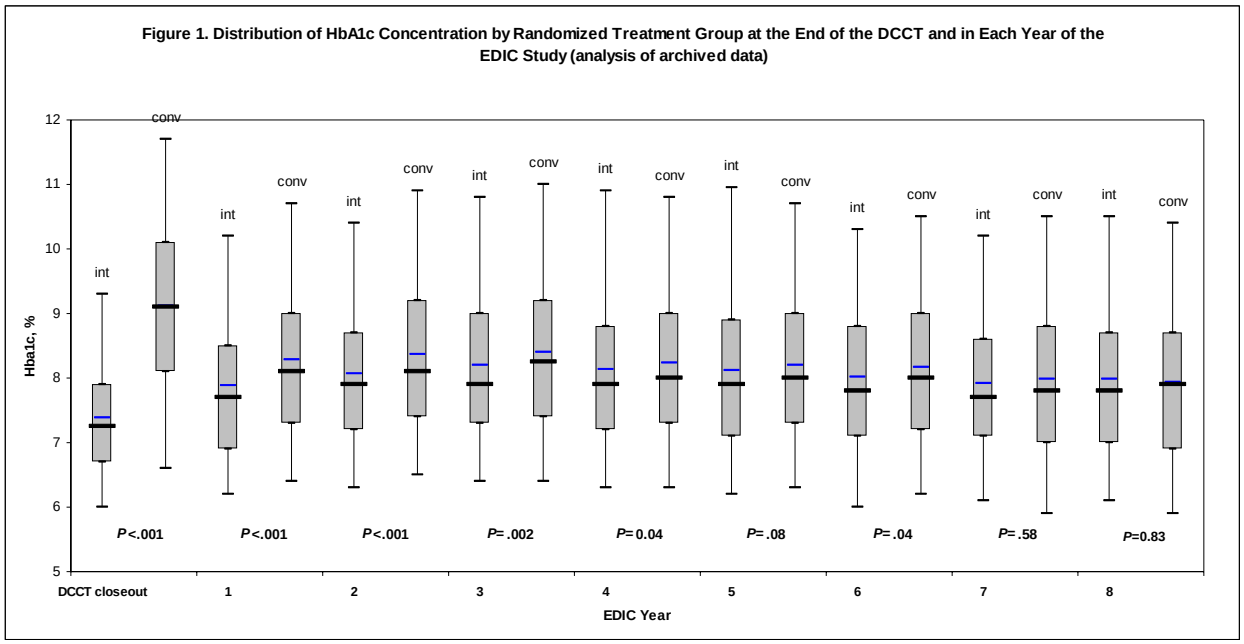
Label	Variable	Intensive (n=676)		Conventional (n=673)		*P*-Value
Attained age, mean (SD), y	ATT_AGE	34	(7)	33	(7)	0.11
Women, No (%)	SEX	330	(49)	313	(47)	0.40
Attained Duration at DCCT Closeout, mean (SD), y	ATT_DU99	12	(5)	12	(5)	0.15
HbA1c, mean (SD), %	HBA1C	7.4	(1.1)	9.1	(1.6)	<0.0001
Body mass 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

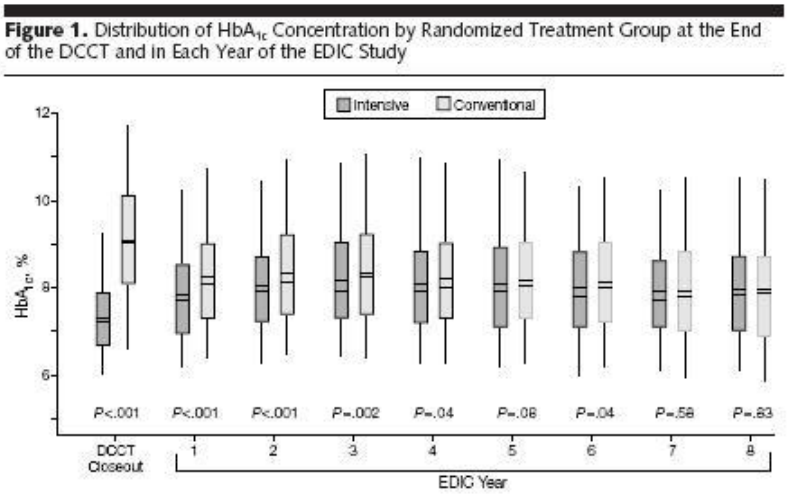
Table 1. Participant Characteristics at EDIC Study Baseline

Characteristic	Original DCCT Treatment Group: Intensive (n = 676)	Original DCCT Treatment Group: Conventional (n = 673)	*P* Value*
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.





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 the archived 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 the archived 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). [(Include the next two sentences? They basically describe the analysis that accompanies the bar chart (Figure 4), which we already talk about in the next-to-last sentence:] 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)

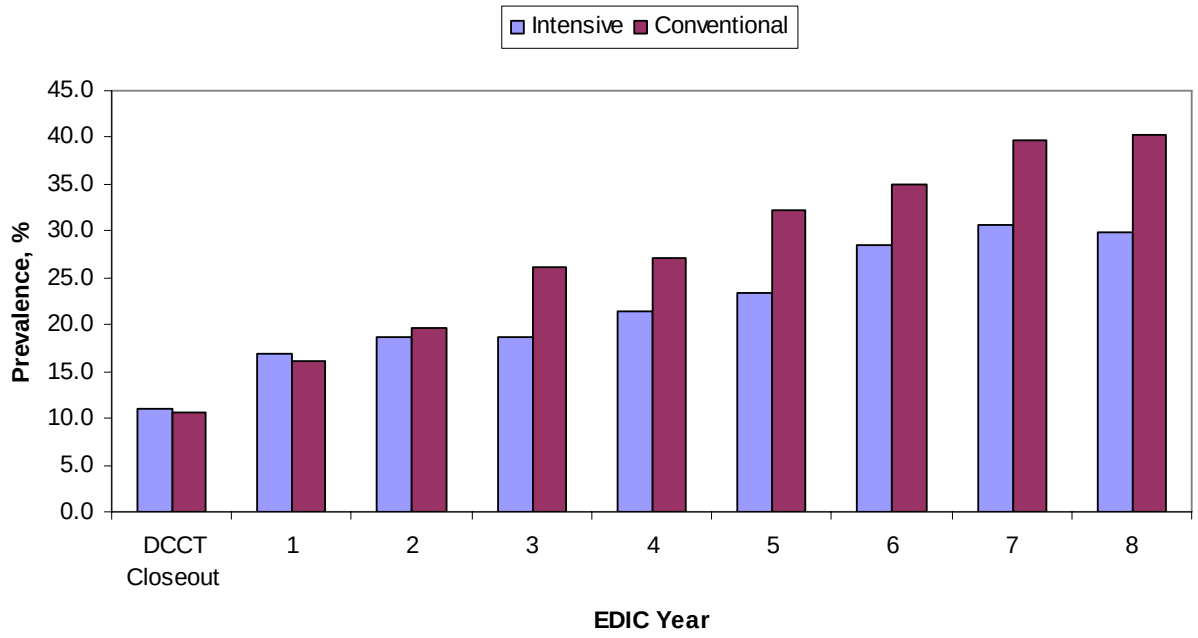
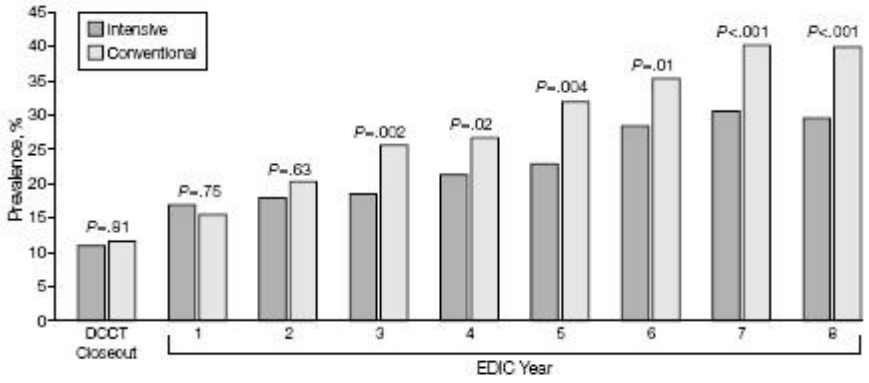


Figure 4. Prevalence of Hypertension at Each Year of the EDIC Study



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

Full Text of Article

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.

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

```
1                                          The SAS System          12:57 Monday, February 12,
2007

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

1          * Filename:  NephInteg.SAS
2            Location:  \\Rtints23\niddk2\05_Users\Sylvia\DCCT_EDIC\IntegCheck\Neph_JAMA
3            Project:   NIDDK Data Repository Integrity Checks (0208866.000.001)
4            By:        Sylvia Tan
5            Purpose:   Analysis of integrity of EDIC Nephropathy archived dataset in the NIDDK
5        ! Data Repository
6            Compare results to tables/text/selected figures in paper published by
7            DCCT-EDIC Research Group in 2003 (JAMA, [290(16)])
8            Last updated:  1/24/07 *;
9
10         options ps=55 ls=75 nonumber formchar='|----|+\---+=|-^<>*' mprint
orientation=portrait
10       ! ;
11
12         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
13           * (SAS dataset edicREN8.sas7bdat, same as edicREN8.xpt file:);
14         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
15
16           * both datasets were copied on 12/20/2006 from the NIDDK server
17             \\Rtints23\niddk2\03_Data_And_Tools\Database\Databases\DCCT-EDIC\EDIC\New-Data
18             and are exactly the same, comparison run using SAS Proc Compare, ID=Mask_Pat
18       ! edicyear *;
19
20         * proc cimport data=niddk.edicREN8 infile=niddkx; run;
21         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.

22
23         proc format;
24           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,
2007

NOTE: Format YESNO has been output.
25          value $GPFMT "EXPERIMENTAL"=Intensive Treatment "STANDARD"=Conventional Treatment;
NOTE: Format $GPFMT has been output.
26          value $RETBASF "PRIM"=Primary Prevention "SCND"=Secondary Intervention;
NOTE: Format $RETBASF has been output.
27          value $GENDERF "F"=Female "M"=Male;
NOTE: Format $GENDERF has been output.
28
29        ods rtf file="C:\DATA\NIDDK\Neph\nephinteg_out.rtf" style=sasdocprinter;
NOTE: Writing RTF Body file: C:\DATA\NIDDK\Neph\nephinteg_out.rtf
30

NOTE: PROCEDURE FORMAT used (Total process time):
      real time           1.01 seconds
      cpu time            0.29 seconds


31        data NEPH_8YR; set niddk.neph_8yr;
32          if group='EXPERIMENTAL' then IntensTx=1;
33          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


34        proc sort; by mask_pat; * deidentified patient id *;
35
36        * check our means with the means file (included with the XPT file) *;
37        *ods html file="c:\temp\neph_means.xls" style=minimal;
38        /*
39        proc means n mean std min max data=neph_8yr;
40          var aer aer00 att_age att_du99 bmi clr00 dbp eddate fsasdate gfrxb99 hba1c
41          hdl height lab_date ldl map pulse sbp scr00 serumcr stdclr tchol trig weight; run;
42        proc freq data=neph_8yr;
43          tables ace base_40 ci_300 ci_40 close_40 close300 clr_70 combined dialysis double
43       ! edicyear
44          edstat f2_ht130 gfrxb70 group ht hyperten lipid new_300 new_40 other_ht p_300 p_40
44       ! ren_insf
45          retbase sex smoke99 trans/missing nocum; run;
46        */
47        *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


48        * 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,
2007

49
50         data NEPH_BASE; set neph_8yr;
51           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


52         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


53
54         ***************************;
55         * EDIC Baseline:  Table 1 *;
56         ***************************;
57         *ods html file="c:\temp\neph_Baselinegrpmeans.xls" style=minimal;
58         proc means mean std data=neph_base; class group;
59           var att_age att_du99 hba1c 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


60         proc univariate data=neph_base plot normal; class group;
61           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


62         proc npar1way wilcoxon ; class group;
63           var att_age att_du99 hba1c 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,
2007

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


64          *ods html file="c:\temp\Baseline diab dur ttest.xls" style=minimal;
65         proc ttest data=neph_base; class group;
66          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


67          *ods html close; run;
68
69         proc freq data=neph_base;
70          tables group*(sex smoke99 close_40 close300 gfrxb70 clr_70 ht f2_ht130)/chisq exact;
70       ! 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


71          * results are close to published, except for diabetes duration (ATT_DU99)
72            where p-value is 0.15 instead of >0.99)... other slight diffs are noted in text *;
73         *ods html close; run;
74
```

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 Obs	Variable	Label	Mean	Std Dev
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: Mu0=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

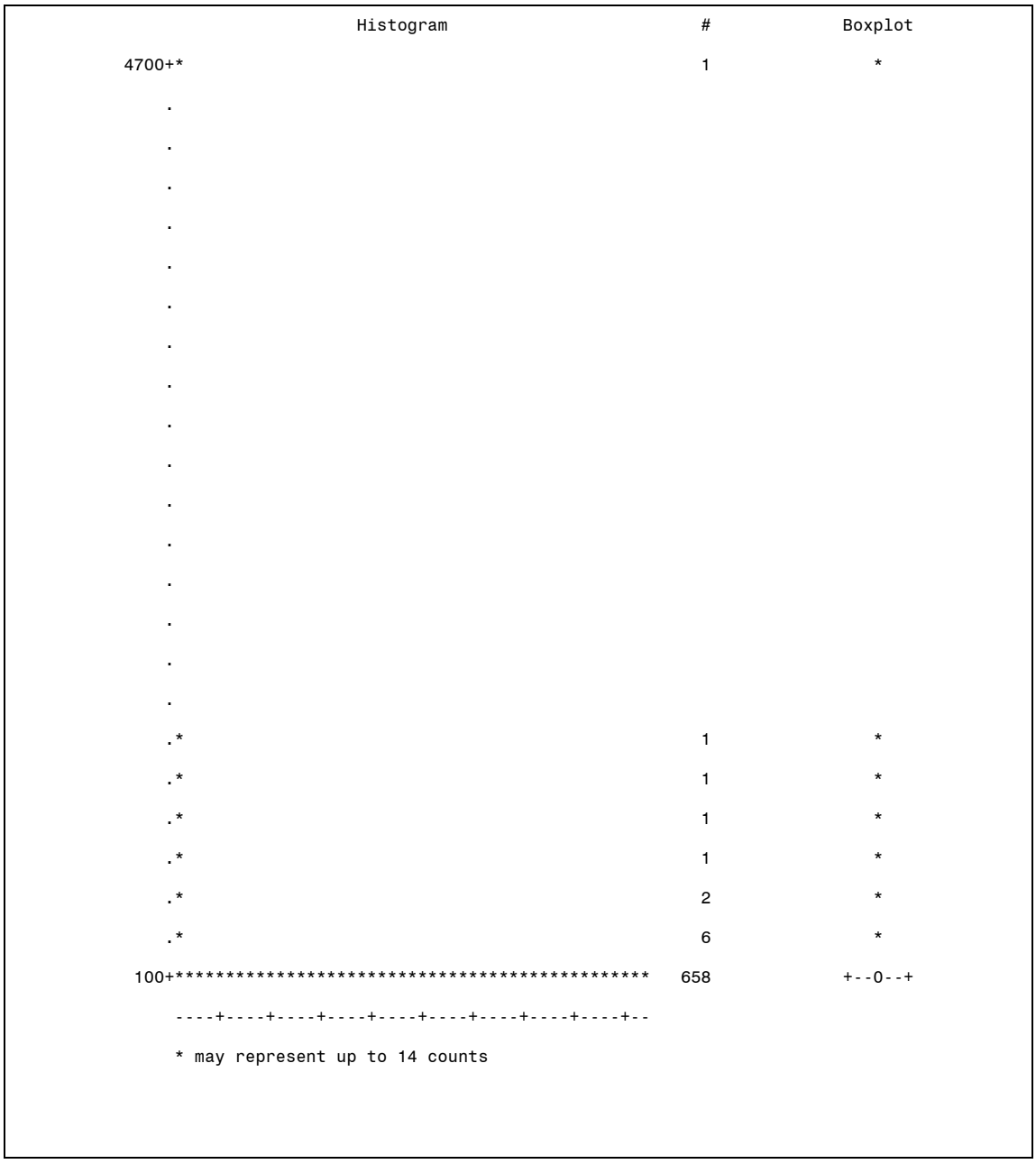
Lowest		Highest	
Value	**Obs**	**Value**	**Obs**
1.44	1345	760.32	409
1.44	1278	889.92	28
1.44	1275	1110.24	1106
1.44	1241	1336.32	885
1.44	1034	4690.08	253

Missing Values

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

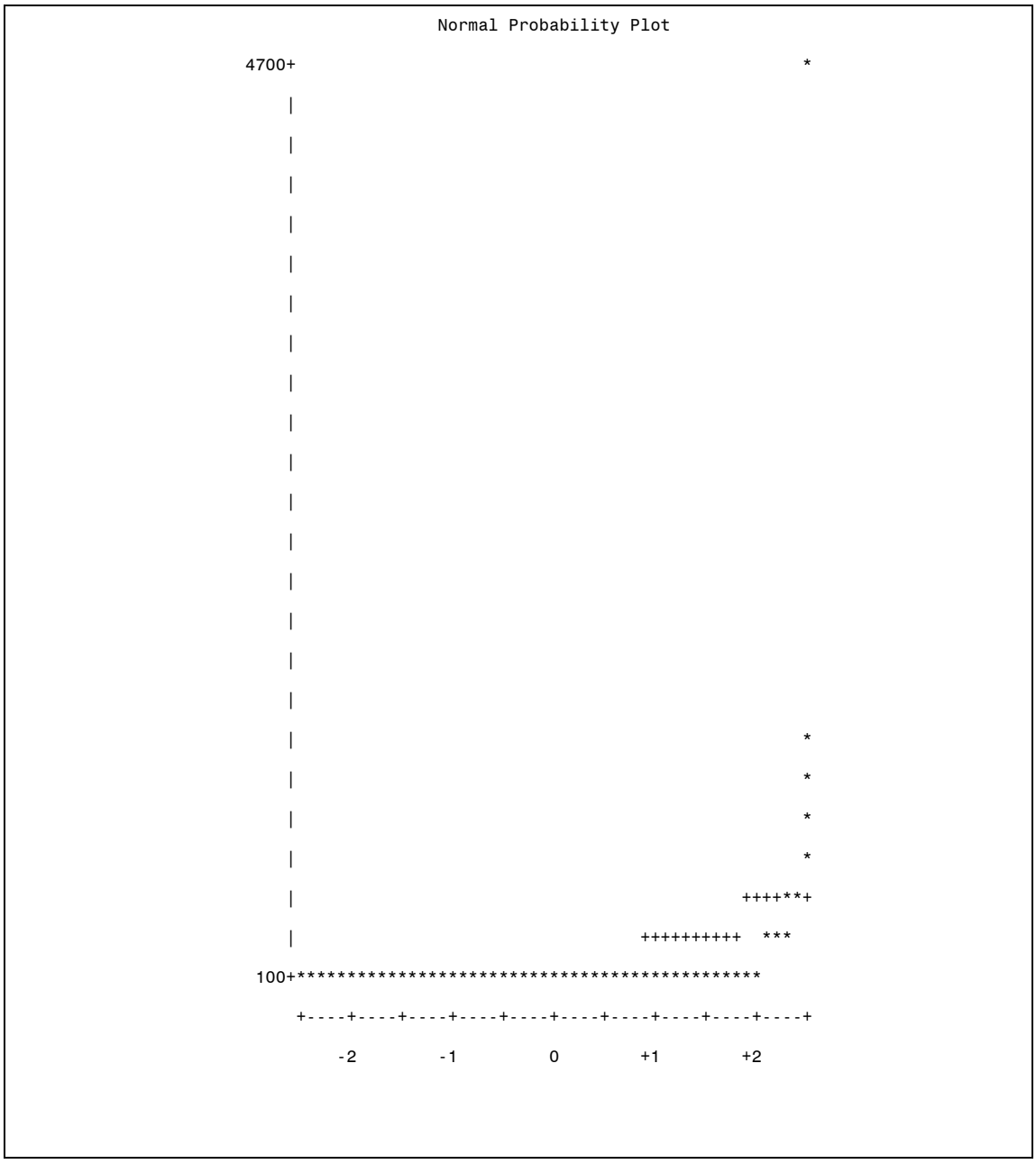
The SAS System: Output for Baseline Characteristics (Table 1)

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 = 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: Mu0=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

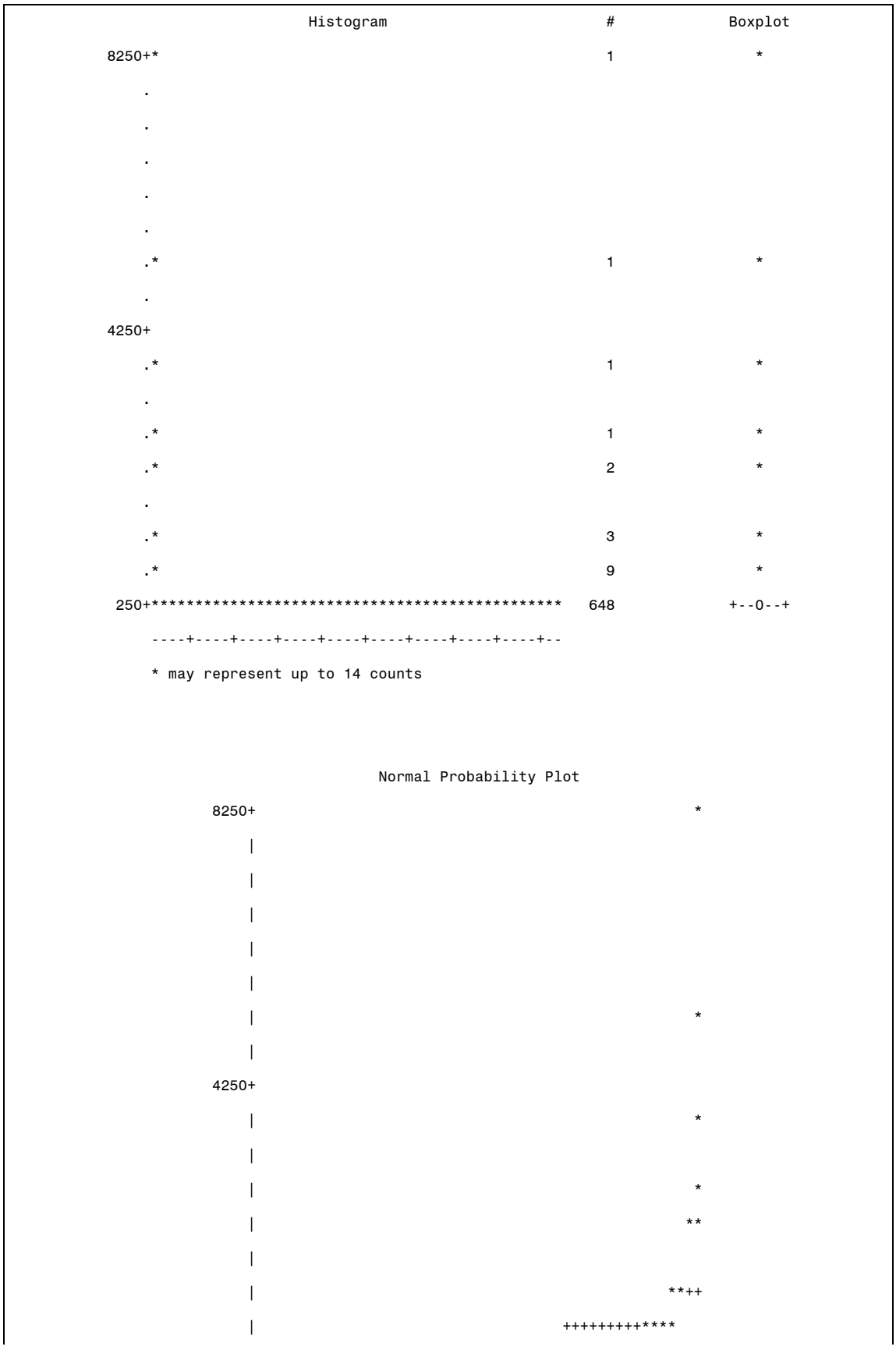
Lowest		Highest	
Value	**Obs**	**Value**	**Obs**
1.44	1293	2060.64	13
1.44	1261	2534.40	442
1.44	1254	3628.80	176
1.44	1183	5126.40	14
1.44	1110	8183.52	893

Missing Values

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

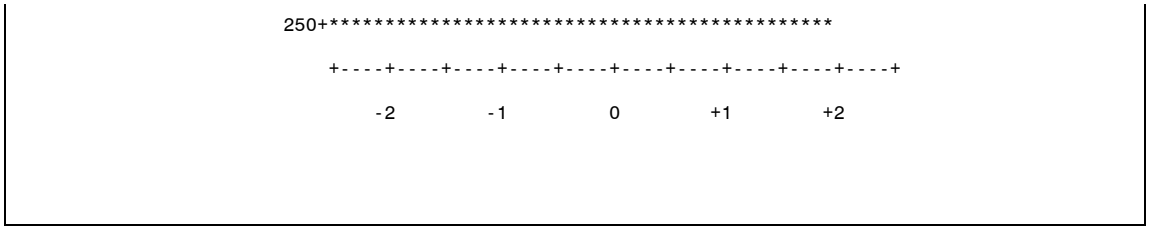
The SAS System: Output for Baseline Characteristics (Table 1)

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



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

The 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) Frequency Percent Row Pct Col Pct	SEX(Gender) Female	 Male	 Total
Intensive Treatment	330 24.46 48.82 51.32	346 25.65 51.18 49.01	676 50.11
Conventional Treatment	313 23.20 46.51 48.68	360 26.69 53.49 50.99	673 49.89
Total	643 47.66	706 52.34	1349 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 38.59 77.00 49.67	155 11.52 23.00 51.67	674 50.11
Conventional Treatment	526 39.11 78.39 50.33	145 10.78 21.61 48.33	671 49.89
Total	1045 77.70	300 22.30	1345 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	

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

The FREQ Procedure

Statistics for Table of GROUP by SMOKE99

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

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 46.40 92.60 51.65	50 3.71 7.40 36.50	676 50.11
Conventional Treatment	586 43.44 87.07 48.35	87 6.45 12.93 63.50	673 49.89
Total	1212 89.84	137 10.16	1349 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	

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

The FREQ Procedure

Statistics for Table of GROUP by CLOSE_40

Statistic	DF	Value	Prob
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

Table of GROUP by CLOSE300

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

Statistics for Table of GROUP by CLOSE300

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

The FREQ Procedure

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)	No	Yes	Total
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

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

The FREQ Procedure

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
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

The SAS System

The FREQ Procedure

Table of GROUP by HT

GROUP(TREATMENT GROUP) / Frequency / Percent / Row Pct / Col Pct	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

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

The FREQ Procedure

Statistics for Table of GROUP by HT

Sample Size = 1349

Table of GROUP by F2_HT130

GROUP(TREATMENT GROUP) Frequency Percent Row Pct Col Pct	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

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	

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

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

08:20 Wednesday, February 14, 2007

```
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     08:20 Wednesday, February 14, 2007
System            14:46 Friday, February 9, 2007

      real time           0.03 seconds
      cpu time            0.01 seconds


83           *ods html file="C:\DATA\NIDDK\Neph\hbameans.xls" style=minimal;
84           proc print data=hbameans; run;

NOTE: There were 18 observations read from the data set WORK.HBAMEANS.
NOTE: The PROCEDURE PRINT printed page 37.
NOTE: PROCEDURE PRINT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


85           *ods html close; run;
86         proc means mean data=neph_8yr;
87           var hba1c; class edicyear group; run;

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The PROCEDURE MEANS printed page 38.
NOTE: PROCEDURE MEANS used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds


88         proc npar1way wilcoxon data=neph_8yr; by edicyear;
89           var hba1c; class group; run;

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The PROCEDURE NPAR1WAY printed pages 39-47.
NOTE: PROCEDURE NPAR1WAY used (Total process time):
      real time           0.17 seconds
      cpu time            0.07 seconds


90
91           ** last sentence on pg.2161... mean levels through the 8 years
**;
92         proc means data=neph_8yr noprint; class group mask_pat; var hba1c;
93           output out=meanhba mean=meanhba; run;

NOTE: There were 11745 observations read from the data set WORK.NEPH_8YR.
NOTE: The data set WORK.MEANHBA has 2701 observations and 5 variables.
NOTE: PROCEDURE MEANS used (Total process time):
      real time           0.06 seconds
      cpu time            0.06 seconds


94           proc univariate data=meanhba; class group; var meanhba; run;

NOTE: The PROCEDURE UNIVARIATE printed pages 48-51.
NOTE: PROCEDURE UNIVARIATE used (Total process time):
      real time           0.03 seconds
      cpu time            0.03 seconds
```

```
                                          The SAS     08:20 Wednesday, February 14, 2007
System            14:46 Friday, February 9, 2007


95          proc npar1way wilcoxon data=meanhba; class group; var meanhba;
run;

NOTE: There were 2701 observations read from the data set WORK.MEANHBA.
NOTE: The PROCEDURE NPAR1WAY printed page 52.
NOTE: PROCEDURE NPAR1WAY used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


96          ** very close to published **;
97
```

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-year 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

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
50% Median	7.85556
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-year 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

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
50% Median	8.17778
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

```
97
98         ***********************************;
99         * Development of Microalbuminauria *;
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           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

```
128
129         ************************************;
130         * Development of Clinical Albuminuria *;
131         ************************************;
132
133           * Figure 2 *;
134         data atrisk1b(keep=mask_pat); set neph_8yr;
135           where close300=0 and IntensTx=1 and edicyear=0;
136           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


137         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


```
138          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


139        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


140          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


141        data atrisk1b; merge atrisk1b(in=in1) neph_7b(in=in7)
142                                neph_8b(in=in8);
143          by mask_pat;
144          if in1 and (in7 or in8);
145          * n=572 as stated in the text *;
146          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


147          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


```
148
149        data atrisk0b(keep=mask_pat); set neph_8yr;
150          where close300=0 and IntensTx=0 and edicyear=0;
151          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


152        data atrisk0b; merge atrisk0b(in=in1) neph_7b(in=in7)
153                               neph_8b(in=in8);
154          by mask_pat;
155          if in1 and (in7 or in8);
156          * n=626, as opposed to n=630 stated in the text *;
157          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


158          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


159
```

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

```
159
160        ************************;
161        * other kidney outcomes *;
162        ************************;
163          ** pg.2163, attempt to replicate results in last sentence of first paragraph under
163      ! Other Kidney Outcomes **;
164        proc means data=neph_8yr noprint; class group mask_pat; var serumcr;
165          output out=meancreat mean=meancreat; run;
```

The SAS System: Log for analyses of Other Kidney Outcomes


```
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


166          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


167          proc npar1way wilcoxon data=meancreat; class group; var meancreat; run;

NOTE: There were 2701 observations read from the data set WORK.MEANCREAT.
NOTE: The PROCEDURE NPAR1WAY printed page 61.
NOTE: PROCEDURE NPAR1WAY used (Total process time):
      real time           0.15 seconds
      cpu time            0.00 seconds


168          ** very close to published **;
169
170          ** pg.2163, attempt to replicate results in last sentence of second paragraph under
170      ! Other Kidney Outcomes **;
171        proc freq data=neph_8yr; where edicyear=7;
172          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


173
174         * table 2 *;
175        data neph_8yr; set neph_8yr;
176          creat_elev=.;
177          if serumcr>=2 then creat_elev=1;
178          else if .<serumcr<2 then creat_elev=0;
179

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


```
180        data doubles; set neph_8yr; if double=1;
181          * double = doubling of serum creatinine level from DCCT baseline *
182          * 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


183        proc sort; by mask_pat edicyear;
184        /*
185        proc print data=doubles; by mask_pat;
186          var edicyear group serumcr scr00 double dialysis trans; run;
187        */
188          * 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;
190          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


191          proc freq; tables edicyear*group;
192          title The first year EDIC subjects doubled their serum creatinine levels from DCCT
bsln
192      ! (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


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

The SAS System: Log for analyses of Other Kidney Outcomes


```
196           we still get n=45. *;
197
198         * Try limiting dataset to patients with complete serum creatinine data at each year
198      ! of EDIC,
199           as stated in the Title of Table 2: Patients with kidney outcomes Through Year 8 in
199      ! the EDIC Study *;
200         title;
201       data NEPH_at1(keep=mask_pat); set neph_8yr; where edicyear=1 and double^=.;

NOTE: There were 1280 observations read from the data set WORK.NEPH_8YR.
      WHERE (edicyear=1) and (double not = .);
NOTE: The data set WORK.NEPH_AT1 has 1280 observations and 1 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


202         proc sort; by mask_pat;

NOTE: There were 1280 observations read from the data set WORK.NEPH_AT1.
NOTE: The data set WORK.NEPH_AT1 has 1280 observations and 1 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.00 seconds
      cpu time            0.00 seconds


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

NOTE: There were 1263 observations read from the data set WORK.NEPH_8YR.
      WHERE (edicyear=2) and (double not = .);
NOTE: The data set WORK.NEPH_AT2 has 1263 observations and 1 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


204         proc sort; by mask_pat;

NOTE: There were 1263 observations read from the data set WORK.NEPH_AT2.
NOTE: The data set WORK.NEPH_AT2 has 1263 observations and 1 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


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

NOTE: There were 1268 observations read from the data set WORK.NEPH_8YR.
      WHERE (edicyear=3) and (double not = .);
NOTE: The data set WORK.NEPH_AT3 has 1268 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 for analyses of Other Kidney Outcomes


```
206          proc sort; by mask_pat;

NOTE: There were 1268 observations read from the data set WORK.NEPH_AT3.
NOTE: The data set WORK.NEPH_AT3 has 1268 observations and 1 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


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

NOTE: There were 1257 observations read from the data set WORK.NEPH_8YR.
      WHERE (edicyear=4) and (double not = .);
NOTE: The data set WORK.NEPH_AT4 has 1257 observations and 1 variables.
NOTE: DATA statement used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


208          proc sort; by mask_pat;

NOTE: There were 1257 observations read from the data set WORK.NEPH_AT4.
NOTE: The data set WORK.NEPH_AT4 has 1257 observations and 1 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.00 seconds


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

NOTE: There were 1262 observations read from the data set WORK.NEPH_8YR.
      WHERE (edicyear=5) and (double not = .);
NOTE: The data set WORK.NEPH_AT5 has 1262 observations and 1 variables.
NOTE: DATA statement used (Total process time):
      real time           0.03 seconds
      cpu time            0.01 seconds


210          proc sort; by mask_pat;

NOTE: There were 1262 observations read from the data set WORK.NEPH_AT5.
NOTE: The data set WORK.NEPH_AT5 has 1262 observations and 1 variables.
NOTE: PROCEDURE SORT used (Total process time):
      real time           0.01 seconds
      cpu time            0.01 seconds


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

NOTE: 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


```
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


212          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


213        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


214          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


215        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


216          proc sort; by mask_pat;
217

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


```
218        data neph_base_doub; merge neph_base firstdoub(in=in0 rename=(edicyear=firstyear))
219          neph_at1(in=in1) neph_at2(in=in2) neph_at3(in=in3) neph_at4(in=in4)
220          neph_at5(in=in5) neph_at6(in=in6) neph_at7(in=in7) neph_at8(in=in8);
221          by mask_pat;
222          if in0 then firstdoub=1;
223          else do; firstdoub=0; firstyear=-1; end; *serum creatinine not doubled from DCCT
bsln
224                                                   during the followup period *;
225          if in1 and in2 and in3 and in4 and in5 and in6 and in7 and in8;
226          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


227          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


228          * now we get the published numerator (n=27),
229          * but denominators are still different... after restricting the sample to those with
229      ! complete
230            creat data at each year of EDIC,
231            i have an N of 1038, but published N in Table 2 is 1349 *;
232
233          ************************************************************;
234
```

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: Mu0=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

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
5%	0.683333
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: Mu0=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

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
10%	0.711111
5%	0.677778
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)		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	320 50.87 99.38 51.86	2 0.32 0.62 16.67	322 51.19
Conventional Treatment	297 47.22 96.74 48.14	10 1.59 3.26 83.33	307 48.81
Total	617 98.09	12 1.91	629 100.00

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	

The SAS System: Output for analyses of Other Kidney Outcomes

The FREQ Procedure

Statistics for Table of GROUP by CLR_70

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

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

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
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)		
Frequency Percent Row Pct Col Pct	Intensive Treatment	Conventional Treatment	Total
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	

The FREQ Procedure

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

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

```
235        ************************************;
236        * Blood pressure / hypertension (HT) *;
237        ************************************;
238          * Figure 4 *;
239        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          12:13 Monday, February 12,
2007

      real time           0.01 seconds
      cpu time            0.01 seconds


240        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


241        data neph_8yr; merge neph_8yr neph_base(keep=mask_pat map rename=(map=map0));
242          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


243          * dont have average map from DCCT, which was adjusted for in the figure...
244            so use DCCT closeout map instead *;
245
246        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


247        proc freq data=neph_8yr; by edicyear;
248          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


249        proc freq data=neph_8yr noprint; by edicyear group;
250          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          12:13 Monday, February 12,
2007

      cpu time            0.01 seconds


251        * to replicate figure 4 *;
252        *ods html file="C:\DATA\NIDDK\Neph\htprevs2.xls" style=minimal;
253        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


254        *ods html close;
255        * check with logistic regression, adjusting for DCCT closeout map instead of DCCT
255      ! average map which was not available *;
256        proc logistic data=neph_8yr descending;
257          by edicyear;
258          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          12:13 Monday, February 12,
2007

      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


259        * either way, results are close to published p-values *;
260
261        ods rtf close; run;
262
```

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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	602 44.63 89.05 50.00	74 5.49 10.95 51.03	676 50.11
Conventional Treatment	602 44.63 89.45 50.00	71 5.26 10.55 48.97	673 49.89
Total	1204 89.25	145 10.75	1349 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	

The FREQ Procedure

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

Statistics for Table of GROUP by HT

EDIC FOLLOWUP YEAR=00

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))			
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	542 41.69 83.13 49.91	110 8.46 16.87 51.40	652 50.15
Conventional Treatment	544 41.85 83.95 50.09	104 8.00 16.05 48.60	648 49.85
Total	1086 83.54	214 16.46	1300 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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	530 40.83 81.41 50.48	121 9.32 18.59 48.79	651 50.15
Conventional Treatment	520 40.06 80.37 49.52	127 9.78 19.63 51.21	647 49.85
Total	1050 80.89	248 19.11	1298 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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	529 40.60 81.26 52.32	122 9.36 18.74 41.78	651 49.96
Conventional Treatment	482 36.99 73.93 47.68	170 13.05 26.07 58.22	652 50.04
Total	1011 77.59	292 22.41	1303 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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	508 39.35 78.64 51.94	138 10.69 21.36 44.09	646 50.04
Conventional Treatment	470 36.41 72.87 48.06	175 13.56 27.13 55.91	645 49.96
Total	978 75.76	313 24.24	1291 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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	496 38.36 76.66 53.10	151 11.68 23.34 42.06	647 50.04
Conventional Treatment	438 33.87 67.80 46.90	208 16.09 32.20 57.94	646 49.96
Total	934 72.24	359 27.76	1293 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) / Frequency / Percent / Row Pct / Col Pct	HT(Current Hypertension (>=140/90)) No	Yes	Total
Intensive Treatment	467 35.73 71.52 52.35	186 14.23 28.48 44.82	653 49.96
Conventional Treatment	425 32.52 64.98 47.65	229 17.52 35.02 55.18	654 50.04
Total	892 68.25	415 31.75	1307 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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	453 34.71 69.37 53.55	200 15.33 30.63 43.57	653 50.04
Conventional Treatment	393 30.11 60.28 46.45	259 19.85 39.72 56.43	652 49.96
Total	846 64.83	459 35.17	1305 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))		
Frequency Percent Row Pct Col Pct	No	Yes	Total
Intensive Treatment	457 35.18 70.09 54.21	195 15.01 29.91 42.76	652 50.19
Conventional Treatment	386 29.72 59.66 45.79	261 20.09 40.34 57.24	647 49.81
Total	843 64.90	456 35.10	1299 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