

Appendix

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Table 4.1 Description of Variables

Age (years)
Gender
Race or ethnic group (White, Black, Hispanic, Asian, Other)
BMI (kg/m ²)
Weight (kg)
Smoking in year before stroke
Alcoholic beverage drinker
Alcohol use in 24 hours before stroke
Alcohol problems
Aspirin use before stroke
Heparin use before stroke
Admission Systolic blood pressure (mmHg)
Admission Diastolic blood pressure (mmHg)
Admission Mean blood pressure (mmHg)
Admission Pulse pressure (mmHg)
Baseline Systolic blood pressure (mmHg)
Baseline Diastolic blood pressure (mmHg)
Baseline Mean blood pressure (mmHg)
Baseline Pulse pressure (mmHg)
History of Diabetes
History of Hypertension
History of Anti-hypertension medications
Calcium channel blocker before stroke
History of Myocardial infarction
History of Angina pectoris
History of Ischemic heart disease
History of Congestive heart failure
History of Valvular heart disease
History Prosthetic valve
History Atherosclerosis
History of Atrial fibrillation
History of Other cardiac disease
History of Stroke
History of Stroke
History of Transient ischemic attack
History of Hepatic Disease
History of Malignancy
History of Hematological Disease
History of Hyperlipidemia
Preexisting disability
Glucose (mg/dl)
Fibrinogen (mg/dl)
CT findings: Edema
CT findings: Mass Effect
NIHSS at Baseline
Stroke Subtype (Small-vessel occlusive, Cardioembolic, Large-vessel occlusive, Other)

Table 4.1 Description of Variables

Percentage of correct dose
Total dose delivered (mg)
Hemorrhage within 36h of Randomization (Asymptomatic or Symptomatic)
Symptomatic Hemorrhage within 36h of Randomization
Onset to treatment time (minutes)
Trial part (1, 2)
Clinical Center
Barthel index, 3 month favorable outcome: 95-100
Modified Rankin scale, 3 month favorable outcome: 0,1
Glasgow outcome scale, 3 month favorable outcome: 1
NIHSS, 3 month favorable outcome: 0,1

Table 4.2 Distribution of Variables by Treatment Group

Variable	Missing Values	Placebo Median	t-PA Median	Placebo Percent	t-PA Percent	P- Value
Age	0	67.2	70.0			0.0202
Age (>70)	0			41.7%	50.6%	0.0247
Sex (male)	0			59.0%	57.1%	0.6352
RACE:White	0			63.5%	65.8%	
RACE:Black	0			28.5%	25.8%	0.7475
Race:Other	0			8.0%	8.4%	
BMI	46	26.7	25.7			0.0590
Weight(Kg)	0	80.0	75.3			0.0080
Rank of Wt.	0	355.0	283.0			0.0080
CURSMK	9			35.8%	34.0%	0.6378
DRINK	18			47.2%	49.5%	0.5742
CURDrnk(<24h)	29			16.3%	16.1%	0.9871
PrDrnkPROB	27			9.0%	9.0%	0.9473
AdAspirin	0			28.5%	40.3%	0.0020
AdHEPARIN	0			19.0%	16.0%	0.7692
AdSYSbp	0	158.0	157.5			0.5777
AdSYSbp>190	0			11.5%	11.0%	0.8218
AdDIAbp	1	88.0	90.0			0.4512
AdDIAbp>100	1			17.3%	18.4%	0.7111
AdMBP	1	110.7	113.3			0.4524
AdMBP>130	1			14.1%	13.6%	0.8539
AdPulseP	1	66.0	70.0			0.5021
BsSYSbp	17	152.0	154.0			0.6130
BsSYSbp>190	17			2.0%	2.3%	0.7470
BsDIAbp	22	86.0	84.0			0.1110
BsDIAbp>100	22			11.5%	9.2%	0.3500
BsMBP	22	109.3	107.3			0.5380
BsMBP>130	22			3.9%	3.4%	0.7286
BsPulseP	22	66.0	70.0			0.0998
PrDM	4			20.2%	21.6%	0.6626
PrHTN	7			65.1%	65.5%	0.8661
PrHTNMED	13			55.4%	56.5%	0.8332
PrCCB	0			25.3%	24.5%	0.8166
PrMI	29			19.6%	22.6%	0.3388
PrAngina	27			21.5%	20.6%	0.7172
PrIHD	29			31.6%	34.4%	0.4662
PrCONGF	28			17.6%	13.9%	0.2100
PrVALvularHD	27			6.1%	8.1%	0.3413
PrPROStheticV	0			0.6%	1.0%	
PrATHRO	87			26.0%	28.4%	0.3299
PrAF	0			18.3%	18.7%	0.8875
PrOtherCARDiac	0			48.1%	48.1%	0.9978
PrSTRK(N)	6			12.2%	13.9%	0.5722
PrSTRK	0			11.9%	13.9%	0.4536
PrTIA	46			15.7%	15.8%	1.0000
PrHEPaticD	15			2.9%	2.6%	0.8217
PrMALignancy	15			10.3%	8.7%	0.5017

Table 4.2 Distribution of Variables by Treatment Group

Variable	Missing Values	Placebo Median	t-PA Median	Placebo Percent	t-PA Percent	P- Value
PrHEMatologicD	7			3.2%	3.5%	0.8066
PrHyCHOL	108			20.5%	24.5%	0.2797
PrDISAbility	0			7.7%	7.1%	0.7766
BsFIBrinogen	54	320.0	313.0			0.2730
BsGLUcose	2	124.0	125.0			0.9714
BsGLU>300	2			6.1%	5.8%	0.8973
BsEdema	8			5.2%	4.3%	0.5928
BsMassEffect	8			4.2%	3.0%	0.4024
BsED/ME	8			6.1%	5.2%	0.6294
BsNIHSS	0	15.0	14.0			0.1000
BsNIHSS>14	0			51.6%	48.4%	0.4226
BsNIHSS:0-5	0			5.1%	13.6%	
BsNIHSS:6-10	0			26.6%	21.6%	
BsNIHSS:11-15	0			21.1%	21.0%	0.0051
BsNIHSS:16-20	0			22.4%	23.6%	
BsNIHSS:>20	0			24.7%	20.3%	
STKTYP:SvOcc	0			9.6%	16.5%	
STKTYP:Cembolic	0			43.9%	43.9%	
STKTYP:LvOcc	0			43.3%	37.1%	0.0639
STPTYP:Other	0			3.2%	2.6%	
PHYGIVE	0	100.1	100.1			0.5110
Rank of Dose	0	316.8	307.3			0.5110
T-Dose	0	72.0	67.5			0.0049
ANYHEM36	0			3.2%	10.3%	0.0004
SYMHEM36	0			0.6%	6.5%	0.0001
OTT(mins.)	0	109.0	90.0			0.7302

Table 5.1 The Medical Histories of the Patients in the Study

Variable	Part 1		Part 2	
	t-PA N=144	Placebo N=147	t-PA N=168	Placebo N=165
	percent			
Stroke	17	17	12	9
Transient ischemic attack	22	14	13	19
Aspirin therapy	41	31	40	26
Diabetes	24	21	20	20
Hypertension	66	64	67	67
Myocardial infarction	25	21	22	20
Atrial fibrillation	17	20	20	16
Angina pectoris	18	22	24	24
Congestive heart failure	14	17	16	19
Valvular heart disease	11	7	6	6
Smoking in year before stroke	43	37	27	35
No preexisting disability	90	91	95	93

Table 5.1a The Medical Histories of the Patients in the Study, Reference 11

Table 1. The Medical Histories of the Patients in the Study.

VARIABLE	PART 1		PART 2	
	t-PA (N = 144)	PLACEBO (N = 147)	t-PA (N = 168)	PLACEBO (N = 165)
	<i>percent</i>			
Stroke	17	17	12	9
Transient ischemic attack	22	14	13	19
Aspirin therapy	41	31	40	26
Diabetes	24	21	20	20
Hypertension	66	64	67	67
Myocardial infarction	25	21	22	20
Atrial fibrillation	18	20	20	16
Angina pectoris	18	22	24	24
Congestive heart failure	14	17	16	19
Valvular heart disease	11	7	6	6
Smoking in year before stroke	43	37	27	35
No preexisting disability	90	91	95	93

Table 5.2 Base-Line Characteristics of the Patients in the Two Parts of the Study, According to Treatment Group

Characteristic	Part 1		Part 2	
	t-PA	Placebo	t-PA	Placebo
	N=144	N=147	N=168	N=165
Age (years)	67±10	66±11	69±12	66±13
Race or ethnic group (%)				
White, non-Hispanic	62	61	69	66
Black	29	31	23	26
Hispanic	8	5	5	7
Asian	1	0	3	1
Other	0	3	1	1
Female sex (%)	42	40	43	42
Weight (kg)	76±15	80±18	76±16	80±21
NIHSS Score				
Median	14	14	14	15
Minimum	1	1	2	2
Maximum	37	32	37	33
Stroke subtype (%)				
Small-vessel occlusive	19	11	14	8
Cardioembolic	42	44	45	44
Large vessel occlusive	35	42	39	45
Other	3	3	2	3
Blood pressure (mmHg)				
Systolic	155±22	153±20	153±22	152±21
Diastolic	85±12	85±13	85±14	87±13
Fibrinogen (mg/dl)	332±94	349±106	311±102	316±86
Glucose (mg/dl)	149±76	152±78	149±66	149±78
CT findings (%)				
Edema	3	3	5	7
Mass effect	3	3	2	5

Table 5.2a Base-Line Characteristics of the Patients in the Two Parts of the Study, According to Treatment Group, Reference 11

Table 2. Base-Line Characteristics of the Patients in the Two Parts of the Study, According to Treatment Group.*

CHARACTERISTIC	PART 1		PART 2	
	t-PA (N = 144)	PLACEBO (N = 147)	t-PA (N = 168)	PLACEBO (N = 165)
Age (yr)	67±10	66±11	69±12	66±13
Race or ethnic group (%)				
White, non-Hispanic	62	61	69	66
Black	29	31	23	26
Hispanic	8	5	5	7
Asian	1	0	3	1
Other	0	3	1	1
Female sex (%)	42	40	43	42
Weight (kg)	76±15	80±18	76±16	80±21
NIHSS score				
Median	14	14	14	15
Minimum	1	1	2	2
Maximum	37	32	37	33
Stroke subtype (%)				
Small-vessel occlusive	19	11	14	9
Cardioembolic	42	44	45	44
Large-vessel occlusive	35	42	39	45
Other	3	3	2	3
Blood pressure (mm Hg)				
Systolic	155±22	153±20	153±22	152±21
Diastolic	85±12	85±13	85±14	86±15
Fibrinogen (mg/dl)	332±94	349±106	311±102	316±86
Glucose (mg/dl)†	149±76	152±78	149±66	149±78
CT findings (%)				
Edema	5	3	4	6
Mass effect	3	2	3	4

*Plus-minus values are means ±SD. Because of rounding, not all columns total 100 percent.

†To convert values for glucose to millimoles per liter, multiply by 0.05551.

Table 5.3 Scores on the NIHSS 24 Hours after the Onset of Stroke

Time to Treatment After Stroke Onset	t-PA		Placebo		Relative Risk (95% CI)	P Value	NIHSS Score		
	No. of Patients	No. with Improvement (%)	No. of Patients	No. with Improvement (%)			t-PA	Placebo	
<i>minutes</i>							<i>Median (IQR)</i>		
Part 1									
0-90	71	36 (51)	68	31 (46)	1.1 (0.8, 1.6)	0.56	9 (3-17)	11 (5-17)	¶
91-180	73	31 (42)	79	26 (33)	1.3 (0.9, 2.0)	0.20	8 (3-17)	12 (8-20)	
0-180	144	67 (47)	147	57 (39)	1.2 (0.9, 1.6)	0.19	8 (3-17)	12 (6-19)	
Part 2									
0-90	86	51 (59)	77	30 (39)	1.5 (1.1, 2.1)	0.02	9 (2-18)	12 (8-20)	
91-180	82	29 (35)	88	35 (40)	0.9 (0.6, 1.3)	0.52	9 (3-20)	14 (6-19)	¶
0-180	168	80 (48)	165	65 (39)	1.2 (0.9, 1.5)	0.19	9 (3-20)	14 (7-19)	
Combined results									
0-90	157	87 (55)	145	61 (42)	1.3 (1.0, 1.7)	0.02	9 (2-17)	12 (6-18)	
91-180	155	60 (39)	167	61 (37)	1.1 (0.8, 1.4)	0.69	8 (3-19)	13 (7-19)	
0-180	312	147 (47)	312	122 (39)	1.2 (1.0, 1.4)	0.06	8 (3-18)	12 (6-19)	

¶p>0.13 by analysis of covariance.

Table 5.3a Scores on the NIHSS 24 Hours After the Onset of Stroke, Reference 11

Table 3. Scores on the NIHSS 24 Hours after the Onset of Stroke.

TIME TO TREATMENT AFTER STROKE ONSET	t-PA		PLACEBO		RELATIVE RISK (95% CI)†	P VALUE‡	NIHSS SCORE	
	NO. OF PATIENTS	NO. WITH IMPROVEMENT (%)*	NO. OF PATIENTS	NO. WITH IMPROVEMENT (%)*			t-PA	PLACEBO
<i>min</i>								
Part 1								
0–90	71	36 (51)	68	31 (46)	1.1 (0.8–1.6)	0.56	9 (3–17)	11 (5–17)¶
91–180	73	31 (42)	79	26 (33)	1.3 (0.9–1.9)	0.23	8 (3–17)	12 (8–20)
0–180	144	67 (47)	147	57 (39)	1.2 (0.9–1.6)	0.21	8 (3–17)	12 (6–19)
Part 2								
0–90	86	51 (59)	77	30 (39)	1.5 (1.1–2.1)	0.02	9 (2–18)	12 (8–20)
91–180	82	29 (35)	88	35 (40)	0.9 (0.6–1.3)	0.52	9 (3–20)	14 (6–19)¶
0–180	168	80 (48)	165	65 (39)	1.2 (0.9–1.5)	0.19	9 (3–20)	14 (7–19)
Combined results								
0–90	157	87 (55)	145	61 (42)	1.3 (1.0–1.7)	0.02	9 (2–17)	12 (6–18)
91–180	155	60 (39)	167	61 (37)	1.1 (0.8–1.4)	0.73	8 (3–19)	13 (7–19)
0–180	312	147 (47)	312	122 (39)	1.2 (1.0–1.4)	0.06	8 (3–18)	12 (6–19)

*Improvement was defined as a 4-point improvement in the NIHSS score from base-line values or complete resolution of the neurologic deficit.

†CI denotes confidence interval.

‡The Mantel–Haenszel test was used with stratification according to clinical center and, for analyses of 0-to-180-minute groups, the time to treatment after the onset of stroke (0 to 90 minutes or 91 to 180 minutes).

§Interquartile range.

¶P>0.18 by analysis of covariance.

||P<0.02 by analysis of covariance.

Table 5.4 Outcomes at Three Months According to the Time to Treatment after the Onset of Stroke

Assessment Instrument	Percentage with Favorable Outcome		Odds Ratio (95% CI)	Relative Risk (95% CI)	P Value
	t-PA	Placebo			
Part 2, 0-180 min					
No. of patients	168	165			
Global test	--	--	1.7 (1.1, 2.6)	--	0.010
Barthel index	50	38	1.6 (1.1, 2.5)	1.3 (1.0, 1.7)	0.026
Modified Rankin scale	39	26	1.7 (1.1, 2.6)	1.5 (1.0, 2.0)	0.019
Glasgow outcome scale	44	32	1.6 (1.1, 2.6)	1.4 (1.0, 1.8)	0.025
NIHSS	31	20	1.7 (1.0, 2.9)	1.5 (1.0, 2.2)	0.033
Part 1, 0-180 min					
No. of patients	144	147			
Global test	--	--	2.1 (1.3, 3.2)	--	0.001
Barthel index	54	39	1.8 (1.1, 2.8)	1.4 (1.1, 1.8)	0.012
Modified Rankin scale	47	27	2.3 (1.4, 3.7)	1.7 (1.3, 2.4)	<0.001
Glasgow outcome scale	47	31	2.0 (1.2, 3.2)	1.5 (1.1, 2.1)	0.005
NIHSS	38	21	2.2 (1.3, 3.7)	1.8 (1.2, 2.6)	0.002
Combined results, 0-90 min					
No. of patients	157	145			
Global test	--	--	1.9 (1.2, 2.9)	--	0.003
Barthel index	53	38	1.8 (1.1, 2.9)	1.4 (1.1, 1.8)	0.010
Modified Rankin scale	40	28	1.7 (1.0, 2.7)	1.4 (1.0, 1.9)	0.035
Glasgow outcome scale	43	32	1.6 (1.0, 2.5)	1.3 (1.0, 1.8)	0.057
NIHSS	34	20	2.0 (1.2, 3.4)	1.7 (1.1, 2.5)	0.008
Combined results, 91-180 min					
No. of patients	155	167			
Global test	--	--	1.9 (1.2, 2.8)	--	0.003
Barthel index	51	38	1.6 (1.1, 2.6)	1.3 (1.0, 1.7)	0.026
Modified Rankin scale	45	25	2.4 (1.5, 3.8)	1.8 (1.3, 2.4)	<0.001
Glasgow outcome scale	47	30	2.0 (1.3, 3.2)	1.6 (1.2, 2.1)	0.002
NIHSS	34	21	2.0 (1.2, 3.3)	1.6 (1.1, 2.3)	0.008

Table 5.4a Outcomes at Three Months According to the Time to Treatment After the Onset of Stroke, Reference 11

Table 4. Outcomes at Three Months According to the Time to Treatment after the Onset of Stroke.

ASSESSMENT INSTRUMENT	PERCENTAGE WITH FAVORABLE OUTCOME*		ODDS RATIO (95% CI)†	RELATIVE RISK (95% CI)†	P VALUE
	t-PA	PLACEBO			
Part 2, 0–180 min‡					
No. of patients	168	165			
Global test	—	—	1.7 (1.2–2.6)	—	0.008
Barthel index	50	38	1.6 (1.1–2.5)	1.3 (1.0–1.7)	0.026
Modified Rankin scale	39	26	1.7 (1.1–2.6)	1.5 (1.1–2.0)	0.019
Glasgow outcome scale	44	32	1.6 (1.1–2.5)	1.4 (1.0–1.8)	0.025
NIHSS	31	20	1.7 (1.0–2.8)	1.5 (1.0–2.2)	0.033
Part 1, 0–180 min‡§					
No. of patients	144	147			
Global test	—	—	2.1 (1.3–3.2)	—	0.001
Barthel index	54	39	1.8 (1.1–2.8)	1.4 (1.1–1.8)	0.012
Modified Rankin scale	47	27	2.3 (1.4–3.6)	1.7 (1.3–2.3)	<0.001
Glasgow outcome scale	47	31	2.0 (1.2–3.1)	1.5 (1.1–2.0)	0.005
NIHSS	38	21	2.2 (1.3–3.7)	1.8 (1.2–2.6)	0.002
Combined results§					
0–90 min‡					
No. of patients	157	145			
Global test	—	—	1.9 (1.2–2.9)	—	0.005
Barthel index	53	38	1.8 (1.2–2.9)	1.4 (1.1–1.8)	0.010
Modified Rankin scale	40	28	1.7 (1.0–2.6)	1.4 (1.0–1.9)	0.035
Glasgow outcome scale	43	32	1.6 (1.0–2.5)	1.3 (1.0–1.8)	0.057
NIHSS	34	20	2.0 (1.2–3.4)	1.7 (1.1–2.5)	0.008
91–180 min‡					
No. of patients	155	167			
Global test	—	—	1.9 (1.3–2.9)	—	0.002
Barthel index	51	38	1.6 (1.1–2.5)	1.3 (1.0–1.7)	0.026
Modified Rankin scale	45	25	2.4 (1.5–3.7)	1.8 (1.3–2.4)	<0.001
Glasgow outcome scale	47	30	2.0 (1.3–3.2)	1.6 (1.2–2.1)	0.002
NIHSS	34	21	2.0 (1.2–3.2)	1.6 (1.1–2.3)	0.008

* Scores of 95 or 100 on the Barthel index, ≤ 1 on the NIHSS and modified Rankin scale, and 1 on the Glasgow outcome scale were considered to indicate a favorable outcome in this intention-to-treat analysis.

†The Mantel–Haenszel test was used for univariate analyses with groups stratified according to clinical center and, for analyses of the 0-to-180-minute groups, the time to treatment after the onset of stroke (0 to 90 minutes or 91 to 180 minutes). For the global test (which used logit-link function) the same stratifying variables were included as covariates. CI denotes confidence interval.

‡Time to treatment after the onset of stroke.

§The results for part 1 were considered hypothesis-generating. The definition of favorable outcomes was derived from part 1 data and required testing in part 2.

Table 5.5 Symptomatic and Asymptomatic Hemorrhages Within 36 hours of Treatment Onset

Type of Hemorrhage	t-PA N=311 (%)	Placebo N=312 (%)
Symptomatic	20 (6.4)	2 (0.6)
Fatal attributable to hemorrhage	9 (2.9)	1 (0.3)
Patient dead at 3 months	15 (4.8)	1 (0.3)
Asymptomatic	13 (4.2)	8 (2.6)
Patient dead at 3 months	4 (1.3)	2 (0.6)
All Hemorrhages	33 (10.6)	10 (3.2)
Patient dead at 3 months	19 (6.1)	3 (1.0)

Table 5.5a Symptomatic and Asymptomatic Hemorrhages Within 36 hours of Treatment Onset, Reference 14

TABLE 1. Symptomatic and Asymptomatic Hemorrhages Within 36 hours of Treatment Onset

Type of Hemorrhage	t-PA (n=311*)	Placebo (n=312)
Symptomatic	20 (6.4)	2 (0.6)
Fatal attributable to hemorrhage	9 (2.9)	1 (0.3)
Patient dead at 3 mo	15 (4.8)	1 (0.3)
Asymptomatic	13 (4.2)	8 (2.6)
Patient dead at 3 mo	4 (1.3)	2 (0.6)
All hemorrhages	33 (10.6)	11 (3.2)
Patient dead at 3 mo	19 (6.1)	3 (1.0)

Values are number (percent).

*One patient had a large cerebral infarction without ICH on a posttreatment CT. This patient subsequently developed an ICH after craniotomy and surgical decompression for the large edematous cerebral infarction. This ICH is not included in the following analyses.

Table 5.6 Association of Base-Line NIHSS Score with Outcome at 12 Months

Treatment Group and NIHSS Score	No. of Patients	Barthel Index	Modified Rankin Scale	Glasgow Outcome Scale
		<i>percentage with favorable outcome</i>		
t-PA				
≤ 9	99	75	68	73
10-14	63	59	51	51
15-20	87	38	28	31
>20	63	17	6	5
Placebo				
≤ 9	78	72	62	62
10-14	73	40	23	33
15-20	84	27	21	25
>20	77	16	4	10

Table 5.6a Association of Base-Line NIHSS Score with Outcome at 12 Months, Reference 4

TABLE 3. ASSOCIATION OF BASE-LINE NIHSS SCORE WITH OUTCOME AT 12 MONTHS.*

TREATMENT GROUP AND NIHSS SCORE	NO. OF PATIENTS	BARTHEL INDEX	MODIFIED RANKIN SCALE	GLASGOW OUTCOME SCALE
		<i>percentage with favorable outcome†</i>		
t-PA				
≤9	99	75	68	73
10-14	63	59	51	51
15-20	87	38	28	31
>20	63	17	6	5
Placebo				
≤9	78	72	62	62
10-14	73	40	23	33
15-20	84	27	21	25
>20	77	16	4	10

*The possible range of scores is 0 to 42, with a higher score reflecting more severe disability. NIHSS denotes National Institutes of Health Stroke Scale.

†Scores of 95 or 100 on the Barthel index, 0 or 1 on the modified Rankin scale, and 1 on the Glasgow Outcome Scale were considered to indicate a favorable outcome.

Table 5.7 Baseline NIH Stroke Scale (NIHSS) by time from stroke onset to treatment (onset-to-treatment time [OTT]) strata and treatment group

NIHSS	OTT Strata				P Value
	0-90 Minute, N=302		91-180 Minute, N=320		
	t-PA	Placebo	t-PA	Placebo	
Number of patients	157	145	153	167	
NIHSS, mean (SD); median	15.2 (7.2); 15	15.0 (6.7); 14	13.5 (7.7); 12	15.4 (6.9); 15	0.061
NIHSS groups, percent					0.030
0-5	8.3	6.2	19.0	4.2	
6-10	19.1	25.5	24.2	27.5	
11-15	24.8	21.4	17.0	21.0	
16-20	25.5	25.5	21.6	19.8	
>20	22.3	21.4	18.3	27.5	

Table 5.7a Baseline NIH Stroke Scale (NIHSS) by time from stroke onset to treatment (onset-to-treatment time [OTT]) strata and treatment group, Reference 8

<i>group</i>	OTT strata				<i>p</i> Value*
	0–90 Minute, n = 302		91–180 Minute, n = 320		
	rt-PA	Placebo	rt-PA	Placebo	
NIHSS					
No. of patients	157	145	153	167	
NIHSS, mean (SD); median	15.2 (7.2); 15	15.0 (6.7); 14	13.5 (7.7); 12	15.4 (6.9); 15	0.06
NIHSS groups, percent					0.03
0–5	8.3	6.2	19.0	4.2	
6–10	19.1	25.5	24.2	27.5	
11–15	24.8	21.4	17.0	21.0	
16–20	25.5	25.5	21.6	19.8	
>20	22.3	21.4	18.3	27.5	

* *p* Value associated with test of the OTT strata by treatment interaction using analysis of variance on ranked data with NIHSS as the outcome. The presence of an interaction implies the NIHSS magnitude varies by OTT and treatment strata.

rt-PA = recombinant tissue-type plasminogen activator.

Table 5.8 Observed Outcomes by Outcome Measure

	Unfavorable	Favorable	Total	% Favorable	95% CI	Relative Risk	Odds Ratio	95% CI
Barthel								
Placebo	193	119	312	38.14%				
t-PA	148	162	310	52.26%				
Total	341	281	622	delta %	14.12%	6.37%	21.86%	1.37 1.78 1.29 2.44
	Unfavorable	Favorable	Total	% Favorable	95% CI	Relative Risk	Odds Ratio	95% CI
Rankin								
Placebo	229	83	312	26.60%				
t-PA	177	133	310	42.90%				
Total	406	216	622	delta%	16.30%	8.93%	23.68%	1.61 2.07 1.48 2.90
	Unfavorable	Favorable	Total	% Favorable	95% CI	Relative Risk	Odds Ratio	95% CI
Glasgow								
Placebo	215	97	312	31.09%				
t-PA	169	141	310	45.48%				
Total	384	238	622	delta%	14.39%	6.84%	21.95%	1.46 1.85 1.33 2.57
	Unfavorable	Favorable	Total	%Favorable	95% CI	Relative Risk	Odds Ratio	95% CI
NIHSS								
Placebo	248	64	312	20.51%				
t-PA	204	106	310	34.19%				
Total	452	170	622	delta%	13.68%	6.76%	20.61%	1.67 2.01 1.40 2.89

Table 5.9 Joint Distribution of Four Outcome Measures

	Glasgow: Unfav & NIHSS: Unfav	Glasgow: Unfav & NIHSS: Fav	Glasgow: Fav & NIHSS: Unfav	Glasgow: Fav & NIHSS: Fav	Total	Barthel Fav.	Rankin Fav.	Glasgow Fav.	NIHSS Fav.
All Patients									
Barthel: Unfav & Rankin: Unfav	325	5	2	5	337				
Barthel: Unfav & Rankin: R:Fav	0	0	3	1	4				
Barthel: Fav & Rankin: Unfav	47	1	15	6	69				
Barthel: Fav & Rankin: Fav.	5	1	55	151	212				
Total	377	7	75	163	622	281	216	238	170
						45.2%	34.7%	38.3%	27.3%

Table 5.9 Joint Distribution of Four Outcome Measures

	Glasgow: Unfav & NIHSS: Unfav	Glasgow: Unfav & NIHSS: Fav	Glasgow: Fav & NIHSS: Unfav	Glasgow: Fav & NIHSS: Fav	Total	Barthel	Rankin	Glasgow	NIHSS
						Fav.	Fav.	Fav.	Fav.
t-PA Patients									
Barthel: Unfav & Rankin: Unfav	141	1	1	3	146				
Barthel: Unfav & Rankin:Fav	0	0	2	0	2				
Barthel: Fav & Rankin: Unfav	24	0	4	3	31				
Barthel: Fav & Rankin: Fav.	2	1	30	98	131				
Total	167	2	37	104	310	162 52.3%	133 42.9%	141 45.5%	106 34.2%

Table 5.9 Joint Distribution of Four Outcome Measures

	Glasgow: Unfav & NIHSS: Unfav	Glasgow: Unfav & NIHSS: Fav	Glasgow: Fav & NIHSS: Unfav	Glasgow: Fav & NIHSS: Fav	Total	Barthel Fav.	Rankin Fav.	Glasgow Fav.	NIHSS Fav.
Placebo patients									
Barthel: Unfav & Rankin: Unfav	184	4	1	2	191				
Barthel: Unfav & Rankin: R:Fav	0	0	1	1	2				
Barthel: Fav & Rankin: Unfav	23	1	11	3	38				
Barthel: Fav & Rankin: Fav.	3	0	25	53	81				
Total	210	5	38	59	312	119 38.1%	83 26.6%	97 31.1%	64 20.5%

Table 5.10 Covariates for Outcome Models

Variables	df	step	Barthel: Chi-Square	Barthel: P-Value	step	Rankin: Chi-Square	Rankin: P-Value
OTT(>90)	1		0.0423	0.8371		0.0327	0.8566
PART(>1)	1		0.8142	0.3669		1.4970	0.2211
CENTER	7		8.8981	0.2601		10.7774	0.1486
BsNIHSS	1		118.8027	<.0001		126.6098	<.0001
BsNIHSS(5)*	4		101.5407	<.0001		102.6094	<.0001
Age	1		35.4821	<.0001		12.7125	0.0004
PrDISABility	1		20.2530	<.0001		12.4883	0.0004
STKTYP	3		17.7841	0.0005		15.1575	0.0017
PrHTN	1		9.7335	0.0018		6.6715	0.0098
BsGLUcose	1		8.5123	0.0035		4.7305	0.0396
PrDM	1		7.3317	0.0068		1.6905	0.1935
PrAF	1		7.0872	0.0078		6.3818	0.0115
CURDrnk	1		6.5454	0.0105		2.6613	0.1028
CURSMK	1		5.0561	0.0245		7.0133	0.0081
Sex	1		3.2935	0.0696			
BsGLU>300	1		2.6681	0.1024		1.9936	0.1580
PrOtherCARDiac	1		2.2514	0.1335			
BsED/ME	1		1.9992	0.1574		3.6179	0.0572
PrCCB	1					2.3607	0.1244
AdHEPARIN	1						
PrSTRK	1						
* 4 df partition of BsNIHSS into Quintiles							
Stepwise Processes (p <.05) with OTT, PART & CENTER fixed in the models							
BsNIHSS	1	1	118.8027	<.0001	1	126.6098	<.0001
Age	1	2	30.5540	<.0001	4	4.7952	0.0285
PrDISABility	1	3	15.5063	<.0001	2	9.4215	0.0021
Weight	1	4	8.3899	0.0038	5	6.5364	0.0106
BsGLUcose	1	5	5.9012	0.0151			
CURSMK	1				3	9.4388	0.0021
BsED/ME	1				6	5.4030	0.0201
PrHTN	1						
PrDM	1						
BsGLU>300	1						

Table 5.10 Covariates for Outcome Models

Variables	df	step	Glasgow: Chi-Square	Glasgow: P-Value	step	NIHSS: Chi-Square	NIHSS: P-Value
OTT(>90)	1		0.0137	0.9067		0.0143	0.9049
PART(>1)	1		0.0040	0.9493		1.1508	0.2834
CENTER	7		11.9179	0.1033		9.6614	0.2086
BsNIHSS	1		131.7685	<.0001		96.3754	<.0001
BsNIHSS(5)*	4		108.1549	<.0001		78.5016	<.0001
Age	1		12.8253	0.0003		12.2659	0.0005
PrDISABility	1		14.4980	0.0001		10.8470	0.0010
STKTYP	3		10.7414	0.0132		9.6074	0.0222
PrHTN	1		5.7992	0.0160		10.2588	0.0014
BsGLUcose	1		4.3772	0.0364			
PrDM	1		3.3053	0.0691		6.8346	0.0089
PrAF	1		6.4352	0.0112		4.1976	0.0405
CURDrnk	1					3.1399	0.0764
CURSMK	1		3.3382	0.0677		5.0497	0.0246
Sex	1						
BsGLU>300	1						
PrOtherCARDiac	1					2.2255	0.1357
BsED/ME	1						
PrCCB	1						
AdHEPARIN	1		3.2820	0.0700			
PrSTRK	1					3.9442	0.0407
* 4 df partition of BsNIHSS into Quintiles							
Stepwise Processes (p <.05) with OTT, PART & CENTER fixed in the models							
BsNIHSS	1	1	131.7685	<.0001	1	96.3754	<.0001
Age	1	3	8.4723	0.0036	6	4.6329	0.0314
PrDISABility	1	2	11.4914	0.0007	3	6.7302	0.0095
Weight	1	4	4.4928	0.0340			
BsGLUcose	1						
CURSMK	1						
BsED/ME	1						
PrHTN	1				2	10.9711	0.0009
PrDM	1				4	6.1059	0.0135
BsGLU>300	1				5	6.5425	0.0105

Table 5.11 Covariate Interactions in Outcome Models

Variables	df	step	Barthel: Chi-Square	Barthel: P-Value	step	Rankin: Chi-Square	Rankin: P-Value
OTT(>90)	1		0.0423	0.8371		0.0327	0.8566
PART(>1)	1		0.8142	0.3669		1.4970	0.2211
CENTER	7		8.8981	0.2601		10.7774	0.1486
BsNIHSS	1		118.8027	<.0001		126.6098	<.0001
Age	1		30.5540	<.0001		4.7952	0.0285
PrDISAbility	1		15.5063	<.0001		9.4215	0.0021
Weight	1		8.3899	0.0038		6.5364	0.0106
BsGLUcose	1		5.9012	0.0151			
CURSMK	1					9.4388	0.0021
BsED/ME	1					5.4030	0.0201
PrHTN	1						
PrDM	1						
BsGLU>300	1						
Interaction Stepwise Processes (p<.05) with all Main Effects fixed in the models							
BsNIHSS*Age	1	1	8.1619	0.0043	1	15.2308	<.0001
			2 interactions entered & removed (p>.05)				
PART*Age	1				2	8.0474	0.0046
OTT*BSED/ME	1				3	3.9657	0.0464

Table 5.11 Covariate Interactions in Outcome Models

Variables	df	step	Glasgow: Chi-Square	Glasgow: P-Value	step	NIHSS: Chi-Square	NIHSS: P-Value
OTT(>90)	1		0.0137	0.9067		0.0143	0.9049
PART(>1)	1		0.0040	0.9493		1.1508	0.2834
CENTER	7		11.9179	0.1033		9.6614	0.2086
BsNIHSS	1		131.7685	<.0001		96.3754	<.0001
Age	1		8.4723	0.0036		4.6329	0.0314
PrDISABility	1		11.4914	0.0007		6.7302	0.0095
Weight	1		4.4928	0.0340			
BsGLUcose	1						
CURSMK	1						
BsED/ME	1						
PrHTN	1					10.9711	0.0009
PrDM	1					6.1059	0.0135
BsGLU>300	1					6.5425	0.0105
Interaction Stepwise Processes (p<.05) with all Main Effects fixed in the models							
BsNIHSS*Age	1	1	14.071	0.0002	1	11.5809	0.0007
PART*Age OTT*BsED/ME	1 1	2	6.8158	0.0090		1 interaction entered & removed (p>.05)	

Table 5.12 Final Covariate Outcome Models

Variables	df	Barthel: Chi-Square	Barthel: P-Value	Rankin: Chi-Square	Rankin: P-Value
OTT(>90)	1	0.5856	0.4441	0.9711	0.3244
PART(>1)	1	0.5706	0.4500	6.1205	0.0134
CENTER	7	12.1715	0.0951	6.6448	0.4668
BsNIHSS	1	0.9613	0.3269	5.7176	0.0168
Age	1	0.0131	0.9089	11.6697	0.0006
PrDISABility	1	13.1957	0.0003	8.9127	0.0028
Weight	1	5.5708	0.0183	5.0570	0.0245
BsGLUcose	1	5.9789	0.0145	~	~
CURSMK	1	~	~	6.7258	0.0095
BsED/ME	1	~	~	6.0101	0.0142
PrHTN	1	~	~	~	~
PrDM	1	~	~	~	~
BsGLU>300	1	~	~	~	~
BsNIHSS*Age	1	8.1619	0.0043	18.9898	p<.0001
PART*Age	1	~	~	7.597	0.0058
OTT*BsED/ME	1	~	~	3.9657	0.0464
As described in the text, the covariates in the model below were used for all subsequent analyses.					
OTT(>90)	1				
PART(>1)	1				
CENTER	7				
BsNIHSS	1				
Age	1				
PrDISABility	1				
PrDM	1				
BsNIHSS*Age	1				

Table 5.12 Final Covariate Outcome Models

Variables	df	Glasgow: Chi-Square	Glasgow: P-Value	NIHSS: Chi-Square	NIHSS: P-Value
OTT(>90)	1	0.4895	0.4842	0.3846	0.5351
PART(>1)	1	6.4990	0.0108	1.8039	0.1792
CENTER	7	5.0710	0.6513	7.1324	0.4152
BsNIHSS	1	3.9173	0.0478	2.2786	0.1312
Age	1	8.5347	0.0035	3.8778	0.0489
PrDISABility	1	10.0594	0.0015	4.3694	0.0366
Weight	1	3.7350	0.0533	~	~
BsGLUcose	1	~	~	~	~
CURSMK	1	~	~	~	~
BsED/ME	1	~	~	~	~
PrHTN	1	~	~	3.9497	0.0469
PrDM	1	~	~	9.5118	0.0020
BsGLU>300	1	~	~	4.4255	0.0297
BsNIHSS*Age	1	15.3878	<.0001	11.1609	0.0008
PART*Age	1	6.7111	0.0096	~	~
OTT*BsED/ME	1	~	~	~	~
As described in the text, the covariates in the model below were used for all subsequent analyses.					
OTT(>90)	1				
PART(>1)	1				
CENTER	7				
BsNIHSS	1				
Age	1				
PrDISABility	1				
PrDM	1				
BsNIHSS*Age	1				

Table 5.14 Covariate Interactions in Global Model

Stepwise (p <.05) Global Covariate Model				Backward stepwise elimination (p~.05)								
Variables	df	Global: Chi-Square	Global: P-Value	step one Global: Chi-Square	one Global: P-Value	step two Global: Chi-Square	two Global: P-Value	step three Global: Chi-Square	three Global: P-Value	step four Global: Chi-Square	four Global: P-Value	
OTT(>90)	1	0.2601	0.6074	0.7056	0.4001	0.7225	0.3962	0.6724	0.4110	0.6002	0.4385	
PART(>1)	1	2.3104	0.1289	1.7689	0.1847	1.8225	0.1708	1.7689	0.1838	1.7083	0.1912	
CENTER	7	10.9900	0.1390									
BsNIHSS	1	126.5625	<.0001	2.6244	0.1059	3.0625	0.0798	3.8381	0.0501	3.9743	0.0462	
Age	1	25.1001	<.0001	1.5129	0.2202	1.8496	0.1735	3.4306	0.0640	2.9819	0.0842	
PrDISABILITY	1	15.2881	<.0001	13.0321	0.0003	12.8164	0.0003	13.3956	0.0003	14.6689	<.0001	
PrDM	1	5.1529	0.0232	5.6611	0.0174	5.9536	0.0148	7.3251	0.0068	8.9999	0.0027	
Weight	1	6.1009	0.0135	4.3681	0.0365	3.8809	0.0483	~	~	~	~	
PrHTN	1	4.7961	0.0288	4.3264	0.0375	3.9204	0.0475	4.8590	0.0275	~	~	
BsED/ME	1	4.6656	0.0309	3.8025	0.0526	~	~	~	~	~	~	
Age*BsNIHSS	1	~	~	15.2100	<.0001	16.3216	<.0001	17.8929	<.0001	18.1476	<.0001	

Final Global Covariate Model			
Variables	df	Parameter Estimate	Standard Error
OTT(>90)	1	-0.1268	0.1636
PART(>1)	1	-0.2175	0.1664
CENTER	7	~	~
BsNIHSS	1	0.0333	0.0668
Age	1	0.0254	0.0147
PrDISABILITY	1	-1.5231	0.3981
PrDM	1	-0.6113	0.2040
Age*BsNIHSS	1	-0.0045	0.0011

4 interactions among the variables in this final Global Covariate model were significant (all p-values <0.01)

Table 5.15 Individual Outcome Odds Ratio Estimates; Unadjusted and Adjusted

t-PA by Placebo Odds Ratio Estimates and 95% Confidence Intervals

Models Adjusted For:	BARTHEL				
	adjusting degrees of freedom	parameter estimate	standard error	ODDS RATIO ESTIMATE	95% Confidence Interval
Nothing	0	~	~	1.78	1.29 2.44
Stratification Factors	9	0.5826	0.1645	1.79	1.30 2.47
Stratification Factors & BsNIHSS, Age, PrDISABILITY, PrDM, BsNIHSS*Age	14	0.7837	0.1990	2.19	1.48 3.23
Stratification factors & covariates entering the stepwise process (see Table 5.12)	15	0.7414	0.2005	2.11	1.43 3.13
Models Adjusted For:	GLASGOW				
	adjusting degrees of freedom	parameter estimate	standard error	ODDS RATIO ESTIMATE	95% Confidence Interval
Nothing	0	~	~	1.85	1.33 2.57
Stratification Factors	9	0.6295	0.1694	1.89	1.35 2.62
Stratification Factors & BsNIHSS, Age, PrDISABILITY, PrDM, BsNIHSS*Age	14	0.7557	0.2012	2.13	1.44 3.16
Stratification factors & covariates entering the stepwise process (see Table 5.12)	15	0.7540	0.2039	2.13	1.43 3.17

Table 5.15 Individual Outcome Odds Ratio Estimates; Unadjusted and Adjusted

t-PA by Placebo Odds Ratio Estimates and 95% Confidence Intervals

Models Adjusted For:	RANKIN				
	adjusting degrees of freedom	parameter estimate	standard error	ODDS RATIO ESTIMATE	95% Confidence Interval
Nothing	0	~	~	2.07	1.48 2.90
Stratification Factors	9	0.7494	0.1744	2.11	1.50 2.98
Stratification Factors & BsNIHSS, Age, PrDISABILITY, PrDM, BsNIHSS*Age	14	0.8869	0.2060	2.43	1.62 3.64
Stratification factors & covariates entering the stepwise process (see Table 5.12)	12	0.8516	0.2129	2.34	1.54 3.56
Models Adjusted For:	NIHSS				
	adjusting degrees of freedom	parameter estimate	standard error	ODDS RATIO ESTIMATE	95% Confidence Interval
Nothing	0	~	~	2.01	1.40 2.89
Stratification Factors	9	0.7219	0.1866	2.06	1.43 2.97
Stratification Factors & BsNIHSS, Age, PrDISABILITY, PrDM, BsNIHSS*Age	14	0.7845	0.2124	2.19	1.45 3.32
Stratification factors & covariates entering the stepwise process (see Table 5.12)	16	0.7867	0.2147	2.20	1.44 3.35

Table 5.16 Global Outcome Odds Ratios; Unadjusted and Adjusted

Models Adjusted For:	GLOBAL				
	adjusting degrees of freedom	parameter estimate	standard error	ODDS RATIO ESTIMATE	95% Confidence Interval
Nothing	0	~	~	1.88	1.41 2.51
Stratification Factors	9	0.6454	0.1497	1.91	1.42 2.56
Stratification Factors & BsNIHSS, Age, PrDISABILITY, PrDM, BsNIHSS*Age	14	0.7569	0.1637	2.13	1.55 2.92
Stratification factors & covariates entering the stepwise process (see Table 5.14)	17	0.7279	0.1646	2.07	1.50 2.86

Table 5.17 Barthel Models: Covariates, t-PA Effect and Interactions

Variable	DF	Est.	Std. Error	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P
OTT (>90)	1	0.1473	0.1942	0.1122	0.1975	0.57	0.1447	0.2735	0.60	0.1117	0.1975	0.57	0.1148	0.1997	0.56	0.1088	0.1977	0.58	0.1367	0.1984	0.49	0.0963	0.1984	0.63
PART (>1)	1	0.1677	0.1965	0.1726	0.1995	0.39	0.1698	0.1999	0.40	0.1502	0.2749	0.58	0.1292	0.2020	0.52	0.1749	0.1997	0.38	0.1789	0.2001	0.37	0.1784	0.2005	0.37
CENTER	7	*	*	*	*	0.06	*	*	0.06	*	*	0.07	*	*	0.68	*	*	0.06	*	*	0.07	*	*	0.08
BsNIHSS	1	0.0653	0.0853	0.1031	0.0861	0.23	0.1075	0.0863	0.21	0.1027	0.0862	0.23	0.1102	0.0875	0.21	0.1018	0.0860	0.24	0.1079	0.0860	0.21	0.2476	0.1205	0.04
Age	1	0.0086	0.0198	0.0056	0.0201	0.78	0.0067	0.0201	0.74	0.0055	0.0201	0.78	0.0072	0.0205	0.73	0.0053	0.0201	0.79	0.0069	0.0201	0.73	0.0412	0.0277	0.14
PrDISABility	1	1.6949	0.4995	1.8154	0.5169	<.01	1.7784	0.5150	<.01	1.8169	0.5170	<.01	1.8472	0.5284	<.01	1.4870	0.7954	0.06	1.8209	0.5210	<.01	1.8393	0.5251	<.01
PrDM	1	0.6615	0.2400	0.6587	0.2425	<.01	0.6876	0.2436	<.01	0.6591	0.2426	<.01	0.6281	0.2461	0.01	0.6612	0.2427	<.01	0.2508	0.3327	0.45	0.6683	0.2426	<.01
Age*BsnIHSS	1	0.0039	0.0013	0.0040	0.0013	<.01	0.0041	0.0013	<.01	0.0040	0.0013	<.01	0.0042	0.0013	<.01	0.0040	0.0013	<.01	0.0041	0.0013	<.01	0.0066	0.0020	<.01
t-PA	1	~	~	0.7837	0.1990	<.01	1.0578	0.2850	<.01	0.8080	0.2861	<.01	0.6349	0.7578	0.40	0.2803	1.0090	0.78	0.9576	0.2239	<.01	5.1643	2.7953	0.06
t-PA*OTT	1	~	~	~	~	~	0.5382	0.3959	0.17	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA* PART	1	~	~	~	~	~	~	~	~	0.0465	0.3921	0.91	~	~	~	~	~	~	~	~	~	~	~	
t-PA*CENTER	7	~	~	~	~	~	~	~	~	~	~	~	~	~	0.16	~	~	~	~	~	~	~	~	
t-PA* PrDISABility	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.5227	1.0293	0.61	~	~	~	~	~	
t-PA*PrDM	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.8466	0.4852	0.08	~	~	
t-PA* (BsNIHSS, Age, Age* BsNIHSS)	3	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.31

Est. = Estimate
 Std. Error = Standard Error
 P = P-value

Table 5.18 Rankin Models: Covariates, t-PA Effects and Interactions

Variable	DF	Est.	Std. Error	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P
OTT(>90)	1	-0.1414	0.2014	-0.1149	0.2057	0.58	-0.1477	0.2931	0.61	-0.1093	0.2059	0.60	-0.1287	0.2083	0.54	-0.1105	0.2061	0.59	-0.1284	0.2062	0.53	-0.0928	0.2074	0.65
PART(>1)	1	-0.2873	0.2035	-0.3049	0.2079	0.14	-0.3053	0.2079	0.14	-0.1086	0.2946	0.71	-0.2635	0.2103	0.21	-0.3068	0.2082	0.14	-0.3089	0.2083	0.14	-0.2910	0.2095	0.16
CENTER	7	*	*	*	*	0.27	*	*	0.28	*	*	0.27	*	*	0.66	*	*	0.28	*	*	0.29	*	*	0.32
BsNIHSS	1	0.1901	0.0885	0.1996	0.0904	0.03	0.1991	0.0905	0.03	0.1958	0.0904	0.03	0.1980	0.0914	0.03	0.1982	0.0905	0.03	0.2009	0.0900	0.03	0.2322	0.1318	0.09
Age	1	0.0470	0.0192	0.0451	0.0197	0.02	0.0405	0.0197	0.02	0.0446	0.0196	0.02	0.0458	0.0199	0.02	0.0450	0.0197	0.02	0.0458	0.0197	0.02	0.0713	0.0295	0.02
PrDISAbility	1	-1.4186	0.5380	-1.5653	0.5546	<.01	-1.5697	0.5556	<.01	-1.5751	0.5551	<.01	-1.5553	0.5628	<.01	-0.8502	0.8191	0.30	-1.5620	0.5555	<.01	-1.5571	0.5549	<.01
PrDM	1	-0.3371	0.2516	-0.3151	0.2557	0.22	-0.3124	0.2564	0.22	-0.3193	0.2563	0.21	-0.2718	0.2593	0.29	-0.3184	0.2559	0.21	-0.0217	0.3563	0.95	-0.3108	0.2563	0.23
AGE*BsnIHSS	1	-0.0058	0.0014	-0.0059	0.0014	<.01	-0.0059	0.0014	<.01	-0.0059	0.0014	<.01	-0.0060	0.0015	<.01	-0.0059	0.0014	<.01	-0.0060	0.0014	<.01	-0.0069	0.0023	<.01
t-PA	1	~	~	0.8869	0.2060	<.01	0.8544	0.2915	<.01	1.0858	0.2967	<.01	-0.3227	0.7693	0.67	-0.1920	1.0621	0.86	1.0023	0.2230	<.01	3.3473	2.6334	0.19
t-PA*OTT	1	~	~	~	~	~	0.0644	0.4088	0.87	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA*PART	1	~	~	~	~	~	~	~	~	-0.3834	0.4048	0.35	~	~	~	~	~	~	~	~	~	~	~	
t-PA*CENTER	7	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA*PrDISAbility	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	-1.1169	1.0829	0.30	~	~	~	~	~	
t-PA*PrDM	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA*(BsNIHSS, Age, Age*BsnIHSS)	3	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	

Est. = Estimate
 Std. Error = Standard Error
 P = P-value

Table 5.19 Glasgow Models: Covariates, t-PA Effects and Interactions

Variable	DF	Est..	Std. Error	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P
OTT(>90)	1	-0.1298	0.1978	-0.1066	0.2010	0.60	-0.0809	0.2828	0.77	-0.1042	0.2011	0.60	-0.1150	0.2035	0.57	-0.1025	0.2012	0.61	-0.1199	0.2015	0.55	-0.0917	0.2024	0.65
PART(>1)	1	-0.0097	0.1997	-0.0200	0.2025	0.92	-0.0194	0.2025	0.92	0.0540	0.2844	0.85	0.0210	0.2053	0.92	-0.0207	0.2027	0.92	-0.0239	0.2029	0.91	-0.0112	0.2039	0.96
CENTER	7	*	*	*	*	0.53	*	*	0.56	*	*	0.53	*	*	0.51	*	*	0.55	*	*	0.59	*	*	0.61
BsNIHSS	1	0.1613	0.0870	0.1704	0.0884	0.05	0.1708	0.0884	0.05	0.1686	0.0885	0.06	0.1664	0.0888	0.06	0.1688	0.0885	0.06	0.1723	0.0885	0.05	0.2386	0.1266	0.06
Age	1	0.0434	0.0193	0.0419	0.0197	0.03	0.0420	0.0197	0.02	0.0416	0.0197	0.03	0.0415	0.0199	0.04	0.0416	0.0197	0.03	0.0426	0.0197	0.03	0.0718	0.0281	0.01
PrDISAbility	1	-1.5589	0.5354	-1.6807	0.5493	<.01	-1.6772	0.5497	<.01	-1.6825	0.5489	<.01	-1.7107	0.5628	<.01	-1.1024	0.8184	0.18	-1.6791	0.5500	<.01	-1.7122	0.5568	<.01
PrDM	1	-0.4707	0.2483	-0.4594	0.2509	0.07	-0.4616	0.2514	0.07	-0.4611	0.2511	0.07	-0.4268	0.2542	0.09	-0.4621	0.2510	0.07	-0.1659	0.3479	0.63	-0.4528	0.2515	0.07
AGE*BsnIHSS	1	-0.0053	0.0014	-0.0054	0.0014	<.01	-0.0054	0.0014	<.01	-0.0054	0.0014	<.01	-0.0054	0.0014	<.01	-0.0054	0.0014	<.01	-0.0054	0.0014	<.01	-0.0067	0.0021	<.01
t-PA	1	~	~	0.7557	0.2012	<.01	0.7818	0.2854	<.01	0.8328	0.2899	<.01	-0.3032	0.7589	0.69	-0.1311	1.0599	0.90	0.8717	0.2244	<.01	4.5549	2.6533	0.09
t-PA*OTT	1	~	~	~	~	~	-0.0516	0.3996	0.90	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA*PART	1	~	~	~	~	~	~	~	~	-0.1476	0.3985	0.70	~	~	~	~	~	~	~	~	~	~	~	
t-PA*CENTER	7	~	~	~	~	~	~	~	~	~	~	~	~	~	0.17	~	~	~	~	~	~	~	~	
t-PA*PrDISAbility	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	-0.9174	1.0800	0.40	~	~	~	~	~	
t-PA*PrDM	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	-0.5950	0.5007	0.23	~	~	
t-PA* (BsNIHSS, Age, Age*BsnIHSS)	3	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.22

Est. = Estimate
 Std. Error = Standard Error
 P = P-value

Table 5.20 NIHSS Models: Covariates, t-PA Effects and Interactions

Variable	DF	Est.	Std. Error	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P
OTT(>90)	1	-0.1155	0.2087	-0.1033	0.2123	0.63	0.1804	0.3137	0.57	-0.0993	0.2124	0.64	-0.1052	0.2134	0.62	-0.1018	0.2124	0.63	-0.1027	0.2126	0.63	-0.0888	0.2130	0.68
PART(>1)	1	-0.2688	0.2107	-0.2818	0.2144	0.19	-0.2790	0.2147	0.19	-0.1287	0.3134	0.68	-0.2623	0.2162	0.23	-0.2825	0.2145	0.19	-0.2814	0.2145	0.19	-0.2973	0.2150	0.17
CENTER	7	*	*	*	*	0.32	*	*	0.30	*	*	0.32	*	*	0.84	*	*	0.32	*	*	0.32	*	*	0.31
BsNIHSS	1	0.1488	0.0913	0.1510	0.0926	0.10	0.1548	0.0926	0.09	0.1485	0.0926	0.11	0.1550	0.0934	0.10	0.1500	0.0927	0.11	0.1509	0.0926	0.10	0.2694	0.1399	0.05
Age	1	0.0328	0.0190	0.0297	0.0194	0.13	0.0308	0.0195	0.11	0.0293	0.0194	0.13	0.0306	0.0197	0.12	0.0295	0.0195	0.13	0.0296	0.0194	0.13	0.0496	0.0295	0.09
PrDISAbility	1	-1.5371	0.6477	-1.6557	0.6596	0.01	-1.6270	0.6585	0.01	-1.6645	0.6603	0.01	-1.5911	0.6587	.02	-1.2460	1.0801	0.25	-1.6554	0.6596	0.01	-1.6221	0.6590	0.01
PrDM	1	-0.7709	0.2787	-0.7599	0.2830	<.01	-0.7854	0.2842	<.01	-0.7668	0.2839	<.01	-0.7127	0.2858	0.01	-0.7627	0.2832	<.01	-0.7766	0.4247	0.07	-0.7736	0.2821	<.01
AGE*BsnIHSS	1	-0.0050	0.0015	-0.0049	0.0015	<.01	-0.0050	0.0015	<.01	-0.0049	0.0015	<.01	-0.0050	0.0015	<.01	-0.0049	0.0015	<.01	-0.0049	0.0015	<.01	-0.0074	0.0024	<.01
t-PA	1	~	~	0.7845	0.2124	<.01	1.0547	0.3077	<.01	0.9303	0.3053	<.01	0.2356	0.7794	0.76	0.1992	1.3348	0.88	0.7796	0.2320	<.01	1.8622	2.5380	0.46
t-PA*OTT	1	~	~	~	~	~	-0.5266	0.4273	0.22	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA*PART	1	~	~	~	~	~	~	~	~	-0.2831	0.4229	0.50	~	~	~	~	~	~	~	~	~	~	~	
t-PA*CENTER	7	~	~	~	~	~	~	~	~	~	~	~	~	~	0.87	~	~	~	~	~	~	~	~	
t-PA*PrDISAbility	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	-0.5990	1.3515	0.66	~	~	~	~	~	
t-PA*PrDM	1	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.0301	0.5708	0.96	~	~	
t-PA*(BsNIHSS, Age, Age*BsnIHSS)	3	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.42	

Est. = Estimate
 Std. Error = Standard Error
 P = P-value

Table 5.21 Global Models: Covariates, t-PA Effects and Interactions

Variable	DF	Est.	Std. Error	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P	Est.	Std. Error	P
OTT(>90)	1	-0.1268	0.1636	-0.1033	0.1650	0.53	0.1176	0.2315	0.61	-0.1007	0.1653	0.54	-0.1100	0.1661	0.51	-0.1008	0.1654	0.54	-0.1145	0.1651	0.49	-0.0892	0.1668	0.59
PART(>1)	1	-0.2175	0.1664	-0.2349	0.1677	0.16	-0.2341	0.1681	0.16	-0.1337	0.2290	0.56	-0.2108	0.1683	0.21	-0.2370	0.1681	0.16	-0.2398	0.1681	0.15	-0.2622	0.1687	0.12
CENTER	7	~	~			0.08			0.07			0.08			0.43			0.08			0.08			0.20
BsNIHSS	1	0.0333	0.0668	0.1379	0.0673	0.04	0.1407	0.0678	0.04	0.1358	0.0675	0.04	0.1408	0.0668	0.04	0.1366	0.0676	0.04	0.1393	0.0676	0.04	0.2412	0.0960	0.01
Age	1	0.0254	0.0147	0.0218	0.0150	0.14	0.0225	0.0151	0.14	0.0215	0.0150	0.15	0.0223	0.0149	0.13	0.0215	0.0151	0.15	0.0223	0.0150	0.14	0.0430	0.0214	0.04
PrDISAbility	1	-1.5231	0.3981	-1.6375	0.4165	<.01	-1.6009	0.4138	<.01	-1.6436	0.4185	<.01	-1.6162	0.4014	<.01	-1.2675	0.7279	0.05	-1.6398	0.4113	<.01	-1.6278	0.4164	<.01
PrDM	1	-0.6113	0.2040	-0.6073	0.2080	<.01	-0.6304	0.2065	<.01	-0.6100	0.2087	<.01	-0.5685	0.2083	<.01	-0.6097	0.2070	<.01	-0.3770	0.2721	0.17	-0.6292	0.2073	<.01
Age*BsNIHSS	1	-0.0045	0.0011	-0.0045	0.0011	<.01	-0.0046	0.0011	<.01	-0.0045	0.0011	<.01	-0.0046	0.0011	<.01	-0.0045	0.0011	<.01	-0.0046	0.0011	<.01	-0.0065	0.0016	<.01
t-PA	1	~	~	0.7569	0.1637	<.01	0.9788	0.2413	<.01	0.8617	0.2475	<.01	-0.2199	0.7665	0.77	0.2076	0.8507	0.81	0.8419	0.1826	<.01			
t-PA*OTT	1	~	~	~	~		-0.4355	0.3325	0.19	~	~	~	~	~	~	~	~	~	~	~	~	~	~	
t-PA*PART	1	~	~	~	~		~	~	~	-0.2005	0.3263	0.54	~	~	~	~	~	~	~	~	~	~	~	
t-PA*CENTER	7	~	~	~	~		~	~	~	~	~	~	~	~	0.47	~	~	~	~	~	~	~	~	
t-PA*PrDISAbility	1	~	~	~	~		~	~	~	~	~	~	~	~	~	-0.5664	0.8660	0.51	~	~	~	~	~	
t-PA*PrDM	1	~	~	~	~		~	~	~	~	~	~	~	~	~	~	~	~	-0.4540	0.4079	0.27	~	~	
t-PA* (BsNIHSS, Age, Age*BsNIHSS)	3	~	~	~	~		~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.37	

Est. = Estimate
 Std. Error = Standard Error
 P = P-value

Table 7.1 ICH Univariate Models

VARIABLE NAME	DF	Scenario I.		Scenario II.		Scenario III.		Scenario IV.	
		P-value	OR	P-value	OR	P-value	OR	P-value	OR
MassEffect	1	0.0002	14.25	0.0014	6.80	0.0033	7.80	0.0069	4.22
ED/ME	1	0.0004	8.46	0.0018	5.40	0.0010	6.18	0.0034	3.80
NIHSS	1	0.0030	1.10	0.0087	1.08	0.0017	1.08	0.0005	1.08
Edema	1	0.0230	4.95	0.0560	3.49	0.0220	4.27	0.0280	3.13
Age	1	0.0540	1.05	0.0400	1.05	0.0170	1.05	0.0130	1.04
GLUcose	1	0.0580	1.00	0.0110	1.01	0.0470	1.00	0.0160	1.00
CURSMK	1	0.0830	0.33	0.1080	0.41	0.0130	0.25	0.0320	0.42
GLU>300	1	0.0840	3.24	0.0210	3.82	0.0990	2.69	0.1000	2.31
CARDIAC	1	0.1240	2.10	0.0620	2.38	0.5460	1.25	0.3700	1.33
AF	1	0.1880	1.96	0.2850	1.69	0.6280	1.25	0.1870	1.62
ASA	1	0.3640	1.52	0.2710	1.62	0.4260	1.35	0.1290	1.63
STK SUBTP	3	0.3700		0.3940		0.3050		0.3860	
CURDrnk<24hrs.	1	0.3740	0.51	0.3080	0.47	0.2150	0.46	0.5870	0.78
Rank of Wt.	1	0.3970	1.00	0.7540	1.00	0.3730	1.00	0.8110	1.00
T-DOSE	1	0.4220	1.01	0.7290	1.01	0.3600	1.01	0.8430	1.00
Weight (kg)	1	0.4960	1.01	0.9400	1.00	0.4890	1.01	0.5940	1.00
RACE	2	0.5100		0.6170		0.0860		0.0370	
Sex	1	0.5090	0.74	0.4380	0.71	0.3930	0.73	0.1590	0.64
MAIgnancy	1	0.5230	0.51	0.4120	0.43	0.5650	0.65	0.2680	0.44
STK	1	0.6070	0.67	0.5930	0.67	0.8130	0.88	0.5060	0.70
CCB	1	0.6290	0.76	0.8090	0.88	0.2230	0.54	0.3650	0.69
RK%DOSE	1	0.6820	1.00	0.7160	1.00	0.6370	1.00	0.4900	1.00
%DOSE	1	0.7100	1.01	0.7970	1.01	0.6590	1.01	0.3100	1.02
HEMatologicD	1	0.7180	1.47	0.7580	1.38	0.8910	0.86	0.1740	2.40
Diabetes	1	0.8290	0.88	0.8450	1.11	0.6590	1.21	0.2190	1.55
OTT (mins.)	1	0.9200	1.00	0.9870	1.00	0.4990	1.00	0.9500	1.00
HTN	1	0.9370	0.96	0.8070	1.12	0.6770	0.85	0.8350	0.93
OTT>90	1	0.9520	1.03	0.7670	1.14	0.5040	0.78	0.6560	1.15
DrnkPROB	1	0.9670		0.4440	0.45	0.9730		0.3040	0.47
Hepatic	1	0.9820		0.9810		0.9770		0.9830	
VALVE Pros.	1	0.9900		0.9900		0.9870		0.9910	
HEPARIN	1	0.9900		0.9850		0.9830		0.9870	
rt-PA	1			0.0001	10.70			0.0004	3.48

Table 7.2 ICH Multivariate Models (NINDS)

VARIABLE	DF	Scenario I.		Scenario II.		Scenario III.		Scenario IV.	
		P-value	OR	P-value	OR	P-value	OR	P-value	OR
MassEffect	1								
ED/ME	1	0.0041	7.81	0.0071	5.52	0.0065	5.82	0.0093	4.10
NIHSS	1	0.0392	1.07	0.0593	1.06	0.0159	1.06	0.0055	1.06
Edema	1								
Age	1	0.1943	1.04	0.2677	1.03	0.0418	1.04	0.0651	1.03
GLUcose	1	0.0902	1.01	0.0086	1.01	0.1349	1.00	0.0528	1.00
CURSMK	1	0.1576	0.37	0.2590	0.51	0.0447	0.30	0.1795	0.55
GLU>300	1								
CARDIAC	1	0.3291	1.75	0.1773	1.99				
AF	1	0.5677	0.68					0.9581	0.98
ASA	1							0.5245	1.26
STK SUBTP	3								
CURDrnk<24hrs.	1								
Rank of Wt.	1								
T-DOSE	1								
Weight (kg)	1								
RACE	2					0.0860	**	0.0370	**
Sex	1							0.6944	0.87
MALignancy	1								
STK	1								
CCB	1								
RK%DOSE	1								
%DOSE	1								
HEMatologicD	1							0.3089	2.06
Diabetes	1								
OTT (mins.)	1								
HTN	1								
OTT>90	1								
DrnkPROB	1								
Hepatic	1								
VALVE Pros.	1								
HEPARIN	1								
rt-PA	1			0.0012	12.00			0.0013	3.50

Table 7.3 ICH Stepwise Models

VARIABLE NAME	DF	Scenario I.			Scenario II.			Scenario III.			Scenario IV.		
		STP	P-value	OR	STP	P-value	OR	STP	P-value	OR	STP	P-value	OR
MassEffect	1	1	0.0029	11.23	2	0.0064	7.58						
ED/ME	1							1	0.0035	7.00	3	0.0069	4.09
BsNIHSS	1	2	0.0326	1.07	4	0.0635	1.06	2	0.0138	1.08	1	0.0021	1.07
Edema	1												
Age	1							6	0.0120	1.06	5	0.0434	1.04
GLUcose	1	4	0.0239	1.01	3	0.0020	1.01				4	0.0669	1.00
CURSMK	1	3	0.0739	0.27	7	0.1413	0.40	3	0.0649	0.33	7	0.1083	0.50
GLU>300	1							5	0.0443	3.97			
CARDIAC	1				5	0.1304	2.16						
AF	1												
ASA	1												
STK SUBTP	3												
CURDrnk<24hrs.	1												
Rank of Wt.	1							7	0.0502	1.00			
T-DOSE	1												
Weight (kg)	1												
RACE	2							8	0.0683	**	6	0.0887	**
Sex	1												
MAIignancy	1										8	0.1739	0.32
STK	1												
CCB	1							4	0.0605	0.33			
RK%DOSE	1												
%DOSE	1												
Hem Dis	1												
Diabetes	1	5	0.1150	0.29	6	0.0962	0.31						
OTT	1												
HTN	1												
OTT>90	1												
DrkPROB	1												
Hepatic	1												
VALVE Pros.	1												
HEPARIN	1												
t-PA	1				1	0.0008	13.66				2	0.0008	3.66

Table 7.4 ICH Constrained Stepwise Models

VARIABLE NAME	DF	Scenario I.			Scenario II.			Scenario III.			Scenario IV.		
		STP	P-value	OR	STP	P-value	OR	STP	P-value	OR	STP	P-value	OR
MassEffect	1												
ED/ME	1	1	0.0037	7.24	1	0.0071	5.64	1	0.0035	7.00	1	0.0069	4.09
NIHSS	1	0	0.0354	1.07	0	0.0644	1.06	0	0.0138	1.07	0	0.0021	1.07
Edema	1												
Age	1	0	0.1312	1.04	0	0.1054	1.04	0	0.0120	1.06	0	0.0434	1.04
GLUcose	1				2	0.0017	1.01				2	0.0669	1.00
CURSMK	1	3	0.1429	0.35				2	0.0649	0.33	4	0.1083	0.50
GLU>300	1	2	0.0543	4.43				3	0.0443	3.97			
CARDIAC	1				4	0.1603	2.09						
AF	1												
ASA	1												
STK SUBTP	3												
CURDrnk<24hrs.	1												
Rank of Wt.	1				5	0.1869	1.00	5	0.0502	1.00			
T-DOSE	1												
Weight (kg)	1												
RACE	2							6	0.0683	**	3	0.0887	**
Sex	1												
MALignancy	1										5	0.1739	0.32
STK	1												
CCB	1							4	0.0605	0.33			
RK%DOSE	1												
%DOSE	1												
HEMatologicD	1												
Diabetes	1				3	0.0802	0.30						
OTT (mins.)	1												
HTN	1												
OTT>90	1												
DrnkPROB	1												
Hepatic	1												
VALVE Pros.	1												
HEPARIN	1												
rt-PA	1				0	0.0007	14.73				0	0.0008	3.66

Table 7.5 ICH Risk Factor Groups and Outcomes

			UnFav	Fav	%Fav	DIFF%	RATIO%	ODDS RATIO
No ICH Risk Factor n = 238	B P t-PA		62	62	50.0%			
			35	79	69.3%	19.3%	1.39	2.26
	R P t-PA		79	45	36.3%			
			50	64	56.1%	19.9%	1.55	2.25
	G P t-PA		74	50	40.3%			
			50	64	56.1%	15.8%	1.39	1.89
	N P t-PA		88	36	29.0%			
			69	45	39.5%	10.4%	1.36	1.59
One ICH Risk Factor n = 278	B P t-PA		86	48	35.8%			
			68	76	52.8%	17.0%	1.47	2.00
	R P t-PA		101	33	24.6%			
			78	66	45.8%	21.2%	1.86	2.59
	G P t-PA		95	39	29.1%			
			72	72	50.0%	20.9%	1.72	2.44
	N P t-PA		110	24	17.9%			
			88	56	38.9%	21.0%	2.17	2.92
> One ICH Risk Factor n = 106	B P t-PA		45	9	16.7%			
			45	7	13.5%	-3.2%	0.81	0.78
	R P t-PA		49	5	9.3%			
			49	3	5.8%	-3.5%	0.62	0.60
	G P t-PA		46	8	14.8%			
			47	5	9.6%	-5.2%	0.65	0.61
	N P t-PA		50	4	7.4%			
			47	5	9.6%	2.2%	1.30	1.33

Table 7.6 ICH Risk Factor Groups and t-PA Effect

Global Tests	no risk factors	one risk factor	>one risk factor	Wald P-Value					
P	1.000	1.260	1.267	0.4137					
t-PA	2.130	2.684	2.699						
t-PA/P	2.130	2.130	2.130						
P	1.000	1.044	1.452						
t-PA	1.853	2.762	2.029						
t-PA/P	1.853	2.646	1.397						
Indices						no risk factors	one risk factor	>one risk factor	Wald P-value
BARTHEL					GLASGOW				
P	1.000	1.294	1.265	0.5742	P	1.000	1.162	1.365	0.2413
t-PA	2.190	2.834	2.770		t-PA	2.140	2.487	2.921	
t-PA/P	2.190	2.190	2.190		t-PA/P	2.140	2.140	2.140	
P	1.000	1.333	1.761		P	1.000	0.931	1.948	
t-PA	2.429	3.010	2.028		t-PA	1.891	2.673	1.562	
t-PA/P	2.410	2.258	1.152		t-PA/P	1.891	2.871	0.802	
RANKIN					NIHSS				
P	1.000	0.910	0.619	0.2815	P	1.000	1.495	1.878	0.1795
t-PA	2.410	2.193	1.492		t-PA	2.220	3.319	4.169	
t-PA/P	2.410	2.410	2.410		t-PA/P	2.220	2.220	2.220	
P	1.000	0.763	1.016		P	1.000	0.948	1.553	
t-PA	2.223	2.330	0.713		t-PA	1.499	3.245	3.441	
t-PA/P	2.223	3.054	0.702		t-PA/P	1.499	3.423	2.216	

Table 8.1.1 Outcomes by NIHSS Quintiles

NIHSS		Q1:0_5						Q2:6_10						Q3:11_15						Q4:16_20						Q5: >20					
		UnF	Fav	%	D%	RR	OR	UnF	Fav	%	D%	RR	OR	UnF	Fav	%	D%	RR	OR	UnF	Fav	%	D%	RR	OR	UnF	Fav	%	D%	RR	OR
B	P	1	15	93.8%				37	46	55.4%				39	27	40.9%				52	18	25.7%				64	13	16.9%			
	t-PA	7	35	83.3%	10.4%	0.89	0.33	14	53	79.1%	23.7%	1.43	3.05	31	34	52.3%	11.4%	1.28	1.58	47	26	35.6%	9.9%	1.39	1.60	49	14	22.2%	5.3%	1.32	1.41
R	P	3	13	81.3%				45	38	45.8%				51	15	22.7%				56	14	20.0%				74	3	3.9%			
	t-PA	9	33	78.6%	-2.7%	0.97	0.85	21	46	68.7%	22.9%	1.50	2.59	38	27	41.5%	18.8%	1.83	2.42	52	21	28.8%	8.8%	1.44	1.62	57	6	9.5%	5.6%	2.44	2.60
G	P	2	14	87.5%				39	44	53.0%				48	18	27.3%				55	15	21.4%				71	6	7.8%			
	t-PA	8	34	81.0%	-6.5%	0.93	0.61	19	48	71.6%	18.6%	1.35	2.24	35	30	46.2%	18.9%	1.69	2.29	51	22	30.1%	8.7%	1.41	1.58	56	7	11.1%	3.3%	1.43	1.48
N	P	6	10	62.5%				54	29	34.9%				53	13	19.7%				60	10	14.3%				75	2	2.6%			
	t-PA	13	29	69.0%	6.5%	1.10	1.34	32	35	52.2%	17.3%	1.50	2.04	43	22	33.8%	14.1%	1.72	2.09	57	16	21.9%	7.6%	1.53	1.68	59	4	6.3%	3.8%	2.44	2.54

NIHSS		All		
B	P	193	119	312
	t-PA	148	162	310
		622		
R	P	229	83	312
	t-PA	177	133	310
		622		
G	P	215	97	312
	t-PA	169	141	310
		622		
N	P	248	64	312
	t-PA	204	106	310
		622		

Table 8.1.2 Outcomes by Age Quintiles

AGE		Q1:25_54					Q2:55_64					Q3:65_69					Q4:70_74					Q5: 75 +				
		UnF	Fav	%	D%	OR	UnF	Fav	%	D%	OR	UnF	Fav	%	D%	OR	UnF	Fav	%	D%	OR	UnF	Fav	%	D%	OR
B	P	26	33	55.9%			42	30	41.7%			36	15	29.4%			37	19	33.9%			52	22	29.7%		
	t-PA	13	34	72.3%	16.4%	2.06	20	37	64.9%	23.2%	2.59	23	26	53.1%	23.6%	2.71	34	31	47.7%	13.8%	1.78	58	34	37.0%	7.2%	1.39
R	P	43	16	27.1%			52	20	27.8%			37	14	27.5%			42	14	25.0%			55	19	25.7%		
	t-PA	18	29	61.7%	34.6%	4.33	28	29	50.9%	23.1%	2.69	30	19	38.8%	11.3%	1.67	36	29	44.6%	19.6%	2.42	65	27	29.3%	3.7%	1.20
G	P	39	20	33.9%			48	24	33.3%			38	13	25.5%			39	17	30.4%			51	23	31.1%		
	t-PA	16	31	66.0%	32.1%	3.78	29	28	49.1%	15.8%	1.93	29	20	40.8%	15.3%	2.02	34	31	47.7%	17.3%	2.09	61	31	33.7%	2.6%	1.13
N	P	40	19	32.2%			58	14	19.4%			42	9	17.6%			45	11	19.6%			63	11	14.9%		
	t-PA	25	22	46.8%	14.6%	1.85	38	19	33.3%	13.9%	2.07	34	15	30.6%	13.0%	2.06	41	24	36.9%	17.3%	2.39	66	26	28.3%	13.4%	2.26
	P		59	56%				72	56%				51	51%				56	46%				74	45%		
	t-PA		47					57					49					65					92			
	tot		106					129					100					121					166			

AGE		all		
B	P	193	119	312
	t-PA	148	162	310
				622
R	P	229	83	312
	t-PA	177	133	310
				622
G	P	215	97	312
	t-PA	169	141	310
				622
N	P	248	64	312
	t-PA	204	106	310
				622
	P		312	
	t-PA		310	
	tot		622	

Table 8.1.3 Models with BsNIHSS vs. with BsNIHSS(5)

Variable	BARTHEL													RANKIN												
	NIHSS Continuous						NIHSS QUINTILES						NIHSS Continuous						NIHSS QUINTILES							
	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P
OTT(>90)	1	-0.1473	0.1942	-0.1122	0.1975	0.57	1	-0.1706	0.1963	0.38	-0.1270	0.1997	0.52	1	-0.1414	0.2014	-0.1149	0.2057	0.58	1	-0.1506	0.2043	0.46	0.1281	0.2086	0.54
PART(>1)	1	-0.1677	0.1965	-0.1726	0.1995	0.39	1	-0.1835	0.1981	0.35	-0.1893	0.2009	0.35	1	-0.2873	0.2035	-0.3049	0.2079	0.14	1	-0.2858	0.2058	0.17	0.3033	0.2097	0.15
CENTER	7	*	*	*	*	0.06	7	*	*	0.08	*	*	0.08	7	*	*	*	*	0.27	7	*	*	0.35	*	*	0.30
BsNIHSS	1	0.0653	0.0853	0.1033	0.0861	0.23	4	*	*	0.35	*	*	0.28	1	0.1901	0.0885	0.1996	0.0904	0.03	4	*	*	0.05	*	*	0.05
Age	1	0.0086	0.0198	0.0056	0.0201	0.78	1	-0.0746	0.0218	<.01	-0.0837	0.0228	<.01	1	0.0470	0.0192	0.0451	0.0197	0.02	1	-0.0371	0.0202	0.07	0.0428	0.0209	0.04
PrDISABILITY	1	-1.6949	0.4995	-1.8154	0.5169	<.01	1	-1.8505	0.5256	<.01	-1.9523	0.5414	<.01	1	-1.4186	0.5380	-1.5653	0.5546	<.01	1	-1.4945	0.5499	<.01	1.6500	0.5676	<.01
PrDM	1	-0.6615	0.2400	-0.6587	0.2425	<.01	1	-0.6729	0.2465	<.01	-0.6637	0.2477	<.01	1	-0.3371	0.2516	-0.3151	0.2557	0.22	1	-0.3535	0.2562	0.17	0.3091	0.2601	0.23
Age*BsNIHSS	1	-0.0039	0.0013	-0.0040	0.0013	<.01	4	*	*	0.02	*	*	0.01	1	-0.0058	0.0014	-0.0059	0.0014	<.01	4	*	*	<.01	*	*	<.01
t-PA	1	~	~	0.7837	0.1990	<.01		~	~	~	0.7825	0.2035	<.01	1	~	~	0.8869	0.2060	<.01		~	~	~	0.8988	0.2108	<.01
OR Estimate	2.1896						2.1869						2.4276						2.4567							

Variable	GLASGOW													NIHSS												
	NIHSS Continuous						NIHSS QUINTILES						NIHSS Continuous						NIHSS QUINTILES							
	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P
OTT(>90)	1	-0.1298	0.1978	-0.1066	0.2010	0.60	1	-0.1478	0.2006	0.46	-0.1188	0.2037	0.56	1	-0.1155	0.2087	-0.1033	0.2123	0.63	1	-0.1169	0.2101	0.58	-0.1102	0.2133	0.61
PART(>1)	1	-0.0097	0.1997	-0.0200	0.2025	0.92	1	-0.0089	0.2018	0.96	-0.0195	0.2043	0.92	1	-0.2688	0.2107	-0.2818	0.2144	0.19	1	-0.2433	0.2113	0.25	-0.2590	0.2147	0.23
CENTER	7	*	*	*	*	0.53	7	*	*	0.65	*	*	0.57	7	*	*	*	*	0.32	7	*	*	0.37	*	*	0.32
BsNIHSS	1	0.1613	0.0870	0.1704	0.0884	0.05	4	*	*	0.05	*	*	0.04	1	0.1488	0.0913	0.1510	0.0926	0.10	4	*	*	0.41	*	*	0.37
Age	1	0.0434	0.0193	0.0419	0.0197	0.03	1	-0.0231	0.0192	0.23	-0.0275	0.0197	0.16	1	0.0328	0.0190	0.0297	0.0194	0.13	1	-0.0188	0.0207	0.36	-0.0218	0.0211	0.30
PrDISABILITY	1	-1.5589	0.5354	-1.6807	0.5493	<.01	1	-1.6862	0.5572	<.01	-1.8106	0.5718	<.01	1	-1.5371	0.6477	-1.6557	0.6596	0.01	1	-1.5961	0.6553	0.01	-1.7110	0.6681	0.01
PrDM	1	-0.4707	0.2483	-0.4594	0.2509	0.07	1	-0.4648	0.2530	0.07	-0.4395	0.2550	0.09	1	-0.7709	0.2787	-0.7599	0.2830	<.01	1	-0.7904	0.2814	<.01	-0.7587	0.2851	<.01
Age*BsNIHSS	1	-0.0053	0.0014	-0.0054	0.0014	<.01	4	*	*	<.01	*	*	<.01	1	-0.0050	0.0015	-0.0049	0.0015	<.01	4	*	*	0.02	*	*	0.02
t-PA	1	~	~	0.7557	0.2012	<.01		~	~	~	0.7540	0.2052	<.01	1	~	~	0.7845	0.2124	<.01		~	~	~	0.7791	0.2151	<.01
OR Estimate	2.1291						2.1255						2.1913						2.1795							

Table 8.1.4 Quintiles of Age times BsNIHSS: Outcomes

Barthel	AGE times BsNIHSS QUINTILES										Total		622
	63-511.9		512-793.9		794-1085.9		1086-1477.9		1478-2575		UnF	F	
	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	
Placebo	0.265	0.735	0.443	0.557	0.657	0.343	0.758	0.242	0.917	0.083			
t-PA	0.132	0.868	0.315	0.685	0.509	0.491	0.638	0.362	0.846	0.154			
Total	23	102	48	76	73	51	87	37	110	15	341	281	622
Odds F		4.43		1.58		0.70		0.43		0.14		0.82	
t-PA to Pla OR		2.38		1.73		1.85		1.77		2.00			

Rankin	AGE times BsNIHSS QUINTILES										Total		622
	63-511.9		512-793.9		794-1085.9		1086-1477.9		1478-2575		UnF	F	
	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	
Placebo	0.429	0.571	0.571	0.429	0.761	0.239	0.894	0.106	0.967	0.033			
t-PA	0.224	0.776	0.402	0.597	0.561	0.439	0.759	0.241	0.954	0.046			
Total	38	87	62	62	83	41	103	21	120	5	406	216	622
Odds F		2.29		1.00		0.49		0.20		0.04		0.53	
t-PA to Pla OR		2.60		1.98		2.49		2.68		1.41			

Glasgow	AGE times BsNIHSS QUINTILES										Total		622
	63-511.9		512-793.9		794-1085.9		1086-1477.9		1478-2575		UnF	F	
	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	
Placebo	0.367	0.633	0.529	0.471	0.702	0.299	0.849	0.152	0.950	0.050			
t-PA	0.197	0.803	0.370	0.630	0.526	0.474	0.741	0.259	0.939	0.062			
Total	33	92	57	67	77	47	99	25	118	7	341	281	622
Odds F		2.79		1.18		0.61		0.25		0.06		0.82	
t-PA to Pla OR		2.36		1.91		2.12		1.95		1.25			

NIHSS	AGE times BsNIHSS QUINTILES										Total		622
	63-511.9		512-793.9		794-1085.9		1086-1477.9		1478-2575		UnF	F	
	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	UnF	F	
Placebo	0.531	0.469	0.657	0.343	0.836	0.164	0.909	0.091	1.000	0.000			
t-PA	0.354	0.645	0.574	0.426	0.667	0.333	0.776	0.224	0.969	0.031			
Total	53	72	77	47	94	30	105	19	123	2	452	170	622
Odds F		1.36		0.61		0.32		0.18		0.02		0.38	
t-PA to Pla OR		2.06		1.42		2.54		2.89		NE*			

*NE=Not estimable

Table 8.1.5 Barthel NIHSS Models

BARTHEL																								
Variable	NIHSS Continuous						NIHSS QUINTILES						AGE times NIHSS Quintiles											
	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P	DF	Estimate	Std. Error	p	Estimate	Std. Error	p	Estimate	Std. Error	p	
OTT(>90)	1	-0.1473	0.1942	-0.1122	0.1975	0.57	1	-0.1779	0.1965	0.37	-0.1270	0.1997	0.52	1	-0.1610	0.1947	0.41	-0.1204	0.1972	0.54	-0.1268	0.1982	0.52	
PART(>1)	1	-0.1677	0.1965	-0.1726	0.1995	0.39	1	-0.1791	0.1982	0.37	-0.1893	0.2009	0.35	1	-0.2233	0.1969	0.26	-0.2359	0.1991	0.24	-0.2344	0.1993	0.24	
CENTER	7	*	*	*	*	0.06	7	*	*	0.06	*	*	0.08	7	*	*	0.05	*	*	0.04	*	*	0.05	
BsNIHSS	1	0.0653	0.0853	0.1033	0.0861	0.23	4	*	*	0.08	*	*	0.28	~	~	~	~	~	~	~	~	~	~	
Age	1	0.0086	0.0198	0.0056	0.0201	0.78	1	-0.0735	0.0219	<.01	-0.0837	0.0228	<.01	~	~	~	~	~	~	~	~	~	~	
PrDISAB	1	-1.6949	0.4995	-1.8154	0.5169	<.01	1	-1.8556	0.5253	<.01	-1.9523	0.5414	<.01	1	-1.7277	0.5073	<.01	-1.8239	0.5250	<.01	-1.8556	0.5336	<.01	
PrDM	1	-0.6615	0.2400	-0.6587	0.2425	<.01	1	-0.6678	0.2469	<.01	-0.6637	0.2477	<.01	1	-0.6968	0.2418	<.01	-0.7033	0.2433	<.01	-0.6976	0.2438	<.01	
Age*BNIHSS	1	-0.0039	0.0013	-0.0040	0.0013	<.01	4	*	*	0.03	*	*	0.01	~	~	~	~	~	~	~	~	~	~	
Age*BNIHSS1	4	~	~	~	~	~	~	~	~	~	~	~	~	4	*	*	<.01	*	*	<.01	*	*	<.01	
t-PA	1	~	~	0.7837	0.1990	<.01	~	~	~	~	0.7825	0.2035	<.01	1	~	~	~	0.6928	0.1971	<.01	0.6233	0.3861	0.11	
t-PA by (age*NIHSS) Interaction	4	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	0.99	
OR Estimate	2.1896						2.1869						1.9993						1.8651					

1, The product age times NIHSS into quintiles

* multiple df variable, no estimates or SEs presented

~ variable not in the model

Table 8.1.6 Rankin and NIHSS Models

Variable	RANKIN																							
	NIHSS Continuous						NIHSS QUINTILES						AGE times NIHSS Quintiles											
	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P	DF	Estimate	Std. Error	p	Estimate	Std. Error	p	Estimate	Std. Error	p	
OTT(>90)	1	-0.1414	0.2014	-0.1149	0.2057	0.58	1	-0.1538	0.2044	0.45	-0.1281	0.2086	0.54	1	-0.1062	0.2009	0.60	-0.0738	0.2051	0.72	-0.0756	0.2065	0.71	
PART(>1)	1	-0.2873	0.2035	-0.3049	0.2079	0.14	1	-0.2801	0.2059	0.17	-0.3033	0.2097	0.15	1	-0.2820	0.2027	0.16	-0.3075	0.2069	0.14	-0.3052	0.2072	0.14	
CENTER	7	*	*	*	*	0.27	7	*	*	0.35	*	*	0.30	7	*	*	0.23	*	*	0.22	*	*	0.23	
BsNIHSS	1	0.1901	0.0885	0.1996	0.0904	0.03	4	*	*	0.06	*	*	0.05	~	~	~	~	~	~	~	~	~	~	
Age	1	0.0470	0.0192	0.0451	0.0197	0.02	1	-0.0360	0.0206	0.08	-0.0428	0.0209	0.04	~	~	~	~	~	~	~	~	~	~	
PrDISAB	1	-1.4186	0.5380	-1.5653	0.5546	<.01	1	-1.4988	0.5497	<.01	-1.6500	0.5676	<.01	1	-1.3837	0.5347	0.01	-1.5248	0.5534	0.01	-1.5334	0.5566	0.01	
PrDM	1	-0.3371	0.2516	-0.3151	0.2557	0.22	1	-0.3457	0.2568	0.18	-0.3091	0.2601	0.23	1	-0.3559	0.2475	0.15	-0.3486	0.2513	0.17	-0.3426	0.2520	0.17	
AGE*BNIHSS	1	-0.0058	0.0014	-0.0059	0.0014	<.01	4	*	*	<.01	*	*	<.01	~	~	~	~	~	~	~	~	~	~	
Age*BNIHSS ¹	1	~	~	~	~	~	~	~	~	~	~	~	~	4	*	*	<.01	*	*	<.01	*	*	<.01	
t-PA	1	~	~	0.8869	0.2060	<.01	1	~	~	~	0.8988	0.2108	<.01	1	~	~	~	0.8929	0.2053	<.01	0.9173	0.4027	0.03	
t-PA by (age*NIHSS) Interaction	4	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	*	*	0.98	
OR Estimate				2.4276							2.4567							2.4422			2.5025			

¹, The product age times NIHSS into quintiles

* multiple df variable, no estimates or SEs presented

~ variable not in the model

Table 8.1.7 Glasgow Age and NIHSS Models

GLASGOW																							
NIHSS Continuous							NIHSS QUINTILES						AGE times NIHSS Quintiles										
Variable	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P	DF	Estimate	Std. Error	p	Estimate	Std. Error	p	Estimate	Std. Error	p
OTT(>90)	1	-0.1298	0.1978	-0.1066	0.2010	0.60	1	-0.1478	0.2006	0.46	-0.1188	0.2037	0.56	1	-0.0946	0.1970	0.63	-0.0663	0.2000	0.74	-0.0740	0.2016	0.71
PART(>1)	1	-0.0097	0.1997	-0.0200	0.2025	0.92	1	-0.0089	0.2018	0.96	-0.0195	0.2043	0.92	1	-0.0010	0.1984	0.99	-0.0158	0.2011	0.94	-0.0132	0.2016	0.95
CENTER	7	*	*	*	*	0.53	7	*	*	0.65	*	*	0.57	7	*	*	0.59	*	*	0.53	*	*	0.54
BsNIHSS	1	0.1613	0.0870	0.1704	0.0884	0.05	4	*	*	0.05	*	*	0.04	~	~	~	~	~	~	~	~	~	~
Age	1	0.0434	0.0193	0.0419	0.0197	0.03	1	-0.0231	0.0192	0.23	-0.0275	0.0197	0.16	~	~	~	~	~	~	~	~	~	~
PrDISAB	1	-1.5589	0.5354	-1.6807	0.5493	<.01	1	-1.6862	0.5572	<.01	-1.8106	0.5718	<.01	1	-1.5245	0.5318	0.01	-1.6322	0.5468	0.01	-1.6672	0.5523	<.01
PrDM	1	-0.4707	0.2483	-0.4594	0.2509	0.07	1	-0.4648	0.2530	0.07	-0.4395	0.2550	0.09	1	-0.4882	0.2435	0.05	-0.4876	0.2457	0.05	-0.4802	0.2469	0.05
Age*BsNIHSS	1	-0.0053	0.0014	-0.0054	0.0014	<.01	4	*	*	<.01	*	*	<.01	~	~	~	~	~	~	~	~	~	~
Age*BsNIHSS ¹	1	~	~	~	~	~	~	~	~	~	~	~	~	4	*	*	<.01	*	*	<.01	*	*	<.01
t-PA	1	~	~	0.7557	0.2012	<.01	1	~	~	~	0.7540	0.2052	<.01	1	~	~	~	0.7335	0.1999	<.01	0.7795	0.3871	0.04
t-PA by (age*NIHSS) Interaction	4	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	*	*	0.94
OR Estimate				2.1291							2.1255							2.0824			2.1804		

1, The product age times NIHSS into quintiles

* multiple df variable, no estimates or SEs presented

~ variable not in the model

Table 8.1.8 NIHSS Age by NIHSS Models

NIHSS																							
Variable	NIHSS Continuous						NIHSS QUINTILES						AGE times NIHSS Quintiles										
	DF	Estimate	Std. Error	Estimate	Std. Error	P	DF	Estimate	Std. Error	P	Estimate	Std. Error	P	DF	Estimate	Std. Error	p	Estimate	Std. Error	p	Estimate	Std. Error	p
OTT(>90)	1	-0.1155	0.2087	-0.1033	0.2123	0.63	1	-0.1169	0.2101	0.58	-0.1102	0.2133	0.61	1	-0.0966	0.2086	0.64	-0.0840	0.2121	0.69	-0.0646	0.2134	0.76
PART(>1)	1	-0.2688	0.2107	-0.2818	0.2144	0.19	1	-0.2433	0.2113	0.25	-0.2590	0.2147	0.23	1	-0.2683	0.2100	0.20	-0.2904	0.2135	0.17	-0.2856	0.2134	0.18
CENTER	7	*	*	*	*	0.32	7	*	*	0.37	*	*	0.32	7	*	*	0.29	*	*	0.26	*	*	0.29
BsNIHSS	1	0.1488	0.0913	0.1510	0.0926	0.10	4	*	*	0.41	*	*	0.37	~	~	~	~	~	~	~	~	~	~
Age	1	0.0328	0.0190	0.0297	0.0194	0.13	1	-0.0188	0.0207	0.36	-0.0218	0.0211	0.30	~	~	~	~	~	~	~	~	~	~
PrDISAB	1	-1.5371	0.6477	-1.6557	0.6596	0.01	1	-1.5961	0.6553	0.01	-1.7110	0.6681	0.01	1	-1.4869	0.6456	0.02	-1.6003	0.6594	0.02	-1.5722	0.6615	0.02
PrDM	1	-0.7709	0.2787	-0.7599	0.2830	<.01	1	-0.7904	0.2814	<.01	-0.7587	0.2851	<.01	1	-0.7745	0.2740	<.01	-0.7732	0.2776	0.01	-0.7810	0.2766	<.01
Age*BNIHSS	1	-0.0050	0.0015	-0.0049	0.0015	<.01	4	*	*	0.02	*	*	0.02	~	~	~	~	~	~	~	~	~	~
Age*BNIHSS ¹	1	~	~	~	~	~	~	~	~	~	~	~	~	4	*	*	<.01	*	*	<.01	*	*	<.01
t-PA	1	~	~	0.7845	0.2124	<.01	1	~	~	~	0.7791	0.2151	<.01	1	~	~	~	0.7913	0.2115	<.01	0.9465	0.4464	0.03
t-PA by (age*NIHSS) Interaction	4	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	~	*	*	0.91
OR Estimate				2.1913							2.1795							2.2063			2.5767		

1, The product age times NIHSS into quintiles

* multiple df variable, no estimates or SEs presented

~ variable not in the model

Table 8.2.1 Outcomes by OTT

Barthel	OTT 0 - 90			OTT 91 - 133			OTT 134 - 154			OTT 155 - 173			OTT 174 - 180			OTT 91 - 154			OTT 155 - 180			OTT 91 - 180		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	tot	UNF	F	tot	UNF	F	tot
Placebo	90	55	145	37	13	50	23	16	39	23	16	39	20	19	39	60	29	89	43	35	78	103	64	167
t-PA	74	83	157	12	19	31	20	20	40	24	18	42	18	22	40	32	39	71	42	40	82	74	79	153
tot	164	138	302	49	32	81	43	36	79	47	34	81	38	41	79	92	68	160	85	75	160	177	143	320
PL odds F		0.61			0.35			0.70			0.70			0.95		0.48		0.81			0.62			
OR		1.84			4.51			1.44			1.08			1.29		2.52		1.17			1.72			

Rankin	OTT 0 - 90			OTT 91 - 133			OTT 134 - 154			OTT 155 - 173			OTT 174 - 180			OTT 91 - 154			OTT 155 - 180			OTT 91 - 180		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	tot	UNF	F	tot	UNF	F	tot
Placebo	104	41	145	44	6	50	28	11	39	26	13	39	27	12	39	72	17	89	53	25	78	125	42	167
t-PA	94	63	157	15	16	31	20	20	40	26	16	42	22	18	40	35	36	71	48	34	82	83	70	153
tot	198	104	302	59	22	81	48	31	79	52	29	81	49	30	79	107	53	160	101	59	160	208	112	320
PL odds F		0.39			0.14			0.39			0.50			0.44		0.24		0.47			0.34			
OR		1.70			7.82			2.55			1.23			1.84		4.36		1.50			2.51			

Glasgow	OTT 0 - 90			OTT 91 - 133			OTT 134 - 154			OTT 155 - 173			OTT 174 - 180			OTT 91 - 154			OTT 155 - 180			OTT 91 - 180		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	tot	UNF	F	tot	UNF	F	tot
Placebo	98	47	145	41	9	50	27	12	39	26	13	39	23	16	39	68	21	89	49	29	78	117	50	167
t-PA	89	68	157	14	17	31	22	18	40	22	20	42	22	18	40	36	35	71	44	38	82	80	73	153
tot	187	115	302	55	26	81	49	30	79	48	33	81	45	34	79	104	56	160	93	67	160	197	123	320
PL odds F		0.48			0.22			0.44			0.50			0.70		0.31		0.59			0.43			
OR		1.59			5.53			1.84			1.82			1.18		3.15		1.46			2.14			

NIHSS	OTT 0 - 90			OTT 91 - 133			OTT 134 - 154			OTT 155 - 173			OTT 174 - 180			OTT 91 - 154			OTT 155 - 180			OTT 91 - 180		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	tot	UNF	F	tot	UNF	F	tot
Placebo	116	29	145	43	7	50	29	10	39	31	8	39	29	10	39	72	17	89	60	18	78	132	35	167
t-PA	104	53	157	16	15	31	29	11	40	29	13	42	26	14	40	45	26	71	55	27	82	100	53	153
tot	220	82	302	59	22	81	58	21	79	60	21	81	55	24	79	117	43	160	115	45	160	232	88	320
PL odds F		0.25			0.16			0.34			0.26			0.34		0.24		0.30			0.27			
OR		2.04			5.76			1.10			1.74			1.56		2.45		1.64			2.00			

Table 8.3.1 Barthel and Rankin Outcomes by Center

Center #	BARTHEL								RANKIN								
	UnF	Fav		Observed					UnF	Fav		Observed					
				odds F	%F	delta %F & SE	delta 95% CI	OR				OR 95% CI	odds F	%F	delta %F & SE	delta 95% CI	OR
4 (n=146)	UnF	Fav							UnF	Fav							
	Plac	48	24	72	0.50	33.3%	24.77% 9.1%		53	19	72	0.36	26.4%	22.26% 7.0%			
	t-PA	31	43	74	1.39	58.1%	7.98% 40.4%	2.77	1.42	38	36	74	0.95	48.6%	7.79% 37.5%	2.64	1.33
	79	67	146	0.85	45.9%			5.41	91	55	146	0.60	37.7%				5.26
1 (n=39)	UnF	Fav							UnF	Fav							
	Plac	13	6	19	0.46	31.6%	23.42% -6.8%		16	3	19	0.19	15.8%	19.21% -7.4%			
	t-PA	9	11	20	1.22	55.0%	15.41% 53.6%	2.65	0.74	13	7	20	0.54	35.0%	13.55% 45.8%	2.87	0.67
	22	17	39	0.77	43.6%			9.43	29	10	39	0.34	25.6%				12.35
5 (n=150)	UnF	Fav							UnF	Fav							
	Plac	45	31	76	0.69	40.8%	20.02% 4.3%		59	17	76	0.29	22.4%	23.58% 8.9%			
	t-PA	29	45	74	1.55	60.8%	8.00% 35.7%	2.25	1.18	40	34	74	0.85	45.9%	7.51% 38.3%	2.95	1.46
	74	76	150	1.03	50.7%			4.31	99	51	150	0.52	34.0%				5.94
3 (n=71)	UnF	Fav							UnF	Fav							
	Plac	21	15	36	0.71	41.7%	18.33% -4.5%		23	13	36	0.57	36.1%	23.89% 1.3%			
	t-PA	14	21	35	1.50	60.0%	11.67% 41.2%	2.10	0.83	14	21	35	1.50	60.0%	11.52% 46.5%	2.65	1.03
	35	36	71	1.03	50.7%			5.34	37	34	71	0.92	47.9%				6.82
8 (n=103)	UnF	Fav							UnF	Fav							
	Plac	33	19	52	0.58	36.5%	12.48% -6.5%		39	13	52	0.33	25.0%	14.22% -3.6%			
	t-PA	26	25	51	0.96	49.0%	9.67% 31.4%	1.67	0.77	31	20	51	0.65	39.2%	9.10% 32.1%	1.94	0.84
	59	44	103	0.75	42.7%			3.64	70	33	103	0.47	32.0%				4.44
2 (n=62)	UnF	Fav							UnF	Fav							
	Plac	22	11	33	0.50	33.3%	-5.75% 28.6%		26	7	33	0.27	21.2%	6.37% -15.1%			
	t-PA	21	8	29	0.38	27.6%	11.67% 17.1%	0.76	0.26	21	8	29	0.38	27.6%	10.93% 27.8%	1.41	0.45
	43	19	62	0.44	30.6%			2.21	47	15	62	0.32	24.2%				4.40
6&9 (n=37)	UnF	Fav							UnF	Fav							
	Plac	8	10	18	1.25	55.6%	-18.71% 50.3%		10	8	18	0.80	44.4%	-12.87% -43.9%			
	t-PA	12	7	19	0.58	36.8%	16.11% 12.9%	0.47	0.13	13	6	19	0.46	31.6%	15.84% 18.2%	0.58	0.16
	20	17	37	0.85	45.9%			1.68	23	14	37	0.61	37.8%				2.12
7 (n=14)	UnF	Fav							UnF	Fav							
	Plac	3	3	6	1.00	50.0%	-25.00% 75.0%		3	3	6	1.00	50.0%	-37.50% -83.6%			
	t-PA	6	2	8	0.33	25.0%	25.52% 25.0%	0.33	0.04	7	1	8	0.14	12.5%	23.52% 8.6%	0.14	0.01
	9	5	14	0.56	35.7%			2.67	10	4	14	0.40	28.6%				1.42
Over all centers	UnF	Fav							UnF	Fav							
	Plac	193	119	312	0.62	38.1%			229	83	312	0.36	26.6%				
	t-PA	148	162	310	1.09	52.3%		1.78	1.29	177	133	310	0.75	42.9%		2.07	1.48
		341	281	622	0.82				2.44	406	216	622	0.53				2.90
	unadjusted delta					14.12% 6.4%			unadjusted delta				16.30% 8.9%				
						3.95% 21.9%							3.76% 23.7%				

Table 8.3.2 Glasgow and NIHSS Outcomes by Center

Center #	GLASGOW								NIHSS																	
	UnF Fav			Observed					UnF Fav			Observed														
				odds F	%F	delta %F & SE	delta 95% CI	OR				OR 95% CI	odds F	%F	delta %F & SE	delta 95% CI	OR	OR 95% CI								
4 (n=146)	Plac	54	18	72	0.33	25.0%	27.70%	12.6%	3.34	1.67	UnF	Fav		57	15	72	0.26	20.8%	14.30%	-0.1%	2.06	0.99				
	t-PA	35	39	74	1.11	52.7%	7.73%	42.9%			48	26	74	0.54	35.1%	7.33%	28.7%	105	41	146			0.39	28.1%	6.70	4.29
		89	57	146	0.64	39.0%					105	41	146	0.39	28.1%											
1 (n=39)	Plac	15	4	19	0.27	21.1%	28.95%	0.4%	3.75	0.97	UnF	Fav		17	2	19	0.12	10.5%	14.47%	-9.0%	2.83	0.55				
	t-PA	10	10	20	1.00	50.0%	14.58%	57.5%			15	5	20	0.33	25.0%	11.97%	37.9%	32	7	39			0.22	17.9%	14.66	
		25	14	39	0.56	35.9%					32	7	39	0.22	17.9%											
5 (n=150)	Plac	54	22	76	0.41	28.9%	15.65%	0.4%	1.98	1.01	UnF	Fav		60	16	76	0.27	21.1%	11.38%	-2.7%	1.80	0.87				
	t-PA	41	33	74	0.80	44.6%	7.78%	30.9%			50	24	74	0.48	32.4%	7.18%	25.4%	110	40	150			0.36	26.7%	3.73	
		95	55	150	0.58	36.7%					110	40	150	0.36	26.7%											
3 (n=71)	Plac	19	17	36	0.89	47.2%	15.63%	-7.2%	1.89	0.74	UnF	Fav		27	9	36	0.33	25.0%	29.29%	7.5%	3.56	1.33				
	t-PA	13	22	35	1.69	62.9%	11.66%	38.5%			16	19	35	1.19	54.3%	11.09%	51.0%	43	28	71			0.65	39.4%	9.56	
		32	39	71	1.22	54.9%					43	28	71	0.65	39.4%											
8 (n=103)	Plac	38	14	52	0.37	26.9%	12.29%	-5.7%	1.75	0.77	UnF	Fav		43	9	52	0.21	17.3%	17.99%	1.3%	2.61	1.06				
	t-PA	31	20	51	0.65	39.2%	9.20%	30.3%			33	18	51	0.55	35.3%	8.50%	34.7%	76	27	103			0.36	26.2%	6.43	
		69	34	103	0.49	33.0%					76	27	103	0.36	26.2%											
2 (n=62)	Plac	23	10	33	0.43	30.3%	0.73%	-22.3%	1.04	0.36	UnF	Fav		27	6	33	0.22	18.2%	5.96%	-14.4%	1.43	0.44				
	t-PA	20	9	29	0.45	31.0%	11.74%	23.7%			22	7	29	0.32	24.1%	10.40%	26.3%	49	13	62			0.27	21.0%	4.70	
		43	19	62	0.44	30.6%					49	13	62	0.27	21.0%											
6&9 (n=37)	Plac	9	9	18	1.00	50.0%	-13.16%	-44.8%	0.58	0.16	UnF	Fav		12	6	18	0.50	33.3%	-1.75%	-31.9%	0.92	0.24				
	t-PA	12	7	19	0.58	36.8%	16.17%	18.5%			13	6	19	0.46	31.6%	15.40%	28.4%	25	12	37			0.48	32.4%	3.50	
		21	16	37	0.76	43.2%					25	12	37	0.48	32.4%											
7 (n=14)	Plac	3	3	6	1.00	50.0%	-37.50%	-83.6%	0.14	0.01	UnF	Fav		5	1	6	0.20	16.7%	-4.17%	-41.8%	0.71	0.06				
	t-PA	7	1	8	0.14	12.5%	23.52%	8.6%			7	1	8	0.14	12.5%	19.19%	33.4%	12	2	14			0.17	14.3%	8.85	
		10	4	14	0.40	28.6%					12	2	14	0.17	14.3%											
Over all Centers	Plac	215	97	312	0.45	31.1%			1.85	1.33	UnF	Fav		248	64	312	0.26	20.5%			2.01	1.40				
	t-PA	169	141	310	0.83	45.5%					204	106	310	0.52	34.2%											
		384	238	622	0.62						452	170	622	0.38												
						unadjusted delta	14.39%	6.8%						unadjusted delta		13.68%	6.8%									
							3.86%	22.0%								3.53%	20.6%									

Table 8.4.1 Outcomes by Stroke Subtype

Barthel	small vessel			cardioembolic			large vessel			other			all patients		
	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot
	Placebo	15	15	30	86	51	137	87	48	135	5	5	10	193	119
t-PA	13	38	51	74	62	136	58	57	115	3	5	8	148	162	310
Total	28	53	81	160	113	273	145	105	250	8	10	18	341	281	622
placebo Odds F		1.00			0.59			0.55			1.00			0.62	
OR		2.92			1.41			1.78			1.67			1.78	

Rankin	small vessel			cardioembolic			large vessel			other			all patients		
	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot
	Placebo	18	12	30	99	38	137	105	30	135	7	3	10	229	83
t-PA	19	32	51	85	51	136	68	47	115	5	3	8	177	133	310
Total	37	44	81	184	89	273	173	77	250	12	6	18	406	216	622
placebo Odds F		0.67			0.38			0.29			0.43			0.36	
OR		2.53			1.56			2.42			1.40			2.07	

Glasgow	small vessel			cardioembolic			large vessel			other			all patients		
	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot
	Placebo	17	13	30	95	42	137	97	38	135	6	4	10	215	97
t-PA	19	32	51	83	53	136	62	53	115	5	3	8	169	141	310
Total	36	45	81	178	95	273	159	91	250	11	7	18	384	238	622
placebo Odds F		0.76			0.44			0.39			0.67			0.45	
OR		2.20			1.44			2.18			0.90			1.85	

NIHSS	small vessel			cardioembolic			large vessel			other			all patients		
	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot	UNF	F	Tot
	Placebo	20	10	30	110	27	137	111	24	135	7	3	10	248	64
t-PA	27	24	51	96	40	136	76	39	115	5	3	8	204	106	310
Total	47	34	81	206	67	273	187	63	250	12	6	18	452	170	622
placebo Odds F		0.50			0.25			0.22			0.43			0.26	
OR		1.78			1.70			2.37			1.40			2.01	

Table 8.5.1 Outcomes by Prior Disability

Barthel	no disability			slight*			moderate*			severe*			all disabilities			all patients		
	UNF	F	TOT	unf	f	tot	unf	f	tot	unf	f	tot	UNF	F	TOT	UNF	F	TOT
Placebo	171	117	288	9	1	10	9	1	10	4	0	4	22	2	24	193	119	312
t-PA	130	158	288	9	4	13	7	0	7	2	0	2	18	4	22	148	162	310
			576			23			17			6			46			622
OR		1.78												2.44				1.78

Rankin	no disability			disability									all patients					
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT			
Placebo	207	81	288	9	1	10	9	1	10	4	0	4	22	2	24	229	83	312
t-PA	158	130	288	9	4	13	7	0	7	2	0	2	19	3	22	177	133	310
			576			23			17			6			46			622
OR		2.10												1.74				2.07

Glasgow	no disability			disability									all patients					
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT			
Placebo	193	95	288	9	1	10	9	1	10	4	0	4	22	2	24	215	97	312
t-PA	150	138	288	9	4	13	7	0	7	2	0	2	19	3	22	169	141	310
			576			23			17			6			46			622
OR		1.87												1.74				1.85

NIHSS	no disability			disability									all patients					
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT			
Placebo	225	63	288	10	0	10	9	1	10	4	0	4	23	1	24	248	64	312
t-PA	184	104	288	11	2	13	7	0	7	2	0	2	20	2	22	204	106	310
			576			23			17			6			46			622
OR		2.02												2.30				2.01

* Modified Rankin Score, R = 2:Slight Disability, R = 3:Moderate Disability, R = 4:Severe Disability

Table 8.6.1 Outcomes by Diabetes Status

Barthel	no diabetes			diabetes			all patients		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT
Placebo	153	96	249	40	23	63	193	119	312
t-PA	102	140	242	46	22	68	148	162	310
			491			131			622
OR		2.19			0.83			1.78	

Rankin	no diabetes			diabetes			all patients		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT
Placebo	184	65	249	45	18	63	229	83	312
t-PA	130	112	242	47	21	68	177	133	310
			491			131			622
OR		2.44			1.12			2.07	

Glasgow	no diabetes			diabetes			all patients		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT
Placebo	172	77	249	43	20	63	215	97	312
t-PA	122	120	242	47	21	68	169	141	310
			491			131			622
OR		2.20			0.96			1.85	

NIHSS	no diabetes			diabetes			all patients		
	UNF	F	TOT	UNF	F	TOT	UNF	F	TOT
Placebo	194	55	249	54	9	63	248	64	312
t-PA	151	91	242	53	15	68	204	106	310
			491			131			622
OR		2.13			1.70			2.01	