

## SUPPLEMENTARY DATA

### The Action to Control Cardiovascular Risk in Diabetes (ACCORD) Study Group

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## SUPPLEMENTARY DATA

**Supplementary Table 1.** Baseline Characteristics associated with Weight Gain at from year 2 to year 6. Both Glycemia Arms.

Baseline Characteristic	Regression Estimate	Means	p-value
Age	-0.09		0.001
Gender			0.15
Male		1.14	
Female		0.44	
Race Ethnicity			0.50
White		0.68	
Hispanic		0.02	
Black		1.51	
Asian		1.00	
Other		1.61	
Education			0.71
Less than high school		1.29	
High School Grad		1.01	
Some College		0.84	
College Grad		0.49	
Live Alone			0.31
Yes		0.74	
No		1.34	
Smoking			0.71
Never		0.065	
Past		1.06	
Present		0.95	
Alcohol			0.17
None		0.67	
1 drink per week or more		1.40	
Secondary			0.62
Primary		0.94	
Secondary		0.69	
A1c	-0.09		0.67
A1c_Category			0.93
< 7.5		0.66	
7.5-8.5		0.87	
> 8.5		0.88	
Blood Glucose	0.003		0.53
Duration of Diabetes	-0.009		0.77
BMI	-0.006		0.90
BMI Category			0.56
< 25		1.83	
[25-30)		0.57	
[30 – 35)		0.69	

SUPPLEMENTARY DATA

<b>Baseline Characteristic</b>	<b>Regression Estimate</b>	<b>Means</b>	<b>p-value</b>
[35-40)		1.37	
40+		0.90	
Waist Circumference	0.009		0.63
Systolic Blood Pressure	-0.006		0.69
Diastolic Blood Pressure	0.047		0.04
MDRD-Estimated GFR	0.005		0.34
LDL	0.005		0.47
HDL-Females	0.058		0.04
HDL-Males	-0.039		0.22
Total Cholesterol	0.009		0.16
Triglyceride Category			0.20
< 150		0.62	
150-499		1.04	
≥ 500		4.12	
Insulin			0.10
No		1.14	
Yes		0.31	
TZD			0.44
No		0.95	
Yes		0.49	
Metformin			0.04
No		0.31	
Yes		1.28	
Sulfonylureas			0.02
No		0.57	
Yes		1.12	
Beta Blockers			0.53
No		0.73	
Yes		1.42	
Calcium Channel Blocker			0.69
No		0.76	
Yes		1.17	
Diuretics			0.47
No		0.77	
Yes		2.18	
CCN_Network			0.26

## SUPPLEMENTARY DATA

**Supplementary Table 2.** Regression coefficients (standard errors) of models of change in A1c associated with change in weight; overall and stratified by baseline HbA1c.

Stratified by Baseline A1c	Intensive Group Regression Coefficient (standard error)	Standard Group Regression Coefficient (standard error)
Base A1c < 7.8	1.15 ( 0.22)	0.72 ( 0.15)
Base A1c 7.8-8.5	0.10 ( 0.18)	0.93 ( 0.15)
Base A1c >8.5	-0.19 ( 0.13)	-0.09 ( 0.10)
Overall	-0.48 ( 0.08)	-0.08 ( 0.06)

**Supplementary Table 3.** Model for change in weight by medications – TZDs/Insulin in each arm of the trial

Medication Combination	Model 1: Not Trial Specific		Model 2: Glycemia Trial Included					Test for difference between arms
	Overall		Intensive		Standard			
TZD   Insulin	Frequency	LS Means	Frequency	LS Means	Frequency	LS Means	p-Value	
A: 0-0-0   0-0	1183	-1.9	97	-2.61	1086	-1.74	0.1983	
B: 0-0-0   0-1	198	0.63	80	1.78	118	0.48	0.1536	
C: 0-0-0   1-1	1103	0.17	224	1.31	879	0.05	0.0079	
D: 0-1-0   0-0	283	-2	107	-2.49	176	-1.34	0.1406	
E: 0-1-0   0-1	359	3.78	252	3.94	107	3.51	0.5619	
F: 0-1-0   1-1	446	1.99	286	3.18	160	0.42	<.0001	
G: 0-1-1   0-0	1627	1.37	959	1.5	668	1.39	0.7283	
H: 0-1-1   0-1	1065	4.63	891	4.83	174	3.9	0.0755	
I: 0-1-1   1-1	1161	3.48	798	4.22	363	2.31	<.0001	
J: 1-1-0   0-0	115	-3.27	7	-5.54	108	-2.42	0.2025	
K: 1-1-0   0-1	158	1.25	100	1.84	58	0.08	0.0935	

SUPPLEMENTARY DATA

Medication Combination	Model 1: Not Trial Specific		Model 2: Glycemia Trial Included				Test for difference between arms
	Overall		Intensive		Standard		
	TZD   Insulin	Frequency	LS Means	Frequency	LS Means	Frequency	LS Means
L: 1-1-0   1-1	122	0.06	43	2.8	79	-1.81	0.0001
M: 1-1-1   0-0	543	0.89	178	1.43	365	0.75	0.2321
N: 1-1-1   0-1	504	3.31	382	3.56	122	2.77	0.2267
O: 1-1-1   1-1	390	1.74	206	3.27	184	0.22	<.0001

Note: The 0's and 1's listed indicate if the person was on TZD and or insulin. The first three values indicates if they were on TZD at the beginning of the trial, started TZD during the first two years and if they were on TZD at the end of the two year period, respectively. The two values after the | indicate if the person was taking insulin at the beginning and or end of the two year period, respectively.

## SUPPLEMENTARY DATA

**Supplementary Table 4.** Predictive values for repeated measures for each factor using repeated measures model using weight and Hba1c from quarterly visits to predict the weight gain between during the first year and second years.

TIME PERIOD	Medication Model	Standard R-square	Intensive R-Square
First Year	Baseline meds and HBa1c only	.0291	.1245
	TZD	.0222	.0065
	Metformin	.0069	.000
	Bolus Insulin unit per Kilogram	.0042	.0042
	Basal Insulin unit per Kilogram	.0022	.0068
Total variability explained (Year #1)		0.0646	0.1420
Second Year	TZD	.0413	.0189
	Baseline meds and HbA1c only	.0300	.0481
	Basal Insulin unit per Kilogram	.0121	.0222
	Bolus Insulin unit per Kilogram	.0106	.0264
	Metformin	.0063	.0011
Total Variability Explained (Year #2)		0.1003	0.1167

## SUPPLEMENTARY DATA

**Supplementary Table 5.** Summary of the weight changes on a variety of TZD insulin combinations in the intensive group in the trial.

<b>TZD/Insulin Combination</b>		<b>Began insulin on Trial</b>	<b>Entered Trial on Insulin</b>
<b>TZD Use</b>	<b>Never on Insulin LSMeans (SE) (N = number of patients)</b>	<b>LSMeans (SE)</b>	<b>LSMeans (SE)</b>
A) None at Baseline or on Trial	-2.9 (0.7)( 95)	2.4 (0.8)( 80)	1.4 (0.5)(223)
B) None at Baseline, some during Followup	-2.5 (0.7)(108)	4.6 (0.5)(252)	3.1 (0.4)(287)
C) None at Baseline, Followup & M24	1.7 (0.3)(958)	5.3 (0.3)(891)	4.5 (0.3)(794)
D) Used at Baseline, Removed during Trial	-4.6 (2.6)( 7)	2.1 (0.7)(100)	2.9 (1.0)( 42)
E) Used at Baseline, Followup & M24	1.5 (0.5)(178)	3.8 (0.4)(382)	3.2 (0.5)(205)