

# Supplementary Appendix

This appendix has been provided by the authors to provide additional information about their research.

This appendix is an on-line supplement to:

Health Status after Treatment for Coronary Artery Disease and Type 2 Diabetes in the BARI 2D Trial

by

Maria Mori Brooks PhD, Sheng-Chia Chung PhD, Tarek Helmy MD, William B. Hillegass MD, Jorge Escobedo MD,  
Kathryn A. Melsop MS, Elaine M. Massaro MS, Robert D. McBane MD, Pamela Hyde RN, Mark A. Hlatky MD  
and the BARI 2D Study Group

Table S1. Comparison of baseline characteristics for patients with and without follow up quality of life data

	Patients with at least one quality of life follow up data n=2163	Patients without any quality of life follow up data n=205	p
Prompt revascularization (%)	49.0	57.1	0.026
Insulin sensitizing (%)	49.9	50.2	0.93
CABG stratum (%)	32.4	30.2	0.53
Age (Mean)	62.3	63.7	0.039
Male (%)	70.6	67.3	0.32
Current Smoking (%)	12.2	16.0	0.12
BMI (Mean)	31.8	31.4	0.45
Prior MI	31.6	36.7	0.14
History of Heart Failure (%)	6.2	11.6	0.0036
Angina (%)			
None/Angina Equivalent	39.7	35.6	0.0021
Stable CCS I or II	43.0	37.1	
Stable CCS III or IV	17.3	27.2	
Duration of Diabetes (Mean)	10.3	11.6	0.089
Insulin Use (%)	27.6	31.3	0.25
DASI (Mean)	19.1	17.3	0.081
Energy (Mean)	51.9	44.9	<0.001
Health Distress (Mean)	40.3	42.4	0.29
Self-Rated Health (Mean)	38.9	35.5	0.050

Tables S2: Missing data among the 2,163 patients with at least one follow-up health status measure.

Cumulative Number of Deaths and Study Withdrawal among 2163 patients

	Death	Study Withdrawal
Year 2	36	13
Year 3	83	36
Year 4	129	47

Missing Data among Patients who were Alive and Participating in BARI 2D

	# of patients in the study	DASI		Energy		Health Distress		Self Rated Health	
		# Missing	%	# Missing	%	# Missing	%	# Missing	%
Baseline	2,163	6	0.28	6	0.28	7	0.32	6	0.28
Year 1	2,163	29	1.34	32	1.48	33	1.53	30	1.39
Year 2	2,114	88	4.16	89	4.21	89	4.21	88	4.16
Year 3	2,044	106	5.19	109	5.33	109	5.33	107	5.23
Year 4	1,820*	129	7.09	130	7.14	130	7.14	130	7.14

\* N=167 patients administratively censored due to study completion

Missing Data Pattern for Each Health Status Variable Accounting for Four Years of Follow-up

	DASI		Energy		Health Distress		Self Rated Health	
	Frequency	Percent	Frequency	Percent	Frequency	Percent	Frequency	Percent
Noncompliance	79	3.7	80	3.7	80	3.7	73	3.4
Dropout	305	14.1	306	14.2	306	14.2	306	14.2
Completers	1779	82.3	1777	82.2	1777	82.2	1784	82.5

Table S3: Estimated randomized treatment effect on health status for patients with at least one follow-up health status measure\*

	DASI		Energy		Health Distress		Self Rated Health		CES-D at year 3 (n=1647)	
	Estimate	P	Estimate	P	Estimate	P	Estimate	P	Estimate	P
<b>Revascularization vs Medical (n=2163)</b>	1.32	0.001	1.36	0.021	-0.47	0.49	1.77	0.007	0.41	0.40
<b>By intended method of revascularization</b>		0.003		0.29		0.18		0.42		0.47
<b>CABG Stratum: Rev vs Med (n=701)</b>	2.73	<0.001	1.95	0.069	-1.37	0.23	2.21	0.060	0.063	0.94
<b>PCI Stratum: Rev vs Med (n=1462)</b>	0.53	0.28	0.96	0.18	0.19	0.82	1.38	0.079	0.67	0.26
<b>Insulin Sensitization vs Insulin Provision (n=2163)</b>	0.55	0.17	-0.40	0.49	-0.48	0.47	0.87	0.18	0.064	0.90

\* Linear mixed models were used to analyze follow up health status scores as the outcome; the randomized treatment parameter was estimated controlling for baseline health status score, baseline angina status, missing data pattern, clinical sites as a random effect. Linear regression models were used to analyze a single follow-up CES-D score per patient by randomized treatment group.

Table S4. Multivariable regression models for health status scores during BARI 2D follow-up adjusting for follow-up angina status.

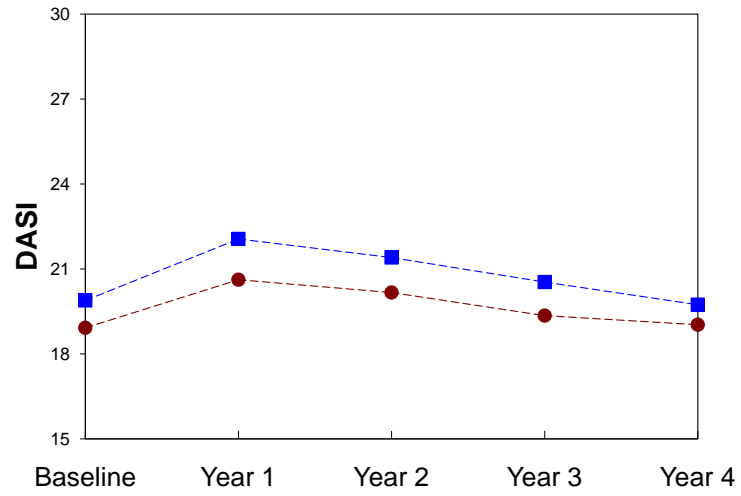
Baseline variables	DASI (0-58.2)		Energy (0-100)		Health Distress (0-100)		Self-Rated Health (0-100)	
	Estimate	p	Estimate	p	Estimate	p	Estimate	p
<b>Randomization</b>								
Revascularization versus Medical in CABG stratum	2.43	<0.001	0.99	0.083	-0.17	0.79	1.47	0.020
Revascularization versus Medical in PCI stratum	0.49	0.29						
Insulin sensitization versus Insulin provision	0.48	0.21	-0.39	0.49	-0.46	0.48	0.92	0.14
<b>Covariates</b>								
Baseline health status score	0.52	<0.001	0.43	<0.001	0.41	<0.001	0.39	<0.001
Follow up years in CABG stratum	-0.083	0.60	-0.28	0.040	-0.76	0.011	-0.26	0.098
Follow up years in PCI stratum	-0.97	<0.001			0.16	0.43		
CABG stratum	-2.42	0.001	1.44	0.033	0.018	0.99	2.94	<0.001
Baseline angina status (reference: no angina)								
Stable CCS1/CCS2	-0.21	0.62	-2.30	<0.001	1.31	0.078	-1.87	0.0094
Stable CCS3/4 or unstable	-0.39	0.52	-1.43	0.11	1.17	0.25	-1.10	0.26
Follow up angina status (reference: no angina)								
Stable CCS1/CCS2	-2.08	<0.001	-2.69	<0.001	2.47	<0.001	-3.44	<0.001
Stable CCS3/4 or unstable	-2.47	<0.001	-5.31	<0.001	5.40	<0.001	-5.46	<0.001
Insulin use at entry	-1.72	<0.001	-2.25	0.0023	1.90	0.025	-2.03	0.013
Duration of diabetes	-0.082	0.0015	-0.11	0.0037	0.14	0.0023	-0.15	<0.001
Age	-0.20	<0.001	-0.11	0.0030	-0.070	0.096	-0.035	0.38
Male sex	2.41	<0.001	2.40	<0.001	-2.19	0.0050	1.71	0.023
Body mass index	-0.17	<0.001	-0.17	0.0011	0.19	0.0021	-0.27	<0.001
Current smoking	-2.96	<0.001	-5.36	<0.001	5.26	<0.001	-6.97	<0.001
History of myocardial infarction	0.022	0.96	-1.55	0.015	1.02	0.16	-1.27	0.071
History of heart failure	-1.97	0.018	-2.82	0.024	4.13	0.0038	-3.62	0.0085
Neuropathy	-1.37	<0.001	-1.43	0.021	1.31	0.062	-1.52	0.026
Missing status (reference: completers)								
Noncompliance	-2.06	0.055	-2.19	0.17	3.14	0.088	-3.62	0.050
Dropout	-2.46	<0.001	-2.97	0.0015	3.97	<0.001	-4.35	<0.001

Table S5: Estimated randomized treatment effect on health status for entire randomized trial based on imputation of outcome

	<b>DASI</b>		<b>Energy</b>		<b>Health Distress</b>		<b>Self-rated Health</b>	
	Estimate	P	Estimate	P	Estimate	P	Estimate	P
<b>Revascularization vs Medical (n=2368)</b>	1.25	0.002	1.34	0.037	-0.18	0.78	1.82	0.013
<b>By intended method of revascularization</b>		0.010		0.23		0.24		0.53
<b>CABG Stratum: Rev vs Med (n=763)</b>	2.59	<0.001	2.08	0.042	-1.12	0.29	2.31	0.062
<b>PCI Stratum: Rev vs Med (n=1605)</b>	0.57	0.22	0.93	0.22	0.34	0.67	1.51	0.1
<b>Insulin Sensitization vs Insulin Provision (n=2368)</b>	-0.67	0.1	0.42	0.55	0.48	0.48	-0.9	0.16

\* Linear mixed models with follow up health status as the outcome; randomized treatment parameter was estimated controlling for baseline health status score, baseline angina status, clinical sites as a random effect. Missing health status outcome data were imputed for every randomized patient in BARI 2D using multiple imputation methods.

PCI stratum



CABG stratum

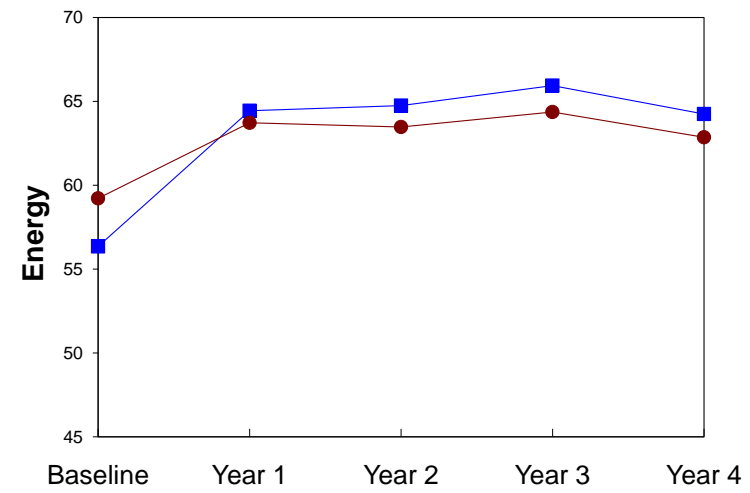
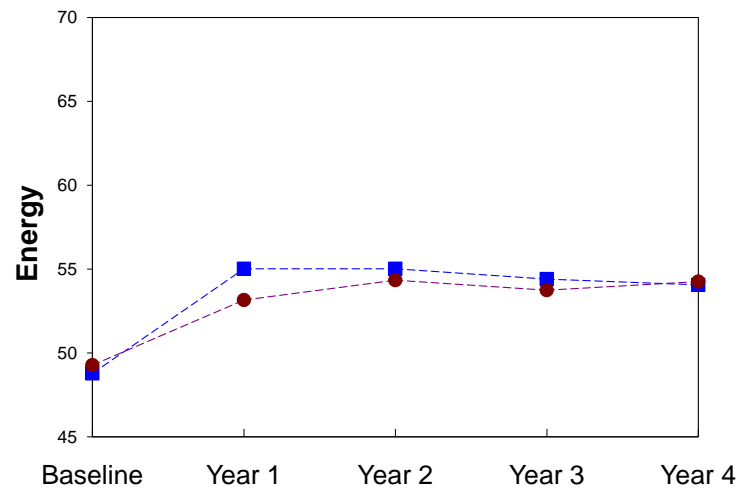
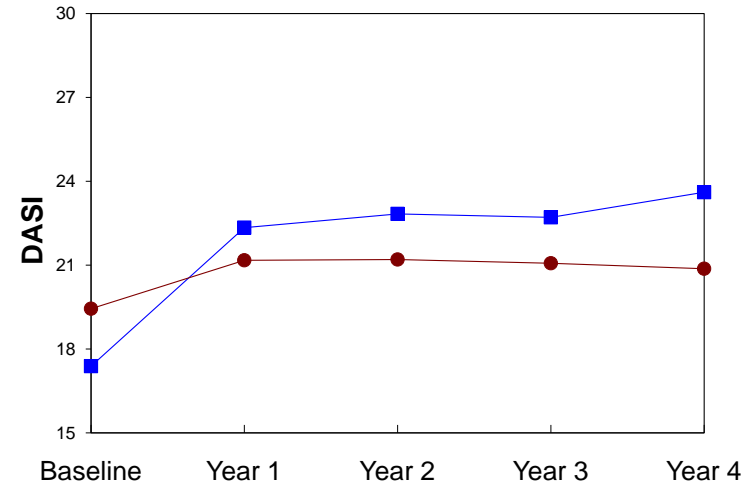
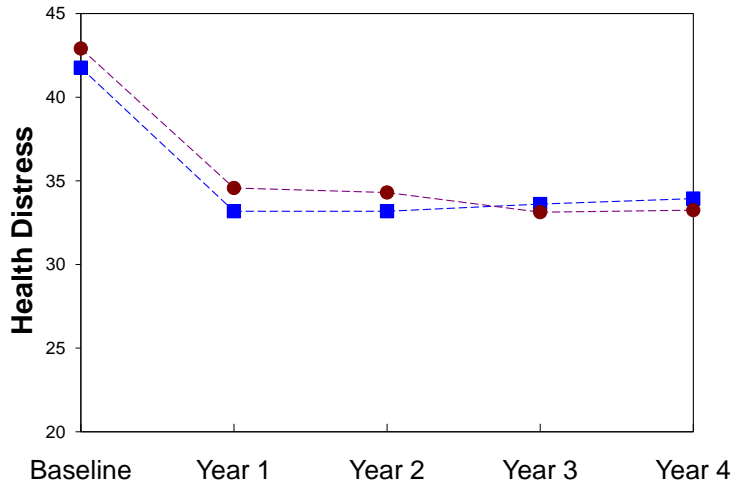


Figure S1 continue.

PCI stratum



CABG stratum

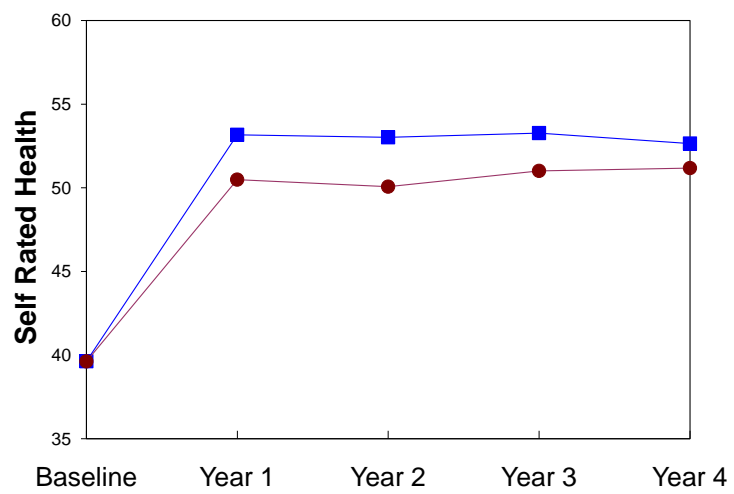
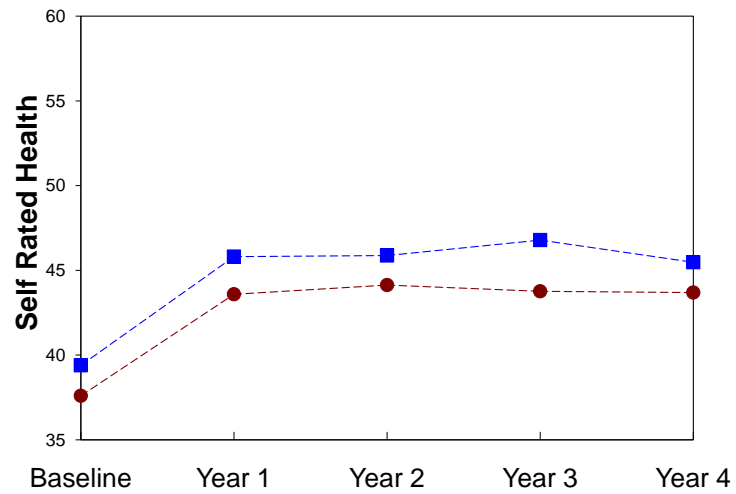
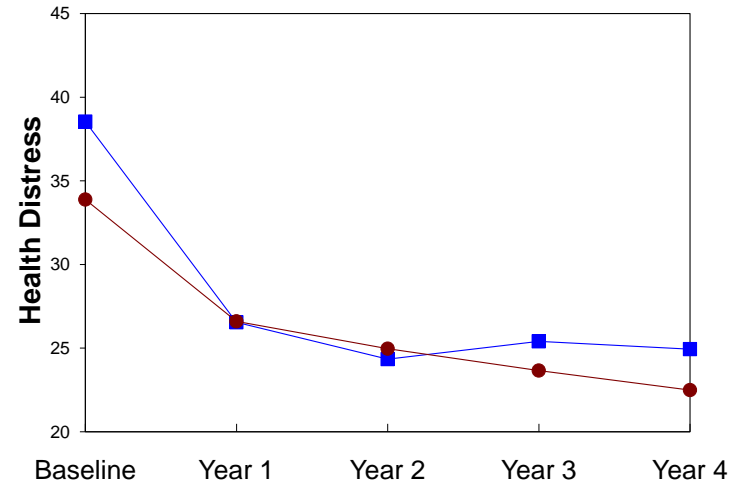


Figure S1: Health status by cardiac randomized treatment and intended method of revascularization. Prompt revascularization (solid symbol: ■ and blue line); Intensive medical therapy (solid symbols: ● and red line).