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Myocardial Viability and Impact of Surgical Ventricular Reconstruction on Outcomes of Patients with Severe Left Ventricular Dysfunction Undergoing Coronary Artery Bypass Surgery: Results of the Surgical Treatment for Ischemic Heart Failure (STICH) Trial

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Abstract

Objective—In the Surgical Treatment for Ischemic Heart Failure (STICH) trial, surgical ventricular reconstruction plus coronary artery bypass surgery was not associated with a reduction in the rate of death or cardiac hospitalization compared to bypass alone. We hypothesized that the absence of viable myocardium identifies patients with coronary artery disease and left ventricular dysfunction who have a greater benefit with coronary artery bypass graft surgery and surgical ventricular reconstruction compared to bypass alone.

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Methods—Myocardial viability was assessed by single photon computed tomography in 267 of the 1,000 patients randomized to bypass or bypass plus surgical ventricular reconstruction in STICH. Myocardial viability was assessed on a per patient basis as well as regionally based on pre-specified criteria.

Results—At 3 years, there was no difference in mortality or the combined outcome of death or cardiac hospitalization between those with and those without viability, and there was no significant interaction between the type of surgery and global viability status with respect to mortality or death plus cardiac hospitalization. Furthermore, there was no difference in mortality or death plus cardiac hospitalization between those with and without anterior wall or apical scar, and no significant interaction between the presence of scar in these regions and the type of surgery with respect to mortality.

Conclusion—In patients with coronary artery disease and severe regional left ventricular dysfunction, assessment of myocardial viability does not identify patients who will derive a mortality benefit from adding surgical ventricular reconstruction to coronary artery bypass graft surgery.

The Surgical Treatment for Ischemic Heart Failure (STICH) trial demonstrated that, in patients with ischemic cardiomyopathy and anterior wall akinesis undergoing coronary artery bypass surgery (CABG), the addition of surgical ventricular reconstruction (SVR) was not associated with a reduction in the rate of death or hospitalization for cardiac causes compared to results of CABG alone. [1] All patients in the SVR hypothesis of STICH were required to have global left ventricular (LV) dysfunction (ejection fraction ≤35%) and regional dysfunction with anterior akinesia or dyskinesia, as determined by the recruiting investigators. However, whether these dysfunctional segments were composed of scarred or viable myocardium was not analyzed in the original report, since systematic application of a dedicated test for myocardial viability was not part of the original study design nor a determinant of treatment assignment.

While viable myocardium is expected to recover after revascularization, scarred tissue is not. Further, a large amount of scarred myocardium may contribute negatively to overall LV function by accelerating or worsening the process of remodeling and by reducing the mechanical contribution of normal or viable myocardium via tethering of adjacent segments. Therefore, excluding scarred anterior wall segments through SVR could potentially result in hemodynamic and clinical improvement. Conversely, identification of myocardial viability in the same areas could lead to the retention of segments with the potential to recover after revascularization without SVR and contribute to improved LV mechanical function. Accordingly, distinguishing between viable versus scarred myocardium in the LV territory targeted for reconstruction may be critical for the success of the procedure and could thus identify a population that will preferentially benefit from SVR.

Single photon emission computed tomography (SPECT) is commonly performed in patients with LV dysfunction being considered for revascularization to identify areas of viable and scarred myocardium. Therefore, we tested in the STICH population the hypothesis that the presence of myocardial scar on SPECT identifies patients with coronary artery disease

(CAD) and LV dysfunction who have the greatest benefit with CABG + SVR compared to CABG alone.

METHODS

Study Design

The rationale and design of the STICH trial have been previously described [1–3] as have been the methods of the viability substudy of the STICH revascularization hypothesis [4]. STICH was a multicenter, non-blinded, randomized trial sponsored by the National Heart, Lung and Blood Institute. A total of 2,136 patients were enrolled at 127 sites in 26 countries, all of whom were candidates for CABG. STICH involved two hypotheses regarding the role of surgery in patients with LV systolic dysfunction. All patients in STICH were eligible for CABG based on clinical and coronary angiographic findings. The STICH revascularization hypothesis enrolled patients who were candidates for CABG or medical therapy, thus excluding patients with left main disease or unstable angina [3]. The STICH SVR hypothesis enrolled patients who were candidates for CABG who also had severe regional dysfunction of the LV anterior wall and were thus eligible for SVR [1]. In this arm of the trial, 1000 patients were enrolled, of whom 499 were assigned to CABG alone and 501 assigned to CABG plus SVR. Myocardial viability testing was performed using SPECT in 267 of the 1,000 patients, of whom 126 were assigned to CABG alone and 141 were assigned to CABG plus SVR. An independent core laboratory funded by the National Heart, Lung, and Blood Institute, in which investigators were unaware of study-group assignments and the individual characteristics of patients, coordinated data collection and analysis for the SPECT studies.

Study Procedures

Four different clinically validated SPECT protocols for assessing myocardial viability were permitted at the enrolling sites. These included thallium imaging using a rest-redistribution or stress-rest-reinjection protocol [5], a dual isotope protocol with rest-redistribution thallium imaging plus stress imaging with a technetium-99m perfusion tracer [6], or imaging with a technetium-99m tracer at rest after the administration of nitroglycerin [7]. Images were stored digitally and sent to the STICH Radionuclide Core Laboratory at Northwestern University for analysis. Core laboratory measurement of regional tracer activity was performed on all SPECT studies using a 17-segment model of the left ventricle [8]. A myocardial segment was deemed viable if the tracer activity in that segment was ≥50% of the activity in the segment with maximal activity. For thallium rest-redistribution imaging, a segment with activity <50% of the maximal myocardial activity on the redistribution images was also defined as viable if the improvement in activity from the rest to redistribution images was ≥12%. Segments not meeting these criteria for viability were deemed to be scarred.

Myocardial viability on a per-patient basis was prospectively defined as the presence of ≥11 viable segments (≥65% of the entire left ventricle). When ≥7 segments were nonviable (≥41% of the left ventricle), the patient was considered to have insufficient mass of viable myocardium. This threshold was selected based on previous retrospective data indicating

that the likelihood for functional improvement after CABG is low when >40% of the LV myocardium is nonviable [9].

Because the SVR procedure involves reconfiguring the anteroapical wall, we specifically explored the impact of anterior wall and apical scarring on the outcomes with CABG alone and CABG+SVR. For this analysis, viability was assessed using a 5-segment model where the left ventricle was divided into septal, inferior, lateral, anterior and apical segments (Supplemental Figure 1).

Patient Follow-up and Outcomes

After enrollment, patients were followed every 4 months for the first year and every 6 months thereafter. The primary outcome was the composite of death from any cause or hospitalization for cardiovascular causes. The secondary end point was death from any cause. Definitions of the trial end points have been previously reported [3]. All end points were adjudicated by an independent clinical events committee. The comparisons of outcomes that were related to treatment were based on intention-to-treat analyses. Analyses that were based on actual treatment received were also performed to account for crossovers.

Statistical Analysis

Baseline patient characteristics are summarized as percentages for categorical variables and means and standard deviations for continuous variables. Comparisons of baseline data between (a) patients with and without a viability test, and (b) patients with and without myocardial viability, given that a test was obtained, were performed using the Pearson chi-square test for categorical variables and the Wilcoxon rank-sum test for continuous variables. Kaplan-Meier event curves for mortality and for death or cardiac hospitalization were created and displayed by groups, and the log-rank test was used to statistically compare groups with respect to these outcomes.

Among the patients with viability assessment, unadjusted and adjusted Cox proportional hazards regression models were used to examine the association between the status of myocardial viability and the outcomes of death and death or cardiac hospitalization. The adjustment variables were baseline clinical factors, including age, creatinine, atrial fibrillation/flutter, diabetes, mitral regurgitation and end systolic volume index (ESVI), known from previous analyses to be key prognostic factors.

The Cox model was also used to examine the association between the randomized treatments (CABG vs. CABG+SVR) and the two outcomes, death and death or cardiac hospitalization, in patients with and patients without viable myocardium. Hazard ratios and 95% confidence intervals for the treatment comparisons were generated using the Cox model. The Cox model was also used to test for an interaction between treatment and viability; that is whether there was a different effect of CABG+SVR compared to CABG alone in patients with versus those without viability. These analyses were performed for overall LV viability, anterior wall viability, apex viability, and the anterior wall and apex combined. All statistical tests were two-sided, and the criterion for statistical significance was $p<0.05$. All statistical analyses were performed using SAS statistical software, version 9.2 (SAS Institute Inc., Cary, North Carolina).

RESULTS

Study Population

Among the 267 patients with a viability assessment, 227 were men and 40 were women. The mean age was 61±9 years, the mean LV ejection fraction was 27±5%, and 89% of patients had a previous myocardial infarction. Table 1 shows a comparison of the baseline characteristics of the patients who underwent a SPECT viability study and those who did not. Both groups were similar in age, gender, history of prior myocardial infarction, CAD distribution, and ejection fraction. Notably, the patients who underwent viability testing less often had a history of diabetes, hypertension, or prior CABG and more often had undergone prior percutaneous coronary intervention. Those who did not undergo viability testing had a higher clinical risk at the time of randomization, as assessed using an equation derived in an independent dataset from multiple variables with known power to predict 5-year risk of death without CABG [10].

Myocardial Viability, Scar, and Outcomes

Myocardial viability was identified in 191 (72%) of the study patients; the remaining 76 were classified as nonviable. Patients with and without viability were similar in age (61±10 vs. 62±9) and ejection fraction (27±6 vs. 28±5%). Patients without viability had larger LV end-diastolic and end-systolic volume indices than those with viability (143±53 vs. 115±41 and 112±48 vs. 85±38 ml/m^2, respectively; both $p<0.0001$).

When treatment allocation was not considered, there was no significant difference in mortality between patients with and those without viability (19 vs. 22% at 3 years, p=0.84, Figure 1A) or in the combined outcome of death or cardiac hospitalization (48 vs. 62% at 3 years, p=0.17, Figure 1B).

Of the 267 patients with a viability test, predominantly non-viable myocardium was identified in either the anterior wall or apex in 221 (83%). At 3 years, there was no difference in mortality between those with and without nonviable myocardium in the anterior wall (19 vs. 21%, respectively, p=0.85), apex (20 vs. 23%, respectively, p=0.96) or the combined anterior wall and apex (20% vs. 22%, respectively, p=0.89). There was also no difference between those with viable versus nonviable myocardium in these territories for the combined outcome of death or cardiac hospitalization.

Interaction Between Myocardial Viability and Treatment

Among the 191 patients with myocardial viability, 99 (52%) underwent CABG+SVR and 92 (48%) underwent CABG alone. Of the 76 patients without viability, 42 (55%) underwent CABG+SVR and 34 (45%) underwent CABG alone. There was no significant interaction between global myocardial viability status and the treatment effect of CABG+SVR versus CABG alone with respect to mortality (p=0.36, Figure 2A) or death plus cardiac hospitalization (p=0.55, Figure 2B).

When regional viability was considered, there was no significant interaction between the presence or absence of viable myocardium in the anterior region and the type of surgery

with respect to mortality (p=0.12, Figure 3A). There was no significant interaction between the presence or absence of scar in the apical region and the treatment effect of CABG+SVR versus CABG alone with respect to mortality (p=0.55, Figure 3B) or death or cardiovascular hospitalization (p=0.70). Similar to the findings in the apex, there was no significant interaction between the presence or absence of viable myocardium in the combined anterior wall and apex and the type of surgery with respect to mortality (p=0.78, Figure 3C) or death or cardiovascular hospitalization (p=0.67).

DISCUSSION

The original results of the SVR hypothesis of the STICH trial demonstrated no survival benefit in adding SVR to CABG [1]. Uncertainty persists whether certain subgroups of patients may benefit from SVR, such as those with larger LV volumes or those with evidence of scar in the anteroapical region [11, 12]. In this substudy of the STICH trial, we demonstrated that an overall assessment of myocardial viability with SPECT imaging does not help predict which patients will be alive or free from cardiac hospitalization 3 years after undergoing CABG or CABG+SVR or which patients will benefit more from performing concomitant SVR at the time of CABG. Furthermore, specifically identifying nonviable myocardium in the anterior wall and apex did not help determine which patients would derive a survival benefit with SVR.

Our findings are similar to those of the viability substudy of the STICH revascularization hypothesis, in which the results of viability testing with SPECT or dobutamine echocardiography were not associated with benefit from adding CABG to optimal medical therapy [4]. However, it must be noted that this study addressed a completely different issue, namely whether the presence of myocardial viability or scar was associated with benefit from SVR in patients in whom the decision for surgical revascularization had already been made. Hence, in these patients, the myocardial viability information would not be used to aid in the decision between medical therapy alone or medical therapy plus revascularization. Instead, the potential value of non-invasive testing would derive from identifying areas without viability (or with scar) that may be surgically excluded from the LV cavity at the time of surgery in order to improve LV performance and, ultimately, patient outcomes. In this context, the results observed with the assessment of global LV viability are not necessarily surprising and suggest that this form of imaging is not helpful for the selection of patients who benefit from adding SVR to CABG. It must be noted that previous studies of patient outcomes with SVR did not report incorporation of viability testing into the decision for SVR [13]. Thus, it is unclear what role non-invasive studies have played in the selection of patients by other investigators.

Based on the study design requiring all patients to be eligible to undergo the SVR procedure, it was expected that the vast majority of patients (82% in the present study) demonstrated evidence of scar on the apical segments. However, only 25% of the patients included in this substudy also had scar on the anterior wall.

Limitations

In this study, SPECT imaging was the only modality used for assessing myocardial viability. Other commonly used tests (such as delayed enhancement cardiac magnetic resonance imaging) have not been examined in the STICH trial. It is possible that the more detailed and quantitative myocardial scarring information provided by delayed enhancement imaging with magnetic resonance would prove useful in the selection of appropriate patients for SVR. This possibility deserves further investigation.

It should also be noted that the SVR hypothesis of the STICH trial was not designed to examine the impact of viability determination on outcomes in these patients. The present observations are based on a post-hoc analysis of a subset of STICH patients who underwent viability testing with SPECT. Hence, the impact of these observations is reduced compared to a trial specifically designed to address this issue. In addition, the reduced number of patients limits the statistical power of our findings. Finally, the decision to enroll patients in this trial could have been influenced by prior viability testing. However, it must be noted that the vast majority of patients in this report had viability testing performed after randomization.

Conclusion

In patients with CAD and severe regional LV dysfunction, assessment of myocardial viability does not identify patients who will benefit in terms of survival from adding SVR to CABG.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

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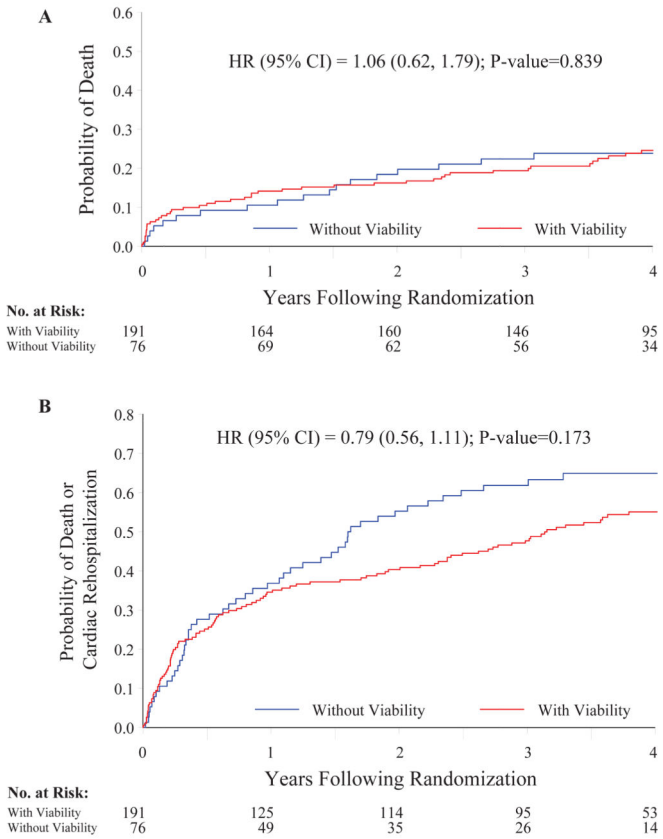

Figure 1.

Kaplan-Meier estimates of the probability of death (panel A) and death or cardiovascular hospitalization (panel B) according to myocardial viability status.

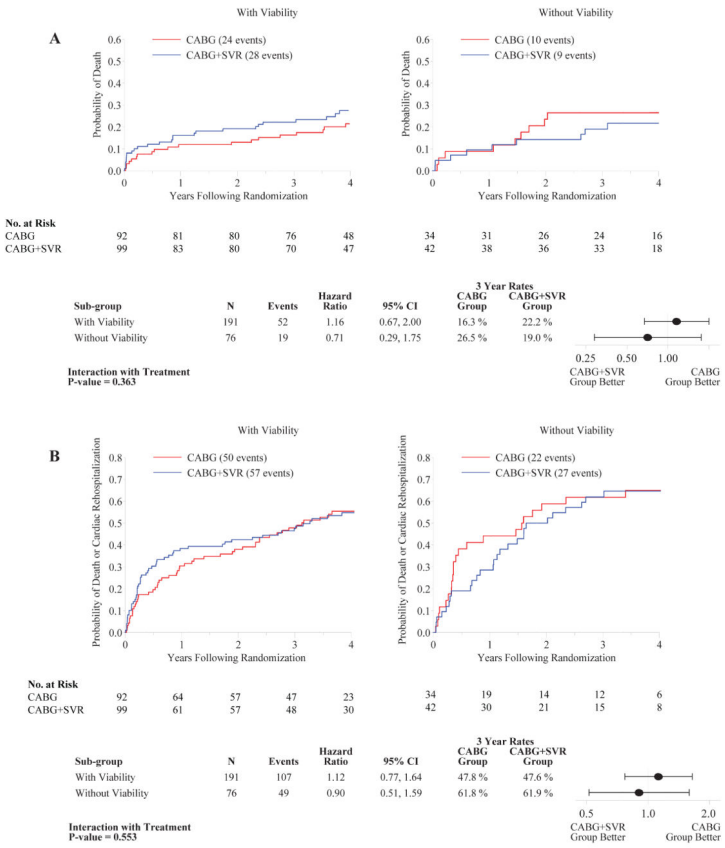

Figure 2.

Kaplan-Meier estimates of the probability of death (panel A) and death or cardiovascular hospitalization (panel B) according to myocardial viability status and treatment. CABG=coronary artery bypass graft surgery; CABG+SVR=coronary artery bypass graft surgery plus surgical ventricular reconstruction.

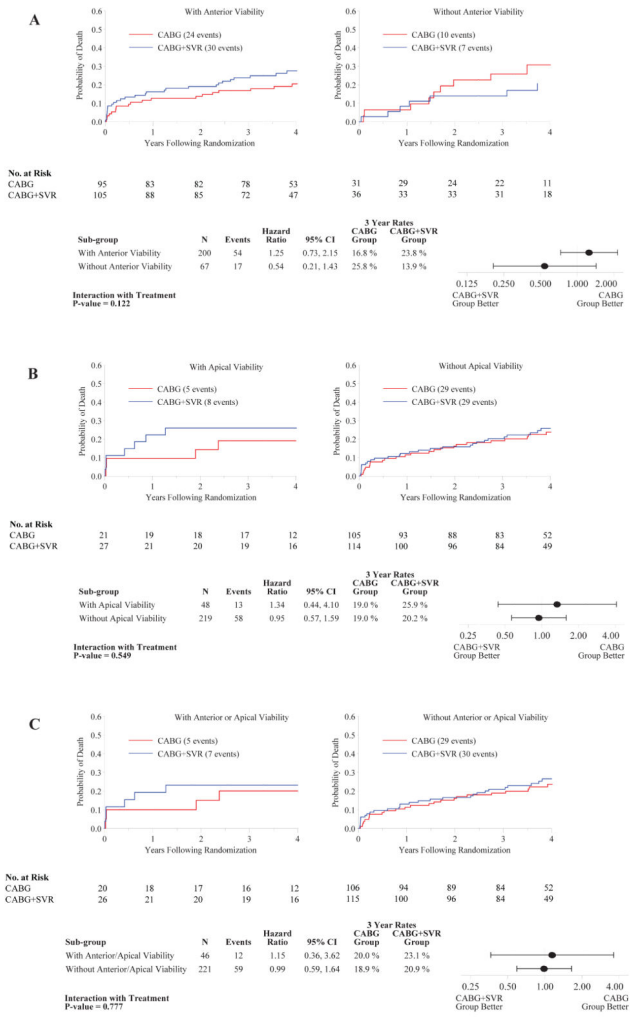

Figure 3.

Kaplan-Meier estimates of the probability of death according to anterior wall myocardial viability status and treatment (panel A), apical myocardial viability status and treatment (panel B), and anterior or apical myocardial viability status and treatment (panel C). CABG=coronary artery bypass graft surgery; CABG+SVR=coronary artery bypass graft surgery plus surgical ventricular reconstruction.

Table 1

Baseline characteristics of patients in STICH SVR hypothesis with and without viability testing.

Clinical characteristics			
Variable	**Patients with a viability test (n=267)**	**Patients without a viability test (n=733)**	**P value**
Age, mean ± SD	61.3 ± 9.5	61.8 ± 9.8	0.627
Female, n (%)	40 (15.0)	107 (14.6)	0.880
Diabetes, n (%)	77 (28.8)	267 (36.4)	0.026
Hyperlipidemia, n (%)	184 (69.4)	534 (73.0)	0.275
Hypertension, n (%)	132 (49.4)	453 (61.8)	<0.001
Current smoker, n (%)	50 (18.7)	167 (22.8)	0.169
Chronic renal insufficiency, n (%)	21 (7.9)	64 (8.7)	0.671
Atrial flutter/fibrillation, n (%)	28 (10.5)	89 (12.1)	0.471
Peripheral vascular disease, n (%)	37 (13.9)	109 (14.9)	0.688
Prior myocardial infarction, n (%)	237 (88.8)	635 (86.6)	0.372
Risk-at-randomization Score,* median (Q1,Q3)	10.0 (4.0, 19.0)	13.0 (6.0, 22.0)	0.002
Previous PCI, n (%)	67 (25.1)	128 (17.5)	0.007
Previous CABG, n (%)	2 (0.7)	22 (3.0)	0.040
Previous ICD, n (%)	5 (1.9)	29 (4.0)	0.108
CCS angina class, n (%)			0.001
no angina	51 (19.1)	198 (27.0)	
I	20 (7.5)	51 (7.0)	
II	72 (27.0)	116 (15.8)	
III	106 (39.7)	302 (41.2)	
IV	18 (6.7)	66 (9.0)	
NYHA HF class, n (%)			<0.001
I	20 (7.5)	66 (9.0)	
II	154 (57.7)	275 (37.5)	
III	80 (30.0)	348 (47.5)	
IV	13 (4.9)	44 (6.0)	
Blood Pressure, mean ± SD			
Systolic	117.7 ± 15.7	121.6 ± 18.1	0.007
Diastolic	73.9 ± 9.9	73.3 ± 11.7	

Clinical characteristics

Variable	Patients with a viability test (n=267)	Patients without a viability test (n=733)	P value
Heart rate, mean ± SD	72.1 ± 11.9	72.7 ± 14.0	0.628
Creatinine (mg/dl)	1.1 ± 0.4	1.1 ± 0.4	0.324
CAD distribution, n (%)			
Left main (≥50%)	42 (15.7)	155 (21.1)	0.057
Number of vessels >50%			0.084
One-vessel	32 (12.0)	55 (7.5)	
Two-vessel	70 (26.2)	205 (28.0)	
Three-vessel	165 (61.8)	473 (64.5)	
Previous CABG, n	2	22	0.007
Bypass graft status, n (%)			
≥1 stenosed or occluded	2 (100)	18 (81.8)	
≥1 occluded	2 (100)	15 (68.2)	
LVEF, mean ± SD	27.3 ± 5.5	26.8 ± 6.0	0.236
EDVI ml/m^2, mean ± SD	122.7 ± 46.4	114.9 ± 40.8	0.045
ESVI ml/m^2, mean ± SD	87.6 ± 39.5	90.2 ± 36.4	0.027
ACE inhibitor/ARB	246 (92.1)	633 (86.4)	0.013
Beta blocker	232 (86.9)	576 (78.6)	0.551
Amiodarone	31 (11.6)	93 (12.7)	0.648
Aspirin	215 (80.5)	593 (80.9)	0.084
Warfarin	26 (9.7)	96 (13.1)	0.151
Clopidogrel	19 (7.1)	62 (8.5)	0.491
Digoxin	43 (16.1)	114 (15.6)	0.832
Diuretic (loop/thiazide)	143 (53.6)	452 (61.7)	0.021
Diuretic (potassium sparing)	112 (41.9)	259 (35.3)	0.056
Nitrate	165 (61.8)	422 (57.6)	0.230
Statin	230 (86.1)	541 (73.8)	<0.001

PCI = Percutaneous Coronary Intervention; CABG = Coronary Artery Bypass Graft surgery; ICD = Implantable Cardiac Defibrillator; CAD = Coronary Artery Disease; NYHA HF = New York Heart Association Heart Failure class; ACE = Angiotensin Converting Enzyme; ARB = Angiotensin Receptor Blocker; LVEF = Left Ventricular Ejection Fraction; EDVI = End Diastolic Volume Index; ESVI = End Systolic Volume Index.

*The risk-at-randomization score ranges from 1 to 32, with higher numbers indicating a higher predicted rate of death.

Table 2

Baseline characteristics of patients who underwent viability testing

Clinical characteristics			
Variable	**Patients Without Myocardial Viability (n=76)**	**Patients With Myocardial Viability (n=191)**	**P value**
Age, mean ± SD	61.7 ± 8.7	61.1 ± 9.8	0.704
Female, n (%)	7 (9.2)	33 (17.3)	0.096
Prior myocardial infarction, n (%)	72 (94.7)	165 (86.4)	0.051
Risk-at-randomization Score, * median (Q1,Q3)	11.0 (5.0, 21.0)	10.0 (4.0, 19.0)	0.526
CCS angina class, n (%)			0.614
no angina	13 (17.1)	38 (19.9)	
I	3 (3.9)	17 (8.9)	
II	23 (30.3)	49 (25.7)	
III	31 (40.8)	75 (39.3)	
IV	6 (7.9)	12 (6.3)	
Highest NYHA HF class within 3 months, n (%)			0.622
I	2 (2.6)	8 (4.2)	
II	30 (39.5)	64 (33.5)	
III	34 (44.7)	84 (44.0)	
IV	10 (13.2)	35 (18.3)	
ACE inhibitor/ARB	72 (94.7)	174 (91.1)	0.319
Beta blocker	66(86.8)	166 (86.9)	0.988
Aspirin	62 (81.6)	153 (80.1)	0.784
Statin	67 (88.2)	163 (85.3)	0.548
CAD distribution, n (%)			
Left main (≥50%)	13 (17.1)	29 (38.2)	0.697
Number of vessels >75%			0.838
None	1 (1.3)	5 (2.6)	
One-vessel	18 (23.7)	42 (22.0)	
Two-vessel	29 (15.2)	81 (42.4)	
Three-vessel	28 (36.8)	63 (33.0)	
LVEF, mean ± SD	27.6 ± 5.41	27.2 ± 5.52	0.649
EDVI ml/m^2, mean ± SD	143.1 ± 53.23	114.6 ± 40.83	<0.001
ESVI ml/m^2, mean ± SD	111.9 ± 47.51	84.6 ± 38.18	<0.001

PCI = Percutaneous Coronary Intervention; CABG = Coronary Artery Bypass Graft surgery; ICD = Implantable Cardiac Defibrillator; CAD = Coronary Artery Disease; NYHA HF = New York Heart Association Heart Failure class; ACE = Angiotensin Converting Enzyme; ARB =

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