Outcomes, Health Policy, and Managed Care

Quality of life and economic outcomes with surgical ventricular reconstruction in ischemic heart failure: Results from the Surgical Treatment for Ischemic Heart Failure trial

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Background Surgical ventricular reconstruction (SVR) is used in conjunction with coronary artery bypass graft surgery (CABG) to improve left ventricular function and clinical outcomes in selected patients with ischemic heart failure. The impact of SVR on quality of life (QOL) and medical costs is unknown.

Methods We compared CABG plus SVR with CABG alone in 1,000 patients with ischemic heart failure, an anterior wall scar, and a left ventricular ejection fraction ≤0.35. In 991 (99% of eligible), we collected a battery of QOL instruments. The principal, prespecified QOL measure was the Kansas City Cardiomyopathy Questionnaire, which evaluates the effects of heart failure symptoms on QOL using a scale from 0 to 100 with higher scores indicating better QOL. Structured QOL interviews were conducted at baseline, 4, 12, 24, and 36 months post randomization and were ≥92% complete. Cost data were collected on 196 (98%) of 200 patients enrolled in the United States.

Results Heart-failure–related QOL outcomes did not differ between the 2 treatment strategies out to 3 years (median Kansas City Cardiomyopathy Questionnaire scores for CABG alone and CABG plus SVR, respectively: baseline 53 versus 54, $P = .53$; 3 years 85 versus 84, $P = .89$). There were no treatment-related differences in other QOL measures. In the US patients, total index hospitalization costs averaged over $14,500 higher for CABG plus SVR ($P = .004$) due primarily to 4.2 extra postoperative, high-intensity care days in the hospital.

Conclusions Addition of SVR to CABG in patients with ischemic heart failure did not improve QOL but significantly increased health care costs. (Am Heart J 2009;157:837-844.e3.)

A subset of patients with ischemic cardiomyopathy develop progressive heart failure as a consequence of adverse ventricular remodeling leading to a depressed ejection fraction, a large akinetic region of myocardium, and an abnormal globular shape to the ventricular chamber. Over the past 25 years, cardiac surgeons have developed a novel procedure for excluding or excising the ventricular scar and reshaping the left ventricle to a more normal geometry.[1,2] This procedure, known as surgical ventricular reconstruction (SVR), has shown encouraging results in observational studies including significant improvement in heart failure symptoms and quality of life (QOL) relative to presurgery status.[2-4] However, it remains unclear what incremental clinical and QOL benefits are specifically provided by the SVR because it is nearly always performed in conjunction with coronary bypass graft surgery (CABG) and in the setting of medical heart failure therapy. In addition, the economic consequences of this procedure have not been previously reported.

Elsewhere, we have reported on the primary results of the Surgical Treatment for Ischemic Heart Failure (STICH) trial comparing CABG plus SVR with CABG alone in 1,000 patients with ischemic heart failure and a

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depressed ejection fraction.[5] Our hypotheses at the start of this trial were that SVR would improve QOL relative to CABG alone and would be cost-effective by conventional criteria. In this article, we provide data on the QOL and cost outcomes, both prespecified secondary trial end points.

Methods

Patient population and clinical results

The STICH trial is a National Heart, Lung, and Blood Institute–sponsored program consisting of 2 international, randomized clinical trials testing 2 related hypotheses about the use of surgical treatment for ischemic heart failure. The left ventricular reconstruction hypothesis compared CABG plus surgical ventricular reconstruction with CABG alone in 1,000 patients with symptomatic heart failure, an anterior wall scar, and a left ventricular ejection fraction ≤0.35.[6] Rationale, trial design, and complete inclusion and exclusion criteria have been described elsewhere.[6] One thousand patients were enrolled into the left ventricular reconstruction hypothesis cohort between September 12, 2002, and January 24, 2006.

As reported elsewhere, SVR had no effect on the primary clinical end point of all-cause death or cardiac hospitalization at a median follow-up of 48 months (hazard ratio 0.99, $P = .89$).[5] The SVR-plus-CABG operation produced a relative decrease of 25% in end-systolic volume index compared with a 7% decrease seen in CABG-alone patients.

Quality of life data collection

Patients were given a structured QOL interview at baseline (after enrollment but before randomized treatment was performed) and at 4, 12, 24, and 36 months post randomization. Baseline interviews were conducted by each site's coordinators, who had been specially trained to conduct the QOL interviews. Follow-up interviews for patients in the United States and Canada were conducted via telephone by trained interviewers from the Duke Clinical Research Institute's Outcomes Research Group. Follow-up interviews for patients in all other countries were conducted by each site's trained coordinators.

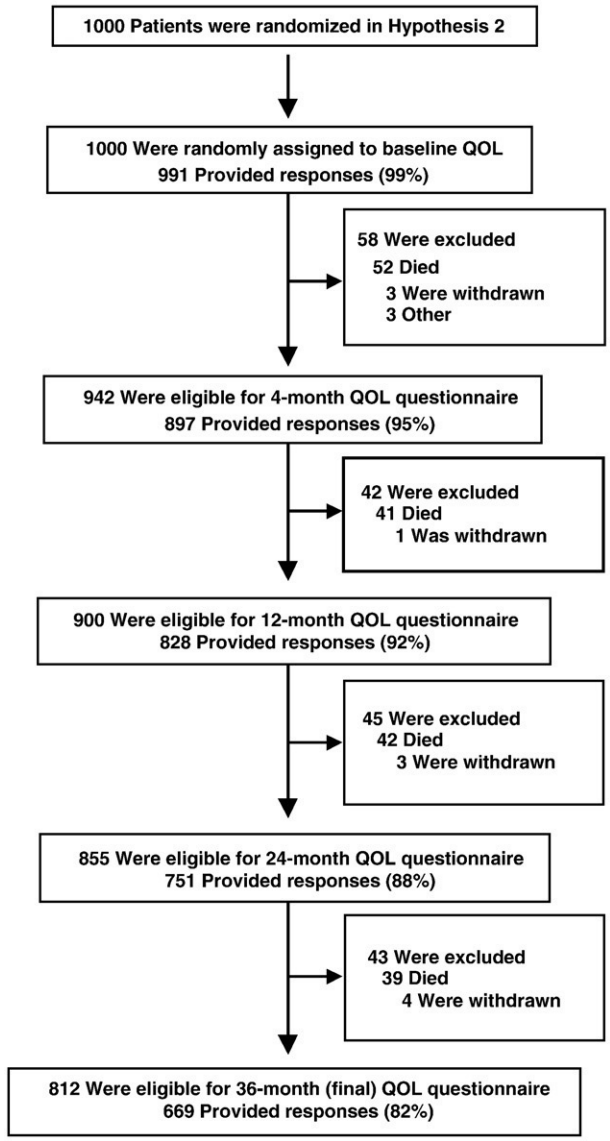
We collected baseline QOL data on 991 (99%) of 1,000 patients randomized into the STICH trial left ventricular reconstruction hypothesis cohort. From a total of 4,509 expected patient contacts, 4,136 QOL questionnaires were collected, representing 82% to 99% of patients eligible for this assessment at each follow-up (Figure 1). Patient refusal was 0.8%, and 6.6% of forms collected were incomplete. A short proxy form was collected for incapacitated patients.

This study was conducted in collaboration with and supported by the National Heart, Lung, and Blood Institute. This part of the study had no other funding. All patients provided informed consent and study protocol approval was obtained from each site's institutional review board or ethics committee. The authors designed the study, collected and analyzed the data, wrote all versions of this paper, and are fully responsible for its contents.

Quality of life measures

Our principal, prespecified QOL measure was the Kansas City Cardiomyopathy Questionnaire (KCCQ) overall summary score.

Figure 1



This figure shows the rate of QOL data collection at each point in follow-up and reasons for missing data.

The KCCQ is a 23-item, disease-specific QOL instrument used to measure the effect of heart failure symptoms on functional limitations, social limitations, self-efficacy, and patient satisfaction with overall QOL.[7] In addition to the overall summary score, scores can be calculated for 6 component subscales. The KCCQ scores range from 1 to 100, with higher scores indicating a more favorable status.[7] A difference of ≥5 points is considered clinically significant.[8]

To assess the effects of angina symptoms on QOL, we used 3 scales from the Seattle Angina Questionnaire: anginal frequency, anginal stability, and QOL.[9] The anginal frequency scale assesses the frequency of angina symptoms in the previous 4 weeks.

Higher scores reflect lower incidence of anginal symptoms. The anginal stability scale measures changes in angina frequency, with a score of 50 representing no change. The QOL scale measures the effect of angina symptoms on patients' perceptions of their QOL, with higher scores being more favorable and a clinically significant difference being ≥5 points.[9]

To supplement these condition-specific scales, we collected a brief overall generic measure of health status (the Medical Outcomes Study Short-Form 12) plus 5 scales (psychological well-being, role physical, role emotional, social function, and vitality) from the Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36).[10] The SF-12 is scored in 2 summary scales —a Physical and a Mental Component.[11] Both the SF-12 and the SF-36 scales were scored by calculating the raw scores then transforming raw scores to a 0-to-100 scale with larger values indicating more favorable health status. The scores were then standardized to a population norm-based score where a value of 50 represents the average value obtained in the US general population in 1998. In brief, *z*-scores were first computed for each scale for each study subject by subtracting the US mean value from 1998 data for that scale and dividing by the SD from the 1998 US population. The result was then multiplied by 10 and added to 50 to produce a norm-based score with a mean of 50 and an SD of 10. A clinically significant difference for this scoring system has not been established but can be approximated by a 1/4 SD or ≥2.5 points.

To assess depressive symptoms, we used the Center for Epidemiologic Stress-Depression Scale (CES-D), a 20-item instrument that assesses if a patient is experiencing mild to moderate depression or has a possibility of major depression.[12] CES-D scores range from 0 to 60, with a score ≥16 indicating depression.[12]

The Cardiac Self-Efficacy Questionnaire is a 13-item questionnaire designed to measure a patient's confidence in controlling their disease symptoms and maintaining physical functioning.[13] Patient responses are scored on a 0-to-100 scale with higher scores reflecting higher patient confidence.

The EuroQoL 5-D is a generic instrument consisting of 2 parts: a 5-dimension assessment of health status that can be mapped to population utility weights and a self-rating (0-100) of current health-related QOL.[14,15]

Resource use and data collection and analysis

Resource use was collected on the case report form by site coordinators for all patients and included information about the length of the surgery, postoperative time in the intensive care unit (ICU), total length of stay, and rates of rehospitalization. We collected index hospitalization cost data from 196 (98%) of 200 patients enrolled in the United States. One patient withdrew immediately, 1 died pre surgery and no hospital bill was collected, 1 refused surgery, and 1 never had the surgery. Hospital costs were collected from UB 92/04 hospital billing data and converted from charges to costs using department-level correction factors in each hospital's annual Medicare Cost Report, as described previously.[16,17] Physician costs were estimated with a previously derived algorithm using physician-based care identified on the clinical case report form and the medical bills.[16,18] Because our analyses took a societal perspective rather than a reimbursement perspective, we assigned costs to each identified unit of physician service rather than employing a global reimbursement rate. Costs were then assigned using the 2008 Medicare Fee Schedule. Costs are reported in 2008 US dollars.

Statistical analyses

Descriptive statistics included percentages for discrete variables and medians with interquartile ranges, means with SDs, or both for continuous variables. Comparisons were performed according to randomized treatment assignment. The χ^2 test was used for discrete variable comparisons, and the Wilcoxon rank-sum variable was used for continuous variables. Reported *P* values were not adjusted for multiple comparisons. Along with the difference in mean costs between the 2 arms, we calculated the difference in median costs using the Hodges-Lehman statistic, and a nonparametric confidence limit for the difference was calculated.

Results

Patient population and baseline characteristics

Baseline characteristics of the 2 treatment arms were well balanced (data not shown).[5] The median age of the study cohort was 62 years (25th and 75th percentiles, 55 and 69 years). Fifteen percent were female and 9% were minorities. At baseline, 49% of patients had Canadian class 3 or 4 angina and 49% had New York Heart Association class 3 or 4 heart failure.

Quality of life outcomes

Both treatment groups significantly improved their KCCQ scores in follow-up compared with the preoperative assessment. The observed improvements in disease-specific health status occurred rapidly and were sustained throughout follow-up (baseline median KCCQ overall summary scores = 53 for CABG alone and 54 for CABG plus SVR; 4-month median scores = 79 and 79; 36-month median scores = 85 and 84). However, median KCCQ overall summary scores did not differ between the 2 treatment groups at baseline or any follow-up interval (Table I). Results in the 6 KCCQ subscales were consistent with the overall summary score comparison.

No treatment differences were seen in the Seattle Angina Questionnaire anginal frequency, anginal stability, or QOL scales (Appendix Table A, available online).

The SF-12 Physical and Mental Component comparisons, reflecting generic health status, showed a single statistically significant difference for the Mental Component at one single time point that was not consistent with the remaining comparisons (Appendix Table A, available online). A similar single significant difference at the same time point was seen for the SF-36 MHI-5, which shares 2 questions with the SF-12 Mental Component. No treatment differences were seen in the other SF-36 scales.

Depressive symptoms decreased significantly postoperatively in both treatment groups but were not different between each group at any point during follow-up (Appendix Table A, available online).

Table I. Kansas City Cardiomyopathy Questionnaire Scores by intention to treat

	CABG alone	CABG + SVR	*P*
KCCQ			
Overall summary			
Baseline			
No. of patients	496	492	
Median (interquartile range)	53 (36-70)	54 (38-72)	.53
Mean ± SD	54 ± 22	54 ± 22	
4 m			
No. of patients	446	443	
Median (interquartile range)	79 (56-92)	79 (63-92)	.26
Mean ± SD	72 ± 24	74 ± 23	
12 m			
No. of patients	411	416	
Median (interquartile range)	84 (59-95)	82 (66-94)	.76
Mean ± SD	76 ± 23	76 ± 22	
24 m			
No. of patients	368	374	
Median (interquartile range)	84 (60-95)	84 (64-94)	.89
Mean ± SD	75 ± 24	77 ± 22	
36 m			
No. of patients	329	335	
Median (interquartile range)	85 (65-95)	84 (63-95)	.89
Mean ± SD	75 ± 25	77 ± 22	
Physical limitation			
Baseline			
No. of patients	484	480	
Median (interquartile range)	63 (38-83)	63 (45-80)	.40
Mean ± SD	59 ± 26	61 ± 25	
4 m			
No. of patients	433	432	
Median (interquartile range)	83 (58-95)	83 (64-96)	.13
Mean ± SD	74 ± 25	76 ± 25	
12 m			
No. of patients	402	411	
Median (interquartile range)	84 (65-100)	88 (67-96)	.86
Mean ± SD	77 ± 25	78 ± 24	
24 m			
No. of patients	363	368	
Median (interquartile range)	88 (60-100)	85 (66-96)	.89
Mean ± SD	77 ± 25	78 ± 23	
36 m			
No. of patients	321	324	
Median (interquartile range)	88 (69-100)	88 (67-96)	.87
Mean ± SD	78 ± 25	78 ± 23	
Symptom stability			
Baseline			
No. of patients	494	492	
Median (interquartile range)	50 (25-50)	50 (50-50)	.38
Mean ± SD	48 ± 25	49 ± 24	
4 m			
No. of patients	436	435	
Median (interquartile range)	50 (50-75)	50 (50-75)	.45
Mean ± SD	57 ± 22	58 ± 22	
12 m			
No. of patients	408	416	
Median (interquartile range)	50 (50-50)	50 (50-50)	.62
Mean ± SD	53 ± 16	53 ± 19	
24 m			
No. of patients	362	372	
Median (interquartile range)	50 (50-50)	50 (50-50)	.82
Mean ± SD	50 ± 14	50 ± 15	
36 m			
No. of patients	328	332	
Median (interquartile range)	50 (50-50)	50 (50-50)	.94
Mean ± SD	49 ± 16	50 ± 13	
Symptom frequency			
Baseline			
No. of patients	493	491	
Median (interquartile range)	67 (50-88)	71 (50-88)	.19
Mean ± SD	65 ± 26	67 ± 26	
4 m			
No. of patients	440	434	
Median (interquartile range)	83 (63-100)	88 (67-100)	.07
Mean ± SD	77 ± 24	80 ± 23	
12 m			
No. of patients	409	415	
Median (interquartile range)	90 (67-100)	90 (71-100)	.94
Mean ± SD	80 ± 24	80 ± 24	
24 m			
No. of patients	367	374	
Median (interquartile range)	92 (67-100)	92 (69-100)	.67
Mean ± SD	80 ± 24	81 ± 24	
36 m			
No. of patients	329	334	
Median (interquartile range)	92 (67-100)	92 (69-100)	.44
Mean ± SD	80 ± 26	82 ± 23	
Symptom burden			
Baseline			
No. of patients	494	492	
Median (interquartile range)	67 (50-92)	75 (50-83)	.23
Mean ± SD	67 ± 25	69 ± 24	
4 m			
No. of patients	441	436	
Median (interquartile range)	83 (67-100)	83 (67-100)	.43
Mean ± SD	79 ± 23	81 ± 21	
12 m			
No. of patients	410	416	
Median (interquartile range)	92 (67-100)	92 (67-100)	.35
Mean ± SD	81 ± 23	81 ± 23	
24 m			
No. of patients	368	373	
Median (interquartile range)	92 (67-100)	92 (67-100)	.90
Mean ± SD	81 ± 23	82 ± 22	
36 m			
No. of patients	329	332	
Median (interquartile range)	92 (67-100)	92 (67-100)	.48
Mean ± SD	81 ± 25	83 ± 21	
Total symptom			
Baseline			
No. of patients	494	492	
Median (interquartile range)	68 (48-86)	71 (52-88)	.18
Mean ± SD	66 ± 24	68 ± 24	
4 m			
No. of patients	441	436	
Median (interquartile range)	84 (65-100)	88 (71-100)	.17
Mean ± SD	78 ± 23	81 ± 21	
12 m			
No. of patients	410	416	
Median (interquartile range)	90 (68-100)	88 (71-100)	.59
Mean ± SD	81 ± 23	81 ± 23	
24 m			
No. of patients	368	374	
Median (interquartile range)	90 (71-100)	90 (71-100)	.78
Mean ± SD	81 ± 23	82 ± 22	

Table I *(continued)*

	CABG alone	CABG + SVR	P
36 m			
No. of patients	329	334	
Median (interquartile range)	90 (70-100)	92 (68-100)	.48
Mean ± SD	80 ± 25	82 ± 21	
QOL			
Baseline			
No. of patients	493	490	
Median (interquartile range)	42 (17-58)	33 (25-58)	.70
Mean ± SD	40 ± 25	39 ± 23	
4 m			
No. of patients	441	433	
Median (interquartile range)	75 (50-92)	75 (58-92)	.47
Mean ± SD	68 ± 27	70 ± 25	
12 m			
No. of patients	409	416	
Median (interquartile range)	75 (50-92)	75 (58-92)	.87
Mean ± SD	71 ± 27	72 ± 25	
24 m			
No. of patients	365	373	
Median (interquartile range)	75 (58-92)	75 (58-92)	.84
Mean ± SD	71 ± 27	71 ± 25	
36 m			
No. of patients	328	333	
Median (interquartile range)	75 (58-92)	83 (50-92)	.82
Mean ± SD	71 ± 27	72 ± 26	
Social limitation			
Baseline			
No. of patients	465	467	
Median (interquartile range)	44 (19-75)	44 (25-75)	.63
Mean ± SD	47 ± 31	48 ± 31	
4 m			
No. of patients	424	412	
Median (interquartile range)	75 (50-94)	75 (50-100)	.29
Mean ± SD	69 ± 29	71 ± 28	
12 m			
No. of patients	387	400	
Median (interquartile range)	81 (58-100)	83 (63-94)	.68
Mean ± SD	75 ± 27	75 ± 26	
24 m			
No. of patients	353	356	
Median (interquartile range)	81 (50-100)	86 (56-100)	.25
Mean ± SD	73 ± 29	76 ± 26	
36 m			
No. of patients	318	309	
Median (interquartile range)	83 (58-100)	83 (56-100)	.68
Mean ± SD	73 ± 31	75 ± 27	
Clinical summary			
Baseline			
No. of patients	496	492	
Median (interquartile range)	65 (46-83)	68 (49-84)	.26
Mean ± SD	63 ± 23	65 ± 22	
4 m			
No. of patients	445	443	
Median (interquartile range)	84 (63-95)	84 (67-96)	.23
Mean ± SD	76 ± 23	78 ± 22	
12 m			
No. of patients	411	416	
Median (interquartile range)	88 (66-97)	86 (70-96)	.66
Mean ± SD	79 ± 22	79 ± 22	
24 m			
No. of patients	368	374	
Median (interquartile range)	88 (65-97)	87 (69-96)	.98
Mean ± SD	79 ± 22	80 ± 21	
36 m			
No. of patients	329	335	
Median (interquartile range)	88 (67-98)	88 (69-98)	.86
Mean ± SD	79 ± 24	80 ± 21	

*0-to-100 scale with higher scores representing better functioning.

No significant treatment-related differences were found in the 0-to-100 general health self-rating scale or the EuroQoL 5-D.

Resource use and medical costs in US patients

Total operative time, need for postoperative pulmonary artery catheters, intra-aortic balloon pumps, and intravenous inotrope therapy were all greater in the CABG-plus-SVR arm (Table II). The CABG-plus-SVR arm had 4.2 extra postoperative intensive care unit days ($P < .001$). Days spent in non-ICU rooms and preoperative days in the hospital did not differ significantly by treatment. Total length of stay for the CABG-only group was 13.5 ± 13.0 days, and for the CABG-plus-SVR group, 16.8 ± 12.3 days ($P = .03$). Rates of any follow-up, all-cause hospitalization from randomization to the latest follow-up were equivalent for the 2 arms (66.7% for CABG alone and 72.5% for CABG plus SVR, $P = .37$).

Total index hospitalization costs were $14,595 higher for CABG plus SVR ($P = .006$) (Table II and Figure 2). The median difference in costs was $10,966 (Hodges-Lehman statistic), and the 95% confidence limit was $3,677 to $18,218 ($P = .004$).

Discussion

The STICH trial provides the first comprehensive clinical, QOL, and economic randomized trial evaluation of the strategy of adding SVR to coronary bypass surgery in patients with advanced ischemic cardiomyopathy. We hypothesized that the benefits of surgically creating a smaller, more normally shaped ventricle would include reduced heart failure symptoms with consequent improved functioning and QOL and reduced need for rehospitalization. We also postulated that if these clinical results were obtained, the incremental cost of the SVR procedure would be judged good value for money based on conventional cost-effectiveness criteria. However, our data do not show any evidence of incremental benefit in health-related QOL by adding SVR to CABG in patients with ischemic heart failure and anterior scar. Because SVR significantly increases costs, we can confidently conclude that there is no justification for routine performance of this technique in STICH-eligible patients.

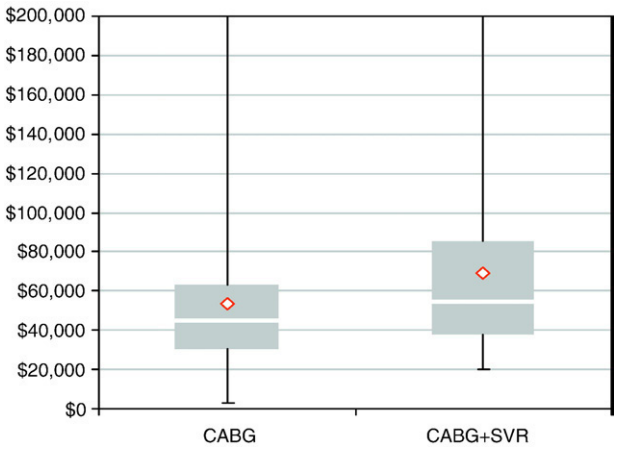
Table II. Index hospital costs and resource use in US patients

	CABG	CABG + SVR	P
Resource use			
Total time in operating room*(h)			
No. of patients	99	96	
Median (interquartile range)	5.4 (4.7-6.6)	6.7 (5.7-7.7)	
Mean ± SD	5.7 ± 1.3	6.8 ± 1.5	<.001
Postoperative time in ICU/CCU*(d)			
No. of patients	99	94	
Median (interquartile range)	2.2 (1.3-4.0)	4.8 (2.0-8.7)	
Mean ± SD	3.4 ± 3.8	7.6 ± 11.5	<.001
Total ICU time† (d)			
No. of patients	100	96	
Median (interquartile range)	4.5 (2.0-7.5)	6.0 (4.0-12.0)	
Mean ± SD	6.0 ± 9.5	9.9 ± 10.6	.0002
Postoperative length of stay*(d)			
No. of patients	99	95	
Median (interquartile range)	7.0 (5.0-10.0)	9.0 (7.0-17.0)	
Mean ± SD	9.5 ± 10.5	13.4 ± 11.7	<.001
Total length of stay†(d)			
No. of patients	100	96	
Median (interquartile range)	11.0 (7.0-16.0)	12.5 (8.0-18.5)	
Mean ± SD	13.5 ± 13.0	16.8 ± 12.3	.03
Other resource use			
PA catheter*			
No. of patients	101	98	
Patients receiving PA catheter (%)	17.8	27.6	.10
IABP for low CO*			
No. of patients	101	98	
Patients receiving IABP (%)	11.9	32.7	.0003
Inotropes for low CO*			
No. of patients	101	98	
Patients receiving inotropes (%)	38.6	62.2	.0008
Costs			
Hospital admission†			
No. of patients	100	96	
Median (interquartile range)	$38 858 ($26 508-$57 841)	$49 011 ($33 586-$77 322)	
Mean ± SD	$50 939 ± 46 458	$64 202 ± 49 172	.006
Physician fees†			
No. of patients	100	96	
Median (interquartile range)	$4750 ($3963-$5959)	$6028 ($4837-$7454)	
Mean ± SD	$ 5183 ± 2306	$ 6515 ± 2463	<.0001
Total index hospitalization cost†			
No. of patients	100	96	
Median (interquartile range)	$44 760 ($30 481-$63 379)	$54 650 ($38 044-$85 794)	
Mean ± SD	$56 122 ± 48 552	$70 717 ± 51 367	.004

Costs are reported in 2008 US Dollars. *CO*, Cardiac output; *CCU*, coronary care unit; *IABP*, intra-aortic balloon pump.
*The data for these items come from the clinical case report form.
†The data for these items come from the hospital bills.

One notable feature of our trial results is the substantial and consistent improvement in multiple domains of QOL observed after surgery compared with the preoperative state. As reported in the primary clinical report from this trial, only 4% of patients had NYHA symptoms class I pre-operatively and 15% had class IV symptoms, whereas postoperatively, 40% of the survivors were class I and 2% were class IV.[5] The KCCQ improved over time by about 30 points, corresponding to a large, clinically important treatment effect. For reference, a 5-point change for this scale is regarded as a small but clinically meaningful change; a 10-point change is considered a moderately large change; and changes >20 points are large.[8] Notably, all 6 subscales of the KCCQ showed the same patterns of improvement. In addition, other measures of both functioning and well-being showed clinically meaningful improvements relative to the preoperative state indicating significant increases in psychological well-being, role functioning, social functioning, and self-efficacy with about a 50% reduction in the prevalence of depressive symptoms. Further insights into these changes will be provided by the second randomized trial in the STICH program, which compares medical therapy alone with medical

Figure 2



A box and whisker plot of the distribution of total index hospitalization costs for the 196 US patients with cost data. Diamond indicates mean; central bar, median; top and bottom of box, 75th and 25th percentiles, respectively. Error bars represent the minimum and maximum, and the plot truncates the baseline costs at $200,000. Two patients in the CABG-plus-SVR group and 1 patient in the CABG-only group were above this figure. The plot shows that the entire distribution of costs for the CABG-plus-SVR arm is shifted up (toward higher cost) relative to the CABG-alone arm indicating that the difference between the 2 arms is not driven by a small proportion of outlier values.

therapy plus CABG in ischemic heart failure patients eligible for CABG.[6]

Several small observational studies have previously reported on the QOL effects of SVR.[3,4] While they observed post-operative improvement in QOL, the small samples and lack of adequate controls made it impossible to discern what role the SVR had in creating the improvement. The 1,198-patient RESTORE registry reported a similar level of improvement in heart failure symptoms to that seen in STICH but was also unable to isolate the contribution of the SVR due to the absence of a control group.[2]

No prior study of SVR has reported on the incremental costs of the procedure in the US healthcare system. We expected the procedure to be at least modestly more expensive initially, as it required more operative time to perform relative to a CABG alone. Our study also shows that the postoperative course was more complex and required higher-intensity, ICU-based care than CABG alone. We cannot discern from our data whether the patient's clinical course prompted the extra use of PA catheters, balloon pumps, inotropic stimulants, and extra time in the ICU or whether this was chosen out of an abundance of caution by the surgeons, who were not blinded to the treatment assignment.

Caveats relevant to our QOL results are primarily those that pertain to the underlying trial. To the extent that a cohort of SVR-eligible patients exists who were not enrolled in the trial, perhaps because clinicians did not have equipoise regarding their enrollment, our results might not be generalizable to such patients. However, one advantage of a large international clinical trial is that differences in equipoise and decision-making among investigators will often result in enrollment of the same broad group of ischemic heart failure patients that are being considered for these procedures in clinical practices. We did not calculate medical costs for patients enrolled in STICH outside the United States, given the absence of suitable cost weights and the possible effects of differences in practice patterns. Although postoperative length of stay differences were smaller in the non-US centers, the CABG-plus-SVR group had a longer length of stay. Although the magnitude of the cost difference between the treatment arms might vary among centers, both in the United States and internationally, performing the SVR procedure clearly increased costs due to a more complex postoperative course, and there was no evidence at all of a late decrease in rehospitalization or repeat cardiac procedures that might have provided some offset of the higher initial costs. In economic terms, any procedure that costs more and does not provide some incremental patient outcome benefits is dominated, meaning that the alternative less costly and equally effective treatment would always be preferred.[18]

In summary, we found no evidence that adding surgical ventricular reconstruction to coronary bypass graft surgery provided any incremental improvements in QOL out to 3 years after surgery. Because SVR increases the complexity of postoperative care and consequently significantly increases the cost of the procedure over CABG alone, our results do not provide any justification for continued use of this procedure in STICH-eligible patients.

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Disclosures

Dr. John Spertus reports that he holds the copyright for the Kansas City Cardiomyopathy Questionnaire and the Seattle Angina Questionnaire. There are no other conflicts of interest to report.

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Appendix A. Supplementary data

Supplemental Table A. Additional QOL measures by intention to treat

	CABG alone	CABG + SVR	*P*
Seattle Angina Questionnaire			
Angina Frequency			
Higher scores = less frequent angina			
Baseline			
No. of patients	488	482	
Median (interquartile range)	70 (40-90)	80 (50-100)	.01
Mean ± SD	64 ± 30	69 ± 29	
4 m			
No. of patients	414	412	
Median (interquartile range)	100 (90-100)	100 (90-100)	.74
Mean ± SD	91 ± 17	91 ± 17	
12 m			
No. of patients	379	392	
Median (interquartile range)	100 (90-100)	100 (90-100)	.77
Mean ± SD	91 ± 16	91 ± 19	
24 m			
No. of patients	345	351	
Median (interquartile range)	100 (80-100)	100 (90-100)	.46
Mean ± SD	90 ± 17	91 ± 18	
36 m			
No. of patients	310	314	
Median (interquartile range)	100 (90-100)	100 (90-100)	.27
Mean ± SD	91 ± 18	92 ± 17	
Angina Stability			
Score of 50 = no change			
Baseline			
No. of patients	477	462	
Median (interquartile range)	50 (25-50)	50 (25-50)	.98
Mean ± SD	49 ± 29	49 ± 29	
4 m			
No. of patients	411	405	
Median (interquartile range)	50 (50-50)	50 (50-50)	.16
Mean ± SD	58 ± 20	59 ± 21	
12 m			
No. of patients	374	388	
Median (interquartile range)	50 (50-50)	50 (50-50)	.88
Mean ± SD	55 ± 17	55 ± 19	
24 m			
No. of patients	344	349	
Median (interquartile range)	50 (50-50)	50 (50-50)	.95
Mean ± SD	52 ± 15	52 ± 15	
36 m			
No. of patients	310	313	
Median (interquartile range)	50 (50-50)	50 (50-50)	.48
Mean ± SD	54 ± 16	53 ± 14	
QOL			
0-100 scale with higher scores representing better QOL			
Baseline			
No. of patients	484	478	
Median (interquartile range)	42 (25-67)	42 (25-67)	.86
Mean ± SD	45 ± 26	45 ± 25	
4 m			
No. of patients	413	410	
Median (interquartile range)	83 (67-100)	83 (58-92)	.39
Mean ± SD	76 ± 25	76 ± 23	
12 m			
No. of patients	381	391	
Median (interquartile range)	83 (67-100)	83 (67-100)	.65
Mean ± SD	78 ± 24	79 ± 22	
24 m			
No. of patients	347	349	
Median (interquartile range)	83 (58-100)	83 (67-100)	.15
Mean ± SD	75 ± 24	78 ± 23	
36 m			
No. of patients	309	314	
Median (interquartile range)	83 (67-100)	83 (67-100)	.68
Mean ± SD	77 ± 24	78 ± 22	
SF-12 Scales			
Scaled to a norm of 50 with a SD of 10			
Physical component			
Baseline			
No. of patients	433	426	
Median (interquartile range)	37 (33-41)	37 (33-42)	.71
Mean ± SD	37 ± 6	37 ± 6	
4 m			
No. of patients	353	352	
Median (interquartile range)	40 (36-43)	40 (36-43)	.57
Mean ± SD	40 ± 6	40 ± 6	
12 m			
No. of patients	343	336	
Median (interquartile range)	41 (37-43)	41 (38-45)	.15
Mean ± SD	40 ± 5	41 ± 5	
24 m			
No. of patients	303	301	
Median (interquartile range)	41 (37-44)	41 (37-44)	.64
Mean ± SD	40 ± 5	41 ± 5	
36 m			
No. of patients	278	277	
Median (interquartile range)	40 (36-44)	41 (38-45)	.07
Mean ± SD	40 ± 5	41 ± 5	
Mental component			
Baseline			
No. of patients	433	426	
Median (interquartile range)	42 (32-53)	41 (33-53)	.74
Mean ± SD	42 ± 13	42 ± 13	
4 m			
No. of patients	353	352	
Median (interquartile range)	54 (41-62)	55 (44-61)	.87
Mean ± SD	51 ± 13	51 ± 12	
12 m			
No. of patients	343	336	
Median (interquartile range)	57 (46-63)	54 (45-62)	.03
Mean ± SD	53 ± 12	52 ± 11	
24 m			
No. of patients	303	301	
Median (interquartile range)	56 (44-61)	55 (44-62)	.60
Mean ± SD	52 ± 12	52 ± 12	
36 m			
No. of patients	278	277	
Median (interquartile range)	56 (45-62)	56 (46-62)	.87
Mean ± SD	53 ± 12	53 ± 11	
SF-36 scales			
Scaled to a norm of 50 with a SD of 10			
SF-36 Mental Health Inventory 5			
Baseline			
No. of patients	489	481	
Median (interquartile range)	41 (32-50)	41 (35-50)	.91
Mean ± SD	42 ± 12	42 ± 12	

(continued on next page)

Appendix A *(continued)*

	CABG alone	CABG + SVR	*P*
4 m			
No. of patients	410	407	
Median (interquartile range)	50 (39-57)	50 (41-57)	.62
Mean ± SD	48 ± 12	49 ± 11	
12 m			
No. of patients	380	389	
Median (interquartile range)	53 (44-60)	50 (41-57)	.04
Mean ± SD	50 ± 11	49 ± 11	
24 m			
No. of patients	345	347	
Median (interquartile range)	50 (41-57)	50 (41-57)	.96
Mean ± SD	49 ± 12	49 ± 11	
36 m			
No. of patients	310	313	
Median (interquartile range)	50 (41-60)	50 (44-57)	.78
Mean ± SD	50 ± 11	49 ± 11	
Role physical			
Baseline			
No. of patients	466	466	
Median (interquartile range)	28 (28-35)	28 (28-42)	.74
Mean ± SD	35 ± 10	35 ± 10	
4 m			
No. of patients	400	393	
Median (interquartile range)	42 (28-56)	42 (28-56)	.61
Mean ± SD	42 ± 12	42 ± 12	
12 m			
No. of patients	372	389	
Median (interquartile range)	49 (35-56)	49 (35-56)	.78
Mean ± SD	45 ± 12	46 ± 11	
24 m			
No. of patients	340	339	
Median (interquartile range)	49 (28-56)	49 (35-56)	.94
Mean ± SD	45 ± 12	45 ± 12	
36 m			
No. of patients	308	309	
Median (interquartile range)	49 (35-56)	56 (35-56)	.29
Mean ± SD	46 ± 11	47 ± 12	
Role emotional			
Baseline			
No. of patients	482	477	
Median (interquartile range)	34 (24-55)	34 (24-55)	.82
Mean ± SD	39 ± 14	38 ± 14	
4 m			
No. of patients	409	402	
Median (interquartile range)	55 (34-55)	55 (34-55)	.48
Mean ± SD	45 ± 13	46 ± 13	
12 m			
No. of patients	377	384	
Median (interquartile range)	55 (45-55)	55 (45-55)	.69
Mean ± SD	47 ± 12	47 ± 12	
24 m			
No. of patients	341	344	
Median (interquartile range)	55 (45-55)	55 (34-55)	.63
Mean ± SD	47 ± 12	47 ± 12	
36 m			
No. of patients	306	308	
Median (interquartile range)	55 (45-55)	55 (45-55)	.90
Mean ± SD	48 ± 12	48 ± 12	
Social function			
Baseline			
No. of patients	490	485	
Median (interquartile range)	41 (30-52)	35 (30-46)	.36
Mean ± SD	39 ± 13	39 ± 13	

Appendix A *(continued)*

	CABG alone	CABG + SVR	*P*
4 m			
No. of patients	410	411	
Median (interquartile range)	52 (35-57)	52 (41-57)	.87
Mean ± SD	47 ± 12	47 ± 11	
12 m			
No. of patients	380	389	
Median (interquartile range)	52 (41-57)	52 (41-57)	.17
Mean ± SD	49 ± 10	48 ± 10	
24 m			
No. of patients	345	349	
Median (interquartile range)	52 (41-57)	52 (41-57)	.12
Mean ± SD	47 ± 11	49 ± 11	
36 m			
No. of patients	308	313	
Median (interquartile range)	52 (41-57)	52 (41-57)	.79
Mean ± SD	49 ± 10	49 ± 11	
Vitality			
Baseline			
No. of patients	489	480	
Median (interquartile range)	44 (37-51)	44 (37-49)	.31
Mean ± SD	44 ± 11	43 ± 10	
4 m			
No. of patients	410	409	
Median (interquartile range)	51 (42-59)	51 (44-59)	.42
Mean ± SD	51 ± 11	51 ± 10	
12 m			
No. of patients	380	390	
Median (interquartile range)	53 (44-59)	51 (44-59)	.66
Mean ± SD	52 ± 11	51 ± 11	
24 m			
No. of patients	345	347	
Median (interquartile range)	51 (44-59)	51 (44-61)	.32
Mean ± SD	51 ± 11	51 ± 10	
36 m			
No. of patients	309	313	
Median (interquartile range)	51 (44-59)	51 (44-61)	.43
Mean ± SD	51 ± 11	51 ± 11	
CES-D (% depressed)			
Baseline			
No. of patients	496	495	
Patients with depression	50.5	53.2	.40
4 m			
No. of patients	449	448	
Patients with depression	29.6	27.0	.42
12 m			
No. of patients	411	417	
Patients with depression	24.4	27.0	.41
24 m			
No. of patients	371	379	
Patients with depression	28.1	24.3	.25
36 m			
No. of patients	333	336	
Patients with depression	20.8	24.8	.25
Cardiac Self-Efficacy Questionnaire			
0-100 Scale with higher scores reflecting more patient confidence			
Maintain functioning			
Baseline			
No. of patients	487	481	
Median (interquartile range)	45 (25-63)	45 (25-67)	.40
Mean ± SD	46 ± 26	47 ± 26	

Appendix A *(continued)*

	CABG alone	CABG + SVR	*P*
4 m			
No. of patients	406	409	
Median (interquartile range)	61 (38-75)	63 (40-75)	.37
Mean ± SD	59 ± 27	61 ± 26	
12 m			
No. of patients	381	386	
Median (interquartile range)	65 (42-80)	64 (45-75)	.98
Mean ± SD	62 ± 27	62 ± 24	
24 m			
No. of patients	344	347	
Median (interquartile range)	63 (44-78)	65 (45-80)	.15
Mean ± SD	61 ± 26	64 ± 25	
36 m			
No. of patients	306	307	
Median (interquartile range)	58 (40-75)	63 (45-75)	.04
Mean ± SD	58 ± 26	63 ± 23	
Control symptoms			
Baseline			
No. of patients	487	482	
Median (interquartile range)	63 (47-75)	63 (47-75)	.75
Mean ± SD	62 ± 21	62 ± 22	
4 m			
No. of patients	412	409	
Median (interquartile range)	75 (62-91)	75 (61-88)	.72
Mean ± SD	73 ± 21	73 ± 19	
12 m			
No. of patients	381	387	
Median (interquartile range)	75 (63-91)	75 (63-88)	.77
Mean ± SD	74 ± 20	75 ± 18	
24 m			
No. of patients	346	347	
Median (interquartile range)	75 (63-92)	75 (61-88)	.52
Mean ± SD	73 ± 20	74 ± 20	
36 m			
No. of patients	311	314	
Median (interquartile range)	75 (63-84)	75 (63-91)	.12
Mean ± SD	72 ± 20	75 ± 18	
General Health Rating			
0 to 100 scale, 0=death, 100=excellent health			
Baseline			
No. of patients	466	458	
Median (interquartile range)	50 (40-70)	50 (40-70)	.60
Mean ± SD	53 ± 20	54 ± 20	
4 m			
No. of patients	387	389	
Median (interquartile range)	70 (50-80)	70 (60-80)	.14
Mean ± SD	67 ± 20	69 ± 19	
12 m			
No. of patients	367	370	
Median (interquartile range)	70 (50-80)	70 (60-80)	.57
Mean ± SD	69 ± 19	69 ± 18	
24 m			
No. of patients	338	339	
Median (interquartile range)	70 (50-80)	70 (60-80)	.15
Mean ± SD	66 ± 20	69 ± 19	
36 m			
No. of patients	298	303	
Median (interquartile range)	70 (60-80)	70 (55-80)	.84
Mean ± SD	69 ± 19	69 ± 19	
EuroQoL Visual Analog Scale			
0-100 scale; 0 = worst imaginable health, 100 = perfect health			
Baseline			
No. of patients	488	487	
Median (interquartile range)	50 (40-70)	50 (40-70)	.96
Mean ± SD	53 ± 21	54 ± 20	
4 m			
No. of patients	420	415	
Median (interquartile range)	70 (60-80)	70 (60-80)	.53
Mean ± SD	69 ± 19	69 ± 19	
12 m			
No. of patients	383	385	
Median (interquartile range)	72 (60-80)	70 (60-80)	.37
Mean ± SD	69 ± 19	69 ± 17	
24 m			
No. of patients	371	352	
Median (interquartile range)	70 (50-80)	70 (50-80)	.78
Mean ± SD	67 ± 21	67 ± 21	
36 m			
No. of patients	330	331	
Median (interquartile range)	70 (50-80)	70 (52-80)	.21
Mean ± SD	66 ± 20	67 ± 21	
EuroQoL Single Summary Index			
Baseline			
No. of patients	475	477	
Median (interquartile range)	69 (52-81)	69 (59-81)	.31
Mean ± SD	62 ± 28	64 ± 30	
4 m			
No. of patients	405	395	
Median (interquartile range)	85 (69-100)	85 (69-100)	.43
Mean ± SD	79 ± 25	79 ± 26	
12 m			
No. of patients	375	379	
Median (interquartile range)	85 (73-100)	85 (73-100)	.57
Mean ± SD	82 ± 22	81 ± 22	
24 m			
No. of patients	356	339	
Median (interquartile range)	85 (69-100)	85 (69-100)	.95
Mean ± SD	80 ± 24	80 ± 24	
36 m			
No. of patients	323	322	
Median (interquartile range)	85 (69-100)	85 (69-100)	.38
Mean ± SD	80 ± 25	81 ± 23	