Clinical Investigation

Perioperative Outcomes after On- and Off-Pump Coronary Artery Bypass Grafting

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Although numerous reports describe the results of off-pump coronary artery bypass grafting (CABG) at specialized centers and in select patient populations, it remains unclear how off-pump CABG affects real-world patient outcomes. We conducted a large, multicenter observational cohort study of perioperative death and morbidity in on-pump (ON) versus off-pump (OFF) CABG.

We reviewed Veterans Affairs Surgical Quality Improvement Program data for all patients (N=65,097) who underwent isolated CABG from October 1997 through April 2011 (intention-to-treat data were available from 2005 onward). The primary outcome was perioperative (30-day or in-hospital) death; the secondary outcomes were perioperative stroke, dialysis dependence, reoperation for bleeding, mechanical circulatory support, myocardial infarction, ventilator support ≥48 hr, and mediastinitis. Propensity scores calculated from age, 17 preoperative risk factors, and year of surgery were used to match 8,911 OFF with 26,733 ON patients.

In the complete cohort, compared with the ON patients (n=53,468), the OFF patients (n=11,629) had less perioperative death (2.02% vs 2.53%, P=0.0012) and lower incidences of all morbidities except perioperative myocardial infarction. In the matched cohort, perioperative death did not differ significantly between OFF and ON patients (1.94% vs 2.28%, P=0.06), but the OFF group had lower incidences of all morbidities except for perioperative myocardial infarction and mediastinitis. A subgroup intention-to-treat analysis yielded similar but smaller outcome differences between the ON and OFF groups.

Off-pump CABG might be associated with decreased operative morbidity but did not affect operative death, compared with on-pump CABG. Future studies should examine the effect of off-pump CABG on long-term outcomes. ***(Tex Heart Inst J 2014;41(2):144-51)***

In the United States, more than 350,000 coronary artery bypass grafting (CABG) operations are performed annually, either in isolation or as part of a more complex cardiac operation.[1] Identifying strategies that improve outcomes for CABG patients could have major socioeconomic implications.

There is ongoing controversy regarding the risks and benefits of on-pump (ON) versus off-pump (OFF) CABG. Some publications have associated OFF CABG with favorable outcomes,[2-10] but others have not.[11-19] Although there are ample data regarding the perioperative outcomes associated with these 2 revascularization strategies, these data have come mostly from small randomized trials or observational studies from dedicated off-pump centers. This makes it hard to apply the findings broadly to the average "real-world" cardiac surgical practice.

The specific objective of this study was to conduct a large, multicenter, retrospective review of all primary, isolated CABG procedures performed at Veterans Affairs (VA) hospitals and to compare risk-adjusted perioperative mortality and morbidity rates of patients who underwent ON CABG with those of patients who underwent OFF.

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Patients and Methods

Patient Population. The VA Surgical Quality Improvement Program (VASQIP) prospectively collects risk-and-outcome data on all patients who undergo cardiac surgery at any of 42 VA cardiac surgery centers.[20] After obtaining institutional review board approval and waiver of informed consent, we requested and received approval for the study from the Department of Veterans Affairs Surgical Quality Use Data Group (SQDUG). We received de-identified data for all patients (N=65,097) who underwent primary isolated CABG at the participating VA hospitals from October 1997 through April 2011. The data fields and definitions of the VASQIP were used. The VASQIP data collection form requires entry of a number for both cardiopulmonary bypass (CPB) and cross-clamp times. Neither field defaults to "0." Hence, a recorded CPB time of zero indicates an off-pump case. Patients who underwent reoperative CABG, any concomitant valve or great-vessel operation, or any operation for atrial fibrillation were excluded.

Outcome and Statistical Analyses. The primary outcome measure was perioperative death (30-day or in-hospital), and the secondary outcome measures were major perioperative morbidities, including stroke, renal failure necessitating dialysis, reoperation for bleeding, the requirement for mechanical circulatory support, perioperative myocardial infarction, ventilator use for ≥48 hours, and mediastinitis. Other outcome measures included operative times and hospital length of stay.

To adjust for baseline characteristic differences between the ON and OFF groups, we performed propensity score matching. To compute the propensity score, we included in the logistic regression variables that were statistically significant in univariate analyses or were considered clinically relevant. Covariates used for propensity scoring included age, sex, diabetes mellitus, prior myocardial infarction, chronic obstructive pulmonary disease, body mass index, peripheral vascular disease, cerebral vascular disease, serum creatinine level, current smoking status, functional status, New York Heart Association heart failure class, Canadian Cardiovascular Society angina class, American Society of Anesthesiology class, priority of surgical intervention, left main disease, 3-vessel disease, left ventricular ejection fraction, and year of surgery.

Using the propensity scores, a greedy matching algorithm matched 8,911 OFF with 26,733 ON patients. We evaluated the success of the propensity matching by making post hoc comparisons, using the Student *t* test for continuous data and the χ^2 test for categorical data. Baseline patient characteristics were similar in the matched OFF and ON patients.

The VASQIP started tracking planned versus unplanned conversions in October 2004. A planned conversion is generally defined as any conversion in which the surgeon's intention was to use CPB for at least part of the procedure, whereas an unplanned conversion is the use of CPB contrary to the surgeon's original intent. For the intention-to-treat analysis, we excluded from the OFF cohort all patients with planned conversions and included only those with unplanned conversions. Our intention-to-treat analysis was conducted on a cohort of patients (n=25,368) who underwent surgery during a period that covered 6 full years (2005–2010) and for whom complete conversion data were available. Within this subgroup, we propensity-matched 3,808 OFF patients with 11,424 ON patients.

All statistical analyses were conducted with the use of SAS version 9.1 (SAS Institute, Inc.; Cary, NC). A *P* value of <0.05 was considered statistically significant.

Results

Of all the patients who underwent isolated CABG during the study period, 17.9% (11,629 of 65,097) underwent off-pump CABG. Most patients in both the ON and OFF groups were male, but the ON and OFF groups had significant differences in their risk profiles (Table I). The ON patients received more bypass grafts than did the OFF patients (3.2 ± 0.89 vs 2.62 ± 1.04, *P* <0.0001). In addition, there was a marginally higher VASQIP-predicted risk of 30-day or in-hospital death (2.5% ± 3.1% vs 2.4% ± 3.1%, *P*=0.056) in the ON group, but the preoperative physician estimate of mortality risk was similar between the 2 groups.

Compared with the ON patients, the OFF patients had a lower incidence of perioperative death (2.02% vs 2.53%, *P*=0.0012) and of all major morbidities except for perioperative myocardial infarction (Table II). Operative times and lengths of stay were significantly longer in the ON group.

Matched Patients. It was possible to match 8,911 OFF patients with 26,733 ON patients by propensity score. The matched OFF and ON cohorts had mostly similar baseline characteristics (Table III). The ON patients received more bypass grafts than did the OFF patients (3.18 ± 0.89 vs 2.66 ± 1.03, *P* <0.0001), despite having a similar incidence of left main and 3-vessel coronary artery disease.

In the matched cohort, the OFF patients had marginally lower perioperative death than did the ON patients (1.94% vs 2.28%, *P*=0.06) (Table IV). The OFF group also had significantly lower incidences of all morbidities except for perioperative myocardial infarction and mediastinitis. The operative times and the hospital lengths of stay were significantly longer in the ON group.

In the intention-to-treat analysis group, the OFF and ON patients had similar perioperative mortality rates (1.79% vs 1.87%, *P*=0.73) (Table V). The OFF group also had a significantly lower incidence of renal

TABLE I. Risk Profile and Operative Variables: All Patients

Variable	Total (N=65,097)	On-Pump (n=53,468)	Off-Pump (n=11,629)	*P* Value
Age (yr)	65,097	63.8 ± 9	64.2 ± 9.3	<0.0001
Male sex	65,097	52,923 (99)	11,518 (99.1)	0.53
VASQIP PROM	64,859	2.5 ± 3.1	2.4 ± 3.1	0.056
Noncardiac risks				
Body mass index (kg/m^2)	64,995	29.3 ± 5.4	29 ± 5.4	<0.0001
Chronic obstructive pulmonary disease	65,094	13,187 (24.7)	3,130 (26.9)	<0.0001
Peripheral vascular disease	65,096	13,032 (24.4)	2,751 (23.7)	0.1
Cerebral vascular disease	65,095	11,208 (21)	2,795 (24)	<0.0001
Serum creatinine (mg/dL)	64,955	—	—	<0.0001
<1.5	—	45,980 (86.2)	9,736 (83.8)	
1.5–3.0	—	6,585 (12.4)	1,614 (13.9)	
>3.0	—	775 (1.5)	265 (2.3)	
Diabetes mellitus therapy	65,092	—	—	0.15
None	—	32,350 (60.5)	7,122 (61.3)	—
Oral	—	12,310 (23)	2,580 (22.2)	—
Insulin	—	8,804 (16.5)	1,926 (16.6)	—
LDL cholesterol ≥100 mg/dL	24,743	8,446 (43.3)	2,178 (41.7)	0.046
Current smoker	65,048	15,656 (29.3)	3,493 (30.1)	0.11
Pulmonary rales	65,093	3,107 (5.8)	586 (5)	0.0011
Functional status = independent	65,095	46,885 (87.7)	10,443 (89.8)	<0.0001
American Society of Anesthesiology class V	65,046	120 (0.2)	13 (0.1)	0.015
Cardiac risks				
Left ventricular ejection fraction ≤0.34	47,160	3,711 (9.9)	973 (10.2)	0.36
Prior myocardial infarction	65,096	27,428 (51.3)	5,761 (49.5)	0.0006
Percutaneous coronary intervention within 72 hrs	65,096	797 (1.5)	180 (1.6)	0.65
Preoperative use of intra-aortic balloon pump	65,086	2,853 (5.3)	525 (4.5)	0.0003
New York Heart Association functional class	65,075	—	—	<0.0001
I/II	—	38,338 (71.7)	8,638 (74.3)	—
III/IV	—	15,110 (28.3)	2,989 (25.7)	—
Canadian Cardiovascular Society angina class	65,074	—	—	<0.0001
I/II	—	16,929 (31.7)	4,454 (38.3)	—
III/IV	—	36,518 (68.3)	7,173 (61.7)	—
Current digoxin use	65,095	2,493 (4.7)	500 (4.3)	0.09
Left main stenosis >50%	62,629	12,657 (24.6)	2,358 (21.1)	<0.0001
3-vessel disease	62,813	30,317 (58.7)	5,285 (47.4)	<0.0001
Operative variables				
Nonelective surgical priority	65,084	9,999 (18.7)	1,838 (15.8)	<0.0001
Internal mammary artery used	65,097	48,939 (91.5)	10,722 (92.2)	0.018
No. total distal bypasses	65,097	3.2 ± 0.89	2.62 ± 1.04	<0.0001

LDL = low-density-lipoprotein; PROM = Predicted Risk of Mortality; VASQIP = Veterans Affairs Surgical Quality Improvement Program

Data are presented as mean ± SD or as number and percentage. $P < 0.05$ was considered statistically significant.

TABLE II. Surgical Outcomes: All Patients

Outcome	Total (N=65,097)	On-Pump (n=53,468)	Off-Pump (n=11,629)	*P* Value
Perioperative myocardial infarction	65,096	507 (1)	117 (1)	0.56
Renal failure necessitating dialysis	65,096	610 (1.1)	87 (0.8)	0.0002
Required new mechanical circulatory support	48,724	684 (1.8)	80 (0.8)	<0.0001
Mediastinitis	65,096	595 (1.1)	99 (0.9)	0.013
Reoperation for bleeding	65,096	1,221 (2.3)	201 (1.7)	0.0002
On ventilator ≥48 hr	65,096	3,590 (6.7)	604 (5.2)	<0.0001
Stroke	65,096	819 (1.5)	113 (1)	<0.0001
Operative death	65,097	1,354 (2.5)	235 (2)	0.0012
Total time in operating suite (hr)	64,827	6.16 ± 1.49	5.77 ± 1.4	<0.0001
Surgery time (skin incision to skin closure) (hr)	64,923	4.68 ± 1.3	4.2 ± 1.27	<0.0001
Hospital length of stay (d)	65,038	9.67 ± 12.18	8.92 ± 10.21	<0.0001

Data are presented as mean ± SD or as number and percentage. $P<0.05$ was considered statistically significant.

failure necessitating dialysis and a trend toward lower incidences of stroke, reoperation for bleeding, and ventilator use ≥48 hr. The operative times, but not the hospital lengths of stay, were significantly longer in the ON group.

Discussion

Our finding that off-pump CABG, compared with on-pump CABG, is associated with improved perioperative morbidity—but with similar perioperative death—is consistent with the findings of other studies.[9,10,17,21] The benefit of the off-pump approach in regard to perioperative death has always been difficult to establish, especially in randomized controlled trials.

The CABG Off or On Pump Revascularization Study (CORONARY), which enrolled 4,752 patients, is to date the largest randomized trial to investigate the relative efficacy of off-pump CABG.[22] That study found no significant differences between off-pump and on-pump CABG in regard to their effects on the rates of the composite primary outcome (the 30-day composite rates of death, myocardial infarction, stroke, or renal failure necessitating dialysis) or any of its individual components. However, the use of off-pump CABG, in comparison with on-pump CABG, significantly reduced the rates of reoperation for perioperative bleeding, acute kidney injury, and respiratory complications, but significantly increased the rate of early repeat revascularization. A follow-up report from the CORONARY study showed similar off- and on-pump outcomes at 1 year, including the need for revascularization.[23] The German Off-Pump Coronary Artery Bypass Grafting in Elderly Patients (GOPCABE) study focused exclusively on patients 75 years of age or older and reported no significant difference between on-pump and off-pump CABG with regard to the composite outcome of death, stroke, myocardial infarction, repeat revascularization, or new renal replacement therapy within 30 days and within 12 months after surgery.[24]

In contrast, 2 large observational studies arising from 2 different state registries associated off-pump CABG with reduced in-hospital mortality rates.[21,25] At a national level, the retrospective analysis of data from 42,477 CABG patients in the Society of Thoracic Surgeons (STS) National Database showed that the off-pump approach reduced risk-adjusted operative death (adjusted odds ratio=0.83, $P=0.03$) and numerous morbidity outcomes. However, that study focused on centers that perform more than 50 off-pump cases per year.[26]

In regard to studies of the VA population, a study of VASQIP CABG data performed in the late 1990s found less risk-adjusted perioperative death and morbidity in off-pump cases.[4] However, that study focused on the 9 VA centers that performed the highest percentage of off-pump cases at the time. In a seminal study conducted in the VA system, the Outcomes Following Myocardial Revascularization: On and Off Cardiopulmonary Bypass (ROOBY) trial, 2,203 patients at 18 participating VA medical centers were randomly assigned to undergo either on-pump or off-pump CABG.[18] There was no significant difference between treatment groups in the rates of the 30-day composite outcome of death or complications (reoperation, new mechanical support, cardiac arrest, coma, stroke, or renal failure) (7.0% and 5.6%, respectively; $P=0.19$). There were also no treatment-related differences in neuropsychological outcomes or the short-term use of major resources. It should be noted

TABLE III. Risk Profile and Operative Variables: Propensity-Matched Patients (3:1)

Variable	Total (n=35,644)	On-Pump (n=26,733)	Off-Pump (n=8,911)	*P* Value
Age (yr)	35,644	63.9 ± 8.9	63.9 ± 9.3	0.76
Male sex	35,644	26,461 (99)	8,828 (99.1)	0.48
VASQIP PROM	35,545	2.4 ± 2.9	2.4 ± 3	0.63
Noncardiac risks				
Body mass index (kg/m^2)	35,644	29.2 ± 5.3	29.3 ± 5.4	0.57
Chronic obstructive pulmonary disease	35,644	6,770 (25.3)	2,233 (25.1)	0.62
Peripheral vascular disease	35,644	6,396 (23.9)	2,129 (23.9)	0.95
Cerebral vascular disease	35,644	5,950 (22.3)	1,983 (22.3)	0.99
Serum creatinine (mg/dL)	35,644	—	—	0.72
<1.5	—	22,911 (85.7)	7,667 (86)	—
1.5–3.0	—	3,411 (12.8)	1,108 (12.4)	—
>3.0	—	411 (1.5)	136 (1.5)	—
Diabetes mellitus therapy	35,644	—	—	0.085
None	—	16,012 (59.9)	5,411 (60.7)	—
Oral	—	6,303 (23.6)	1,999 (22.4)	—
Insulin	—	4,418 (16.5)	1,501 (16.8)	—
LDL cholesterol ≥100 mg/dL	15,117	4,812 (43.5)	1,707 (42.2)	0.17
Current smoker	35,644	7,906 (29.6)	2,627 (29.5)	0.87
Pulmonary rales	35,642	1,403 (5.3)	449 (5)	0.44
Independent functional status	35,644	23,830 (89.1)	7,924 (88.9)	0.57
American Society of Anesthesiology class V	35,644	40 (0.2)	9 (0.1)	0.28
Cardiac risks				
Left ventricular ejection fraction ≤0.34	29,636	2,157 (9.7)	744 (10)	0.43
Prior myocardial infarction	35,644	13,338 (49.9)	4,440 (49.8)	0.91
Percutaneous coronary intervention within 72 hrs	35,644	376 (1.4)	138 (1.6)	0.33
Preoperative use of intra-aortic balloon pump	35,642	1,274 (4.8)	409 (4.6)	0.5
New York Heart Association functional class	35,644	—	—	0.25
I/II	—	19,244 (72)	6,470 (72.6)	—
III/IV	—	7,489 (28)	2,441 (27.4)	—
Canadian Cardiovascular Society angina class	35,644	—	—	0.44
I/II	—	9,105 (34.1)	3,075 (34.5)	—
III/IV	—	17,628 (65.9)	5,836 (65.5)	—
Current digoxin use	35,644	1,106 (4.1)	392 (4.4)	0.29
Left main stenosis >50%	35,644	5,941 (22.2)	1,967 (22.1)	0.77
3-vessel disease	35,644	14,397 (53.9)	4,773 (53.6)	0.63
Operative variables				
Nonelective surgical priority	35,644	4,344 (16.3)	1,438 (16.1)	0.8
Internal mammary artery used	35,644	24,638 (92.2)	8,212 (92.2)	0.98
No. total distal bypasses	35,643	3.18 ± 0.89	2.66 ± 1.03	<0.0001

LDL = low-density-lipoprotein; PROM = Predicted Risk of Mortality; VASQIP = Veterans Affairs Surgical Quality Improvement Program

Data are presented as mean ± SD or as number and percentage. $P < 0.05$ was considered statistically significant.

that less than a quarter of the patients screened in the ROOBY trial actually received a treatment assignment, so this study's findings may not be applicable to typical VA CABG patients.

A pooled analysis of more than 80 trials that compared on-pump and off-pump outcomes showed no significant differences in rates of postoperative myocardial infarction, stroke, renal insufficiency, or coronary reintervention.[16] However, off-pump CABG increased all-cause death compared with on-pump CABG. Of note, trials that reported only 30-day mortality rates showed no significant differences in mortality rates (risk ratio [RR]=0.63; 95% confidence interval [CI], 0.33–1.2), but trials that reported more than 30 days of follow-up manifested a significantly increased risk of death in association with off-pump CABG (RR=1.34; 95% CI, 1.08–1.67; *P*=0.009).

In our entire VA CABG cohort, the ON and OFF groups had significant differences in their risk profiles (Table I), including greater prevalence of cerebrovascu-

TABLE IV. Surgical Outcomes: Propensity-Matched Patients (3:1)

Outcomes	Total (n=35,644)	On-Pump (n=26,733)	Off-Pump (n=8,911)	*P* Value
Perioperative myocardial infarction	35,644	240 (0.9)	86 (1)	0.56
Renal failure necessitating dialysis	35,644	302 (1.1)	65 (0.7)	0.0012
Required new mechanical circulatory support	29,594	363 (1.6)	59 (0.8)	<0.0001
Mediastinitis	35,644	265 (1)	78 (0.9)	0.33
Reoperation for bleeding	35,644	612 (2.3)	148 (1.7)	0.0004
On ventilator ≥48 hr	35,644	1,823 (6.8)	476 (5.3)	<0.0001
Stroke	35,644	425 (1.6)	89 (1)	<0.0001
Operative death	35,644	609 (2.3)	173 (1.9)	0.06
Total time in operating suite (hr)	35,553	6.14 ± 1.46	5.8 ± 1.4	<0.0001
Surgery time (skin incision to skin closure) (hr)	35,566	4.67 ± 1.3	4.24 ± 1.27	<0.0001
Hospital length of stay (d)	35,613	9.61 ± 11.96	8.9 ± 10.18	<0.0001

Data are presented as mean ± SD or as number and percentage. $P<0.05$ was considered statistically significant.

TABLE V. Surgical Outcomes: Propensity-Matched Patients (3:1) in the Intention-to-Treat Subgroup

Outcomes	Total (n=15,232)	On-Pump (n=11,424)	Off-Pump (n=3,808)	*P* Value
Perioperative myocardial infarction	15,232	115 (1)	29 (0.8)	0.18
Renal failure necessitating dialysis	15,232	139 (1.2)	22 (0.6)	0.0008
Required new mechanical circulatory support	15,232	192 (1.7)	48 (1.3)	0.071
Mediastinitis	15,232	105 (0.9)	34 (0.9)	0.88
Reoperation for bleeding	15,232	229 (2)	58 (1.5)	0.059
On ventilator ≥48 hr	15,232	794 (7)	233 (6.1)	0.076
Stroke	15,232	165 (1.4)	39 (1)	0.051
Operative death	15,232	214 (1.9)	68 (1.8)	0.73
180-day death	15,232	304 (2.7)	111 (2.9)	0.4
Total time in operating suite (hr)	15,223	6.19 ± 1.44	5.93 ± 1.45	<0.0001
Surgery time (skin incision to skin closure) (hr)	15,220	4.72 ± 1.28	4.38 ± 1.34	<0.0001
Hospital length of stay (d)	15,227	9.13 ± 10.12	8.89 ± 10.49	0.22

Data are presented as mean ± SD or as number and percentage. $P<0.05$ was considered statistically significant.

lar disease, plasma creatinine ≥1.5 mg/dL, and chronic obstructive pulmonary disease in the OFF group. The ON group, in contrast, had a greater prevalence of New York Heart Association class III/IV, Canadian Cardiovascular Society angina class III/IV, left main disease, 3-vessel disease, and urgent or emergent operation. Therefore, it appears that surgeons were more likely to select the on-pump approach for "sicker hearts" and the off-pump technique for patients with other organ-system problems.

A consistent finding of our study (Tables I and III) and others is that off-pump patients receive fewer coronary bypass grafts than do on-pump patients,[14,16-18,27] except perhaps at dedicated, high-volume off-pump centers.[7] One possible explanation for this is that performing multiple grafts off-pump can be a technical challenge that might be overcome with experience. No doubt a greater prevalence of 3-vessel coronary artery disease in the ON group (Table I) could explain that group's greater number of bypass grafts, but in the matched cohort, where the numbers of patients with 3-vessel and left main disease were similar (Table III), the ON group still received more grafts than did the OFF group. In addition, Shroyer and colleagues[18] found that graft patency was lower in their off-pump group than in their on-pump group. Because graft patency and completeness of revascularization are associated with patients' survival,[28,29] longer-term outcomes might favor on-pump CABG. In fact, we recently reported that off-pump CABG is associated with diminished long-term survival in a veteran cohort.[30]

Limitations. Propensity matching helped us level the playing field in comparing the ON and OFF groups. However, as is true of observational studies in general, the possibility of unmeasured confounders and biases is a limitation. Center- and surgeon-level data were not available to us, so the effects of the learning curve for off-pump CABG and surgeons' experience could not be evaluated. Because VASQIP began tracking conversions (planned vs unplanned) from off-pump to on-pump surgery in October 2004, we performed our full-cohort analysis on an "as-treated" basis and supplemented it with an "intention-to-treat" subgroup analysis. Unplanned conversion from off-pump to on-pump CABG is generally associated with poor outcomes[31,32]; therefore, as expected, the as-treated analysis influenced the results in favor of the off-pump cohort.

Strengths. The study's strengths derive from its use of a large, robust, and validated prospective database that is mandatory for all VA cardiac centers and is known for its completeness; this database represents the real-world experience in the VA system. The clinical implication of this study is that for the average VA surgical practice, surgeons should evaluate their own expertise and their patients' condition when deciding whether to perform on-pump or off-pump revascularization. There should be no pressure to perform or avoid on-pump CABG. Rather, the focus should be on which surgical approach is best for the patient.

Conclusion. Off-pump CABG might be associated with a reduced incidence of major operative morbidity but did not affect operative death, compared with on-pump CABG. Future studies should examine the effect of the revascularization strategy on long-term outcomes. Further work is also needed to determine the applicability of these findings beyond the VA health system.

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