Trends Over Time in the Relative Use and Associated Mortality of On-Pump and Off-Pump Coronary Artery Bypass Grafting in the Veterans Affairs System

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IMPORTANT
Numerous studies have compared the results of on-pump and off-pump coronary artery bypass grafting (CABG), but little is known about how either the relative use of these procedures or their associated perioperative mortality have changed with time.

OBJECTIVE
To examine trends in off- and on-pump CABG use and outcomes over time.

DESIGN
Retrospective analysis of data from the Veterans Affairs Surgical Quality Improvement Program (VASQIP).

SETTING
Data were collected from 42 Veterans Affairs cardiac surgery centers.

PARTICIPANTS
All Veterans Affairs patients (n = 65,097) who underwent isolated primary CABG from October 1997 to April 2011.

INTERVENTIONS
Patients underwent either on-pump (ON) or off-pump (OFF) CABG.

MAIN OUTCOMES AND MEASURES
The percentages of ON vs OFF cases as a function of time. We also evaluated trends over time in rates of conversion from OFF to ON CABG, perioperative mortality (30-day or in-hospital), and VASQIP predicted risk of mortality.

RESULTS
The relative use of OFF CABG peaked at 24% in 2003, followed by a slow and mostly consistent decline to stabilize at about 19%. The conversion rate decreased with time and has stayed less than 3.5% since 2007 (P < .001). Perioperative mortality rates decreased over time for both ON and OFF CABG (P < .001) and have stayed less than 2% for the entire cohort since 2006. The mortality associated with converted cases was high regardless of the surgery year and exceeded the VASQIP predicted risk of mortality.

CONCLUSIONS AND RELEVANCE
There has been a decline in the relative use of OFF CABG in the Veterans Affairs system since 2003. This trend may affect the training of future generations in OFF surgery and influence conversion rates and outcomes.
Coronary artery bypass grafting (CABG) continues to be one of the most commonly performed procedures in the United States.1,2 The predominately older and male Veterans Affairs (VA) population, with its high prevalence of hyperlipidemia, hypertension, diabetes, and cigarette smoking, represents a population highly susceptible to coronary artery disease and the need for CABG.3 Every year, approximately 4000 isolated CABG procedures are performed in the VA system at 42 cardiac surgery facilities.3

Conventional CABG is performed with the patient on cardiopulmonary bypass (CPB). However, several physiologic derangements are associated with CPB, including thrombocytopenia, activation of complement factors, immune suppression, and inflammatory responses.4 Furthermore, manipulating an atherosclerotic ascending aorta during cannulation and cross-clamping can incur embolization and stroke risk. In an attempt to prevent CPB-related morbidity, some surgeons have advocated the use of off-pump (OFF) CABG, reporting favorable outcomes from using this strategy,5-8 whereas others have not found a significant benefit to OFF CABG.9-14 A high-profile study conducted in the VA system, the Outcomes Following Myocardial Revascularization: On and Off Cardiopulmonary Bypass (ROOBY) trial, reported no significant difference in perioperative outcomes from using this strategy,5-8 whereas others have not found a significant benefit to OFF CABG.9-14

Our hypothesis is that after an initial spate of enthusiasm for OFF CABG, interest in it may have waned with time and that this loss of interest will manifest as a decline in OFF cases after an earlier peak. The specific objectives of this study were to conduct a large, multicenter, retrospective review of all primary isolated CABG procedures performed at VA hospitals and to compare time trends in the use of on-pump (ON) vs OFF CABG. In addition, we evaluated trends in the rates of conversion from OFF to ON CABG and in perioperative mortality.

Methods

Patient Population

The VA Surgical Quality Improvement Program (VASQIP) prospectively collects risk and outcomes data on all patients who undergo cardiac surgery at any of 42 VA cardiac surgery centers.15 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. We evaluated data for all patients (n = 65 097) who underwent primary isolated CABG at the participating VA hospitals between October 1997 and April 2011. Patients who underwent reoperative CABG, any concomitant valve or great-vessel operation, or any other cardiac procedure were excluded. The data fields and definitions of the VASQIP were used.

The VASQIP data collection form requires entry of a number for both CPB and cross-clamp times. Hence, if a case is performed OFF, “0” is recorded for the CPB time. Neither field defaults to 0, which ensures that a recorded CPB time of 0 indicates an OFF procedure. The VASQIP started tracking the type of conversion (planned vs unplanned vs unknown conversions) in October 2004. A planned conversion is generally defined as any scenario in which the surgeon’s intention was to use CPB for at least part of the procedure, whereas an unplanned conversion is defined as the use of CPB in cases in which the surgeon had originally intended not to use it. However, as with all database definitions, users’ interpretations may vary. An intention-to-treat designation of ON vs OFF status was applied to the cohort of patients who underwent surgery over the period from January 2005 through December 2010 and for whom complete data sets on conversion were available (n = 25 368). Unplanned OFF to ON conversions were analyzed as OFF cases, and both planned conversions and conversions not known to be planned or unplanned were excluded from the intention-to-treat analysis. A subgroup analysis was conducted to evaluate the impact of the center’s OFF CABG volume on OFF CABG use trends and conversion rates. High-volume centers were defined as those that performed at least 50 OFF CABG cases per year in 2002 and 2003.

In the VASQIP database, each patient’s predicted risk of mortality (PROM) is reported. The PROM is automatically calculated by using a risk model developed from national VA data collected during the 3 years that immediately preceded the year of surgery. Correlation coefficients are calculated between the outcome (survival or death) and various potential preoperative risk factors. The most important, reliable, and objective risk factors are then used to prepare the risk-scoring system.16 The mean yearly VASQIP PROM values were calculated to serve as reference benchmarks for actual yearly mortality outcomes. Actual mortality rates lower than the mean PROM reflect an improvement in risk-adjusted outcomes with time; conversely, actual mortality rates higher than the mean PROM reflect a worsening in risk-adjusted outcomes with time.

Outcome and Statistical Analyses

The primary outcome measure was the annual percentage of ON vs OFF CABG cases. Other outcome measures included trends over time of perioperative mortality (90-day or in-hospital) and the rate of conversion from OFF to ON CABG. The mortality rates were calculated as raw percentages for each year of the study period. Significance of changes in use and mortality rates across time for continuous variables were determined using regression analysis and the F statistic. For dichotomous variables, we used logistic regression and the χ2 statistic. Both statistics test for a linear relationship with a nonzero slope. A P value < .05 indicated a statistically significant trend. All statistical analyses were conducted with SAS version 9.1 (SAS Institute Inc).

Results

Relative Use of ON vs OFF CABG

Of all the patients who underwent CABG during the study period, 17.9% (11 629 of 65 097) underwent OFF CABG. The relative use of OFF CABG peaked at 24% in 2003, followed by a slow and mostly consistent decline after that to stabilize at about 19% (Figure 1).
Mortality Rates
The perioperative mortality of the entire cohort has stayed less than 2% since 2006. Mortality rates decreased over time for both ON and OFF CABG (Figure 2) ($P$ trend value < .001 for both ON and OFF). In addition, the PROM decreased with time for both the ON and OFF cases ($P$ trend value < .001 for both ON and OFF). The trend was similar for the actual mortality and PROM for the intention-to-treat subgroup (Figure 3).

Conversions
The conversion rate decreased with time and has stayed less than 3.5% since 2007 (Figure 4) ($P$ trend value < .001). The PROM for converted cases was around 2% between 2005 and 2010, but the actual mortality of converted cases was 3.8%. In fact, actual mortality reached a high (10% and 9.5%, respectively) for unplanned conversions in 2008 and 2010 (Table).

Impact of Center Volume
Only 7 of the 42 centers qualified as high-volume OFF CABG centers. These centers witnessed no decline in the use of OFF CABG, which stood at 54% in 2003 and fluctuated between 51% and 58% thereafter. The high-volume centers had a lower overall conversion rate than the low-volume centers (1.8% vs 3.6%; $P$ < .001).

Discussion
In the 42 cardiac surgery centers of the VA system, the use of OFF CABG peaked a decade ago, when almost a quarter of all isolated CABG cases were performed OFF (Figure 1). This reflects the reality that although OFF CABG offers the advantage of avoiding CPB and aortic manipulation, it is an inherently more technically difficult operation to perform. In addition, in general, there has been no evidence of a clear benefit of OFF CABG in terms of hard clinical endpoints. From a patient’s perspective, both ON and OFF CABG are typically associated with a sternotomy incision and thus are perceived to be equally invasive. Therefore, many surgeons have little incentive to perform OFF CABG on a routine basis, and it is unlikely that there will be any resurgence of OFF CABG in the foreseeable future.

The results of the ROOBY trial\textsuperscript{15,16} and a recent Cochrane pooled analysis\textsuperscript{13} of more than 80 trials that compared ON and OFF favored the short- and mid-term outcomes of ON CABG. But there are also convincing data in favor of OFF. The Coronary Artery Bypass Surgery Off or On Pump Revascularization Study (CORONARY), the largest randomized trial to date to investigate the relative efficacy of OFF CABG,\textsuperscript{19} reported that the use of OFF CABG, as compared with ON CABG, significantly reduced the rates of reoperation for perioperative bleeding, acute kidney injury, and respiratory complications but increased the rate of early repeated revascularization. At 12...
months after CABG, CORONARY reported similar outcomes for the ON and OFF cohorts. The CORONARY study incorporated higher-risk patients and involved experienced OFF surgeons.

Two large observational studies associated OFF CABG with reduced in-hospital mortality. An analysis of the Society of Thoracic Surgeons National Database showed that the OFF approach reduced risk-adjusted operative mortality and numerous morbidity outcomes. However, the study focused on centers that perform more than 50 OFF cases per year.

The OFF approach has its avid advocates among surgeons and at dedicated OFF centers that report excellent outcomes. In addition, the OFF strategy is particularly useful for patients with hostile aorta and certain high-risk patient profiles. Therefore, OFF is a valuable technique in the armamentarium of cardiac surgeons and is here to stay, but its use rate has plateaued, as shown by our data, and is unlikely to increase in the foreseeable future.

The reduction in the perioperative mortality of both ON and OFF CABG with time is consistent with, and an extension of, a national trend in CABG mortality reported for the 1990s. Because the VASQIP PROM is time sensitive and continuously updated with data from the 3 years preceding the year of surgery, a decrease in PROM with time represents a decline in risk-adjusted mortality (Figure 2). We believe that part of this effect is probably due to the continuous feedback of the data to physicians who are caring for the patients and the use of the VASQIP database by the VA for quality control and program oversight. This, coupled with improvement in technology and perioperative care, has undoubtedly contributed to better CABG outcomes.

The overall conversion rate decreased over time from more than 5% in 2005 to less than 2% in 2010 (Figure 4). Contemporary OFF CABG series from experienced centers report a conversion rate around 2%. One can speculate that over time, surgeons gained more experience and were therefore less likely to convert when faced with anatomic and technical challenges, including difficult target exposure and intramyocardial or small targets. In our study, the decline in unplanned conversions with time was modest (from 1.5% to 0.6%) and was not the main factor driving the decrease of the overall conversion rate. But because unplanned conversions are typically related to hemodynamic instability, experience may be of limited help in mitigating the risk associated with such conversions.

What is clear from our data is that converted cases are associated with increased mortality (Table). Conversion from OFF to ON CABG is generally associated with poor outcomes. In fact, a recent meta-analysis reported that, overall, conversion increased mortality risk by an odds ratio of 6.18 (95% CI, 4.65-8.20), whereas emergency conversion further raised the odds ratio of mortality to 6.99 (95% CI, 5.18-9.45).

The impact of surgical volume on use rates of OFF CABG and conversion rates highlights the importance of experience in choosing a revascularization strategy. In the VA system, it appears that the overall decline in OFF use is primarily driven by the lower-volume OFF centers, which constitute the majority of the centers.

Our study is limited by the absence of center- and surgeon-level data, so the effects of the learning curve for OFF CABG and surgeons’ experience on OFF use, conversion rates, and outcomes could not be evaluated. The conversion rate varied widely (0%-55%) across surgeons in the ROOBY trial. Because our data were not derived from a trial designed to specifically capture all conversions from OFF to ON CABG, it is possible that we may not have captured all conversions and, therefore, that we underestimated the conversion rate. In addition, the classification of planned vs unplanned conversions is limited because it is subject to the surgeon’s and data manager’s interpretation of the database definitions. 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, thus representing the “real-world” experience in the VA system.

The clinical implication of this study is that for the average VA surgical practice, there should be no pressure to either perform or avoid ON CABG. Rather, the focus should be on
which is the best approach for the patient. Converted cases have higher mortality, and this should be considered when planning an operation and in the formulation of the perioperative care. High-volume OFF centers are best suited to taking on the challenge of training future surgeons in valuable OFF skills, and the routine use of OFF CABG might someday be confined to these high-volume centers.

In conclusion, the rate of use of OFF CABG has decreased and reached a stable plateau. Perioperative mortality has decreased consistently over time for both OFF and ON CABG, but the mortality associated with converted cases is high and does not follow this trend. Further work is needed to determine the generalizability of these findings beyond the VA health system.

REFERENCES
On- or Off-Pump Coronary Artery Bypass Grafting
How Are You Trending?
Edward Y. Sako, MD, PhD

In the ongoing effort to improve the care of our patients, certain dogmas are continually examined and questioned. Well over a decade ago, the need to place a patient on cardiopulmonary bypass (the pump) to arrest the heart to perform coronary artery bypass grafting was challenged. The techniques and maneuvers required, along with the marketing of a variety of devices to aid in the procedure, were widely disseminated. The requisite comparison studies then ensued, pitting the benefits of avoiding the adverse effects or complications associated with the pump against the potential for less than optimal grafting with its associated long-term problems. In the end, the practicing cardiac surgeon had to make a decision about how to perform the most common operation in our specialty.

By now, most cardiac surgeons have been exposed to the concept of off-pump coronary artery bypass grafting (OFF CABG), with a good number having tried it at one point or another. Many have made up their mind as to where in their armamentarium this procedure lies. In this regard, the article by Bakaeen et al1 is very timely. The investigators used the well-established Veterans Affairs cardiac surgery database to examine the use of OFF CABG from the period of introduction to very recently. Though criticized because of the restriction to Veterans Affairs facilities, this database is still a pioneer in the creation of a risk-stratified collection of outcomes of every cardiac procedure performed in the system.2 Studies of the treatment of coronary artery disease in this population also are widely applicable to the male population of the United States at risk because the risk factors are mirrored in the 2 groups.

The results of this study were confirmatory to many of us in the field, namely, that the use of OFF CABG peaked some years ago and has since declined and then stabilized. Furthermore, a breakdown of the individual centers showed that a select number continues to contribute the majority of cases. This, too, appears to be in line with what one sees. Certain centers (surgeons) continue to feel comfortable with and are very proficient with the technically challenging operation and thus apply it as their procedure of choice.

Where to go from here? It is clear that OFF CABG will continue to have a role in the foreseeable future. Its use will continue to be driven by those who feel comfortable with the technique and this will not necessarily be a result of formal training. Results of such studies as the Outcomes Following Myocardial Revascularization: On and Off Cardiopulmonary Bypass (ROOBY) trial, which suggested less effective graft patency in the OFF CABG group, may not apply to all surgeons.3 This and future studies will continue to refine the optimal indications.

REFERENCES