

Five-Year Outcome After Off-Pump or On-Pump Coronary Artery Bypass Grafting in Elderly Patients

Editorial, see p 1872

BACKGROUND: The 30-day and 1-year follow-up analysis of the GOPCABE trial (German Off-Pump Coronary Artery Bypass Grafting in Elderly Patients) revealed no significant difference in the composite end point consisting of death, stroke, myocardial infarction, new renal replacement therapy, or repeat revascularization. The 5-year follow-up data of this trial are reported here.

METHODS: From June 2008 to September 2011, a total of 2539 patients aged ≥ 75 years were randomly assigned to undergo off-pump or on-pump coronary artery bypass grafting (CABG) at 12 centers in Germany. The primary outcome was all-cause mortality at 5 years. The secondary 5-year outcomes were a composite of death, myocardial infarction, and repeat revascularization. Furthermore, the impact of complete versus incomplete revascularization was assessed.

RESULTS: After a median follow-up of 5 years, 361 patients (31%) assigned to off-pump CABG and 352 patients (30%) assigned to on-pump CABG had died (hazard ratio off-pump/on-pump CABG, 1.03; 95% CI, 0.89–1.19; $P=0.71$). The composite outcome of death, myocardial infarction, and repeat revascularization occurred in 397 (34%) after off-pump and in 389 (33%) after on-pump CABG (hazard ratio, 1.03; 95% CI, 0.89–1.18; $P=0.704$). Incomplete revascularization occurred in 403 (34%) patients randomly assigned to off-pump and 354 (29%) patients randomly assigned to on-pump CABG ($P<0.001$). Five-year survival rates were 72% (95% CI, 67–76) with incomplete versus 76% (95% CI, 74–80) with complete revascularization (log-rank test: $P=0.02$) after off-pump CABG and 72% (95% CI, 67–76) versus 77% (95% CI, 74–80) after on-pump CABG (log-rank test: $P=0.03$), respectively. Cox regression analysis revealed a hazard ratio incomplete/complete revascularization of 1.19 (95% CI, 1.01–1.39; $P=0.04$).

CONCLUSIONS: In elderly patients ≥ 75 years of age, the 5-year survival rates and the combined outcome of death, myocardial infarction, and repeat revascularization, as well, were similar after on-pump and off-pump CABG. Incomplete revascularization was associated with a lower 5-year survival rate, irrespective of the type of surgery.

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Clinical Perspective

What Is New?

- Off-pump and on-pump coronary artery bypass grafting provide similar long-term outcomes in elderly patients.
- Incomplete revascularization was associated with a lower 5-year survival rate, irrespective of the type of surgery.

What Are the Clinical Implications?

- In elderly patients with coronary heart disease undergoing coronary artery bypass grafting, the operative technique is not decisive, either for short-term or for long-term outcomes.
- Incomplete revascularization, however, may be associated with reduced late survival.

Numerous studies have compared on-pump and off-pump coronary artery bypass grafting (CABG). These efforts eventually culminated in 3 large-scale trials,¹⁻³ totaling nearly 10 000 randomly assigned patients. All 3 trials found no difference in outcomes after off-pump CABG in comparison with on-pump CABG, with similar rates of death, myocardial infarction, stroke, new dialysis, or repeat revascularization within 30 days and 1 year after surgery, respectively. After 5 years, 2 trials reported conflicting results with respect to survival and major adverse events.^{4,5} A consistent feature of all 3 trials was that patients who were operated on off-pump received fewer grafts than the respective on-pump cohort. In the GOPCABE trial (German Off-Pump Coronary Artery Bypass Grafting in Elderly Patients) a higher number of patients in the off-pump group received fewer coronary grafts than initially planned.³ This raises questions about the clinical long-term efficacy and durability of off-pump CABG. Extended follow-up of the GOPCABE study population should clarify the long-term impact of the operative technique and the completeness of revascularization.

METHODS

The data that support the findings of this study are available from the corresponding author on reasonable request.

Study Oversight

The GOPCABE trial has been described in detail previously.³ In brief, the GOPCABE trial was a prospective, randomized multicenter trial conducted at 12 German institutions. These study centers were all proponents of off-pump CABG and nominated surgeons experienced with both surgical techniques to ensure the best medical outcome. For the enrollment of patients planned for surgical revascularization, the qualifying criterion was age of at least 75 years. A unique

feature of the trial was that neither morphological characteristics like small, diffusely diseased vessels nor impaired left ventricular function were exclusion criteria. During the study period, all potentially eligible patients were registered in a study log, resulting in an all-comers study design with a well-defined, representative patient sample. A certified ethics committee and the local institutional review board of each participating center approved the study protocol. All patients gave written, informed consent, which included the collection of prolonged follow-up information.

Follow-Up Outcome

Follow-up information was obtained by telephone calls from patients, their next of kin, or their primary care physicians. Study sites were encouraged to acquire follow-up information on a yearly basis but at least once at 5 years after surgery. Data collection and data clearing were performed at the Herz- und Gefäß-Klinik GmbH, Bad Neustadt Germany.

For the 5-year follow-up study, the primary end point was all-cause mortality. Additional outcome events were the rate of myocardial infarction and repeated coronary revascularization.

There was no external funding to support the follow-up, but the corresponding author received an internal institutional grant for data management and trial organization.

Completeness of Revascularization

Before randomization, the anticipated number of grafts and information about the corresponding target vessels were required to be entered into the data template. Revascularization was defined as complete when the number of performed coronary anastomoses was equal to or higher than the number of anticipated anastomoses. Vice versa, when the performed number of coronary anastomoses was lower than expected, myocardial revascularization was recorded as incomplete.

Statistical Analysis

The initial study population consisted of 2403 randomly assigned patients. The study population for this analysis included all randomly assigned patients with available data 1 year after randomization (2370 patients; 98.6% of the initial study population). Analysis was performed according to the intention to treat.

Overall survival rates were analyzed using Kaplan-Meier plots, and a comparison between on-pump and off-pump CABG was performed with the log-rank test. Long-term outcomes for complete versus incomplete revascularization are reported as time-to-event analysis using Cox regression, after testing the assumption of proportional hazards. The treatment effect is expressed as the hazard ratio with 95% CIs, derived from the Cox proportional hazards model.

RESULTS

Enrollment, Randomization, and Follow-Up

Enrollment, randomization, and follow-up of the GOPCABE study population has been described previously³ and is shown in [Figure 1 in the online-only Data Supplement](#)

ment. From June 2008 to September 2011, 2539 patients were randomly assigned to on-pump or off-pump CABG. Between randomization and surgery, 136 patients were excluded because of the unavailability of the designated study surgeon for an urgent operation, a necessary additional cardiovascular procedure, or withdrawn patient consent. Allocated surgery by a designated study surgeon was performed in 2403 patients. For 2394 patients, the primary end point, a combination of death, myocardial infarction, stroke, new renal replacement therapy, or repeat revascularization within 30 days after surgery, could be evaluated. One year after surgery, the data of 2370 patients were available for analysis of the primary end point. Baseline characteristics of these patients are shown in Table I in the online-only Data Supplement. Follow-up information after ≥ 5 years regarding the vital status and eventually the date of death could be obtained in 2206 patients, representing 92% of the entire study population. The trial observed 11 260 patient-years with an average mortality rate of 6.3% per year (95% CI, 5.9–6.8). The deceased 713 patients had a median survival period of 3.3 years; the remaining surviving patients had a median follow-up time of 5.3 years.

Survival

During follow-up, 361 patients assigned to off-pump and 352 patients assigned to on-pump died. Five-year survival of the entire cohort was 75.4% (95% CI, 74–77), 75.4% (95% CI, 73–78) for the off-pump group and 75.5% (95% CI, 73–78) for the on-pump group, respectively. The hazard ratio for off-pump versus on-pump CABG was 1.03 (95% CI, 0.89–1.19; $P=0.71$; Table, Figure 1).

Myocardial Infarction and Repeat Revascularization

During follow-up, 36 myocardial infarctions and 77 repeat revascularizations were recorded, with no significant differences between the groups (Table).

Table. Five-Year Outcome Events

Outcome	Off-Pump CABG	On-Pump CABG	Hazard Ratio (95% CI)	P Value
Death	361/1179 (31)	352/1191 (30)	1.03 (0.89–1.19)	0.71
Myocardial infarction	21/993 (2.1)	15/991 (1.5)	1.69 (0.78–3.7)	0.181
Repeat revascularization	43/1025 (4.1)	34/1023 (3.2)	1.34 (0.83–2.15)	0.228
Composite*	397/1179 (34)	389/1191 (33)	1.03 (0.89–1.18)	0.704

Data are shown as number/total number (%). CABG indicates coronary artery bypass grafting.

*Composite outcome consisting of death, myocardial infarction, and repeat revascularization within 5 years after surgery.

Completeness of Revascularization

Incomplete revascularization with fewer anastomoses than anticipated occurred more often in patients assigned to off-pump CABG (34% versus 29%; $P<0.001$). In 403 of the 1187 patients (34%) assigned to off-pump CABG, fewer coronary anastomoses were performed than anticipated. The survival rate of this subgroup was 72% (95% CI, 67–76) versus 76% (95% CI, 74–80) of the group with complete revascularization (log-rank test $P=0.02$; Figure 2).

In the on-pump group, 354 of the 1207 patients (29%) were revascularized with fewer grafts than anticipated. Their survival was 72% (95% CI, 67–76) versus 77% (95% CI, 74–80) for the group of patients with a complete revascularization (log-rank test: $P=0.03$; Figure 2).

In both groups, patients with complete and incomplete revascularization were structurally different with unevenly distributed baseline characteristics. In the off-pump group (Table II in the online-only Data Supplement), the incompletely revascularized patients were more often male, older, had a higher logistic EuroSCORE,⁶ and a higher percentage of an impaired left ventricular function and pulmonary hypertension. In the on-pump cohort (Table III in the online-only Data Supplement), patients with incomplete revascularization had a higher logistic EuroSCORE, a higher proportion of peripheral artery disease, insulin-dependent diabetes mellitus, and a recent myocardial infarction. Incomplete revascularization was associated with decreased long-term survival with similar survival curves for both operative techniques (Figure 2). For the entire patient cohort, Cox regression analysis for all-cause mortality revealed a hazard ratio regarding incomplete/complete revascularization of 1.19 (95% CI, 1.01–1.39; $P=0.04$).

DISCUSSION

The GOPCABE trial compared off-pump CABG with on-pump CABG in 2394 elderly patients who were at least 75 years old. Five years after surgery there was no significant difference between the groups regarding death, myocardial infarction, and repeat revascularization. It seems intuitive that avoidance of the extracorporeal circulation may offer a benefit early after the CABG procedure with less inflammation and embolization. However, the technique of an arrested heart may result in a better quality of each single anastomosis and more complete revascularization, which may lead to a better short- and long-term outcome. None of these possible consequences were apparent in the GOPCABE trial.

The currently published evidence on long-term outcome after off-pump versus on-pump CABG is inconclusive. A propensity-matched study using data of the New York State Cardiac Surgery reporting system

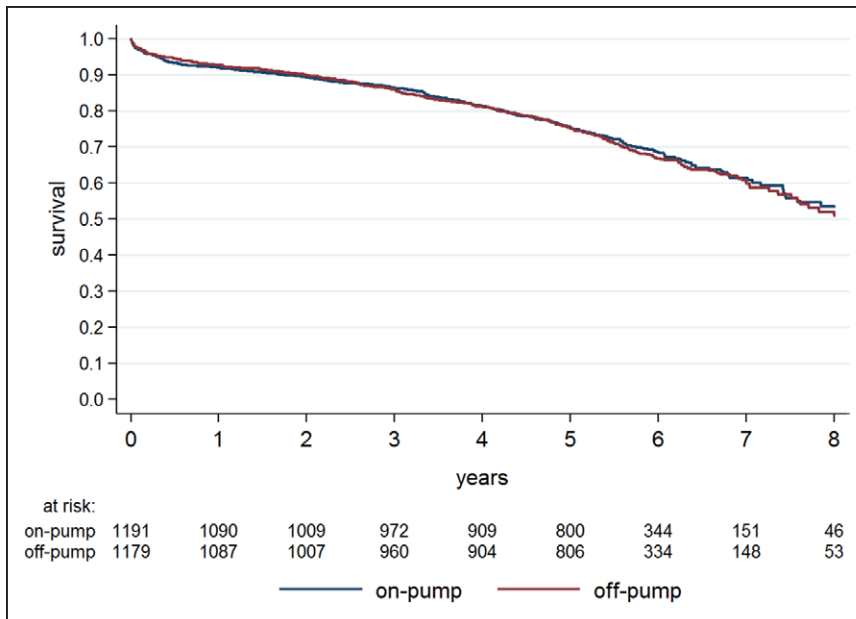


Figure 1. Long-term survival after on-pump or off-pump coronary artery bypass grafting (CABG).

Kaplan-Meier survival curves of patients scheduled to off-pump (red line) or on-pump (blue line) CABG.

found a lower risk of death within 30 days for off-pump CABG, but no significant difference between on-pump and off-pump CABG after 7 years.⁷ A comparable analysis using data from a Korean registry revealed similar 30-day and 1-year survival rates for on-pump and off-pump CABG, but a survival disadvantage for off-pump CABG after a median follow-up of 6.4 years.⁸ One meta-analysis of 11 randomized, controlled trials with follow-up time ranging from 1 to 6 years found a survival disadvantage for off-pump CABG.⁹

In a comparison of our results with the recent large-scale multicenter studies of off-pump CABG versus on-pump CABG,^{4,5} equivalent 5-year survival is in line with the CORONARY trial (CABG Off or On Pump Re-

vascularization Study).⁴ However, it is contrary to the findings of the ROOBY trial (Outcomes Following Myocardial Revascularization: On and Off Cardiopulmonary Bypass), in which an increased mortality and higher rate of graft failure were observed in patients undergoing off-pump CABG.⁵ The most cited limitation of the ROOBY trial addressed the level of experience of the participating surgeons.¹⁰ The median prestudy off-pump CABG experience of the surgeons who had participated in the GOPCABE trial was 322 procedures, in comparison with >100 procedures in the CORONARY trial and a median of only 50 off-pump procedures in the ROOBY trial.

At 5 years, the mortality rate in the GOPCABE study population was higher than the respective rates of

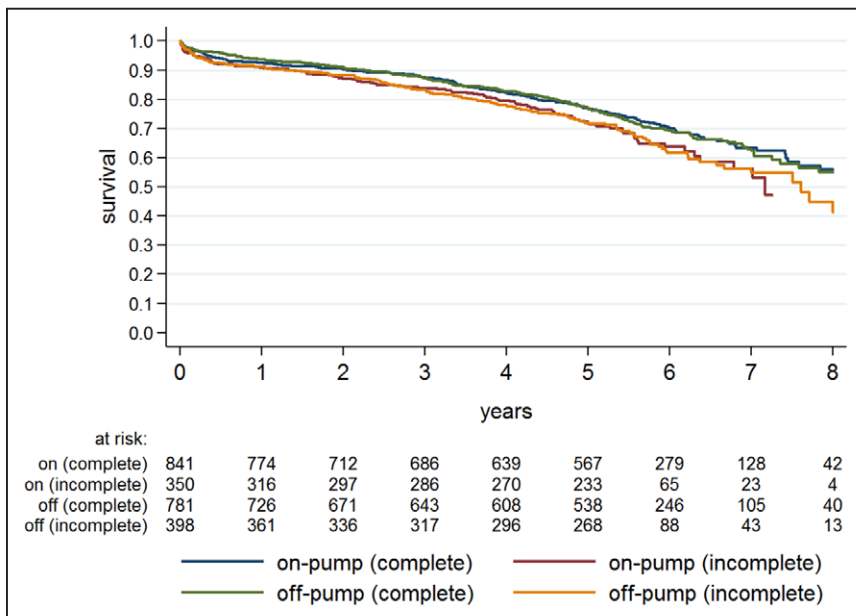


Figure 2. Survival after complete and incomplete revascularization.

Kaplan-Meier survival curves of patients scheduled to off-pump or on-pump coronary artery bypass grafting (CABG) with either complete or incomplete revascularization.

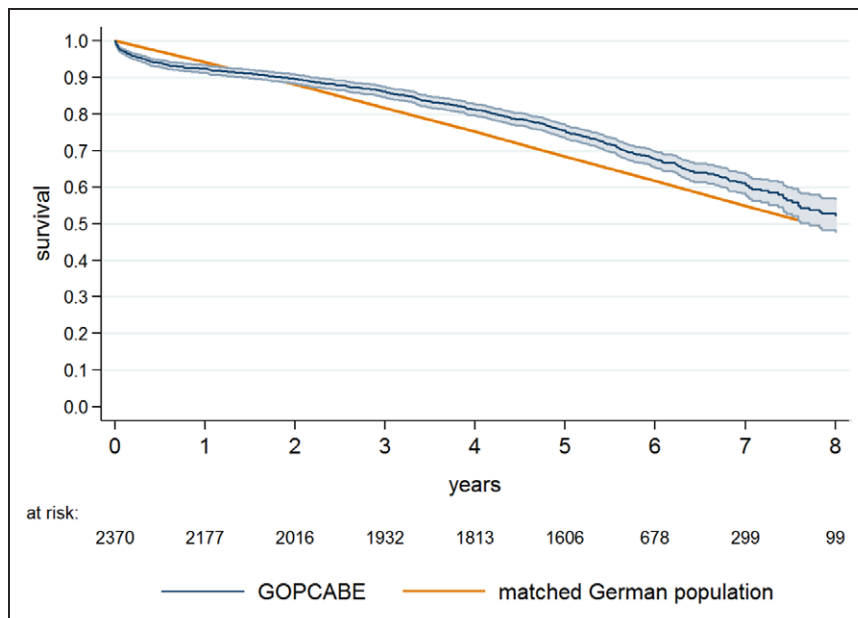


Figure 3. Survival of the GOPCABE (German Off-Pump Coronary Artery Bypass Grafting in Elderly Patients) patient population in comparison with the general population.

Kaplan–Meier survival curve of the whole GOPCABE study cohort with 95% CIs (blue line) and the expected survival rate of an age- and sex-matched German population (orange line), calculated according to the mortality table derived from the Bundesamt für Statistik.¹¹

death in the CORONARY⁴ and ROOBY⁵ trials (25.4% versus 14.1% and 13.6%, respectively). GOPCABE exclusively enrolled elderly patients with a mean age of 78 years versus 68 years in the CORONARY trial and 63 years in the ROOBY trial, respectively. Thus, a higher all-cause mortality rate was expected. Comparison of the survival curves of the GOPCABE population with an age- and sex-matched population (Figure 3) demonstrates an increased risk of death shortly after surgery. Thereafter, the GOPCABE survival curve followed a flattened course, crossing the survival curve of the general population at 1.5 years and showing a higher survival rate within the next 5 to 6 years. This is consistent with a recent publication from a Swedish registry showing superior life expectancy in patients undergoing CABG at >55 years in comparison with the general population.¹² This survival benefit for patients undergoing CABG is remarkable, considering that patients with coronary heart disease treated medically or with percutaneous coronary intervention (PCI) had a midterm survival similar to the general population.¹³

The second important finding in the GOPCABE trial is that patients who received fewer revascularized coronary vessels than initially planned showed an inferior survival during the 5-year follow-up. It is interesting to note that this was irrespective of the operative technique. There are many definitions characterizing complete or incomplete revascularization.¹⁴ The absence of a universal definition makes comparisons among studies examining completeness of revascularization challenging. However, a similar definition for the completeness of revascularization was used in 1 study investigating the SYNTAX trial (Synergy between PCI with TAXUS and Cardiac Surgery) population.¹⁵ In this analysis, patients were categorized as incompletely revascularized if the

number of treated coronary segments was lower than anticipated. Incomplete revascularization was more common in patients treated by PCI (PCI 43%; CABG 37%). Incompletely revascularized patients had a lower, albeit not significantly different 3-year survival rate and a higher rate of major adverse cardiovascular events in the PCI arm.

Incomplete revascularization according to our applied definition occurred in 29% of all patients assigned to on-pump CABG and in 34% of those assigned to off-pump CABG. This absolute 5% difference is likely to be the result of the more challenging off-pump technique. However, incomplete revascularization was a rather common event in both groups and occurred in one-third of all patients, irrespective of the operative technique. Various reasons may be responsible for an incomplete revascularization: (1) preoperative misjudgment of the number of necessary and graftable vessels; (2) calcified target vessels; (3) target vessels that cannot be identified (eg, because of an intramuscular course); (4) difficult exposure (eg, because of hemodynamic instability); and (5) target vessel corresponding to an infarcted scar area without reasonable viable myocardium. Only 2 reasons (numbers 3 and 4) can be related to the applied surgical method, namely off-pump. In contrast, all reasons from 2 to 5 are related to the preoperative morbidity of the patient. To which extent preexisting factors or the incomplete revascularization itself leads to the final result of reduced survival cannot be determined. It is, however, reasonable to assume that incomplete revascularization reflects, to some degree, the severity of coronary heart disease and, hence, it may be a surrogate marker for a worse prognosis. Both subgroups of patients with incomplete revascularization showed significant differences in baseline characteristics. Taken

together, incomplete revascularization characterized a structurally different patient group, with incomplete revascularization occurring in sicker patients. The difference in baseline characteristics and the bias in favor of complete revascularization is well known from analysis of multiple trials and registries.¹⁴ All efforts to adjust for these differences with multivariate regression are limited and no propensity matching would be able to eliminate the bias of additional confounders when one patient group is obviously sicker than the other. Accordingly, the inability to achieve a complete revascularization may be considered as the manifestation rather than the cause of a worse patient prognosis. However, given the worse prognosis that was observed, every effort should be undertaken to achieve a complete revascularization whenever possible.

Limitations

The study results were based on information provided by the telephonically performed follow-up 5 years after surgery. Practical problems in communicating with the large number of elderly, chronically ill patients, and financial restrictions, as well, rendered a more frequent follow-up or an actual follow-up patient visit not feasible. No attempt was made to differentiate between cardiac and noncardiac causes of death because of the inherent difficulties to determine the cause of death in an elderly patient population. Although a recall bias for events like myocardial infarction and repeat revascularization is possible, it would have similarly affected both groups. Furthermore, such a bias is unlikely for all-cause mortality. Finally, the present analysis does not allow a causal conclusion, whether incomplete revascularization per se or preexisting morbidity precluding complete revascularization is responsible for the reduced survival.

In summary, the 5-year GOPCABE follow-up found a similar outcome in elderly patients with coronary heart disease randomly assigned to on-pump or off-pump CABG. Neither an adverse effect nor an advantage of the respective operative technique was detected. Incomplete revascularization, although more frequent with off-pump CABG, was a common event in both groups and was associated with an inferior survival. CABG, in general, appeared to confer a midterm survival benefit in comparison with an age- and sex-matched general population.

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