

Research Article

Utilization of Vein Grafts in Coronary Artery Bypass Grafting: Reasons and Outcomes in a Bilateral Mammary Artery First Center

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Objectives. Despite guideline recommendations for use of bilateral internal mammary artery (BIMA) in coronary artery bypass grafting (CABG), a large proportion of patients still receive saphenous vein grafts (SVG). We herein aimed to identify reasons for SVG use at a center with a BIMA utilization rate between 60 and 70% and compare outcomes of patients undergoing CABG with either BIMA or left internal mammary artery (LIMA) plus SVG. **Methods.** Between 2013 and 2022, 4145 consecutive patients underwent isolated CABG at our center. Of those, 2067 patients received BIMA (group 1) and 1206 patients received LIMA/SVG (group 2). A propensity score-matched analysis was performed to adjust for baseline differences. **Results.** Group 2 presented with higher age, more female patients, and more patients with acute coronary syndrome including NSTEMI/STEMI with more urgent/emergency CABG. In unadjusted analysis group 2 presented adverse 30-day outcomes compared to group 1 with a higher mortality (18/2067, 0.9% vs. 34/1206, 2.8%; $p < 0.001$), higher rate of re-revascularization (52/2067, 2.5% vs. 50/1206, 4.1%; $p < 0.001$), more stroke (20/2067; 1.0% vs. 33/1206, 2.7%; $p < 0.001$), and more postoperative renal failure (17/2067, 0.8% vs. 27/1206, 2.2%; $p = 0.001$). After adjustment for baseline characteristics, 30-day outcomes were comparable. **Conclusions.** After adjustment for baseline characteristics no differences in outcomes were found between groups suggesting a safe applicability of BIMA even in patients with acute coronary syndrome undergoing urgent/emergency CABG. Reasons for SVG use were higher age, female gender, and acute coronary syndrome with urgent/emergency CABG. Outcomes of both groups were excellent with low rates of primary endpoints.

1. Introduction

According to recent guidelines for myocardial revascularization coronary artery bypass grafting (CABG) is recommended for treatment of complex coronary artery disease (CAD) in patients with intermediate to high SYNTAX (Synergy between Percutaneous Coronary Intervention with TAXUS and Cardiac Surgery) score and with type 2 diabetes [1, 2]. Although results of randomized controlled trials and retrospective studies are partly contradictory, there is a wide consensus for utilization of the left (LIMA) and right internal mammary artery (RIMA), usually referred to as bilateral mammary artery (BIMA), in CABG since long-term patency rates were shown to be superior

compared to saphenous vein grafts (SVG) or the radial artery [3, 4]. Especially patients with diabetes mellitus (DM) and reduced left ventricular function benefit from utilization of BIMA during CABG in terms of long-term survival and freedom from re-revascularization [5, 6]. However, despite clear recommendations for BIMA use in CABG, when appropriate and anatomically and clinically suitable, there is still a large proportion of patients receiving LIMA plus SVG in the real world as reflected by a BIMA use of 11.3% in North America as documented in the Society of Thoracic Surgeons Adult Cardiac Surgery registry and around 30% in Europe as documented in a large multicenter registry [7, 8]. Reasons for these low rates of BIMA utilization are likely multifactorial and differ according to investigated countries

but main considerations may include longer procedure times with BIMA use in CABG, higher risk of wound healing disorders or deep sternal wound infections (DSWI), and a technically more demanding procedure [9, 10]. In our center, a BIMA first strategy is implemented, leading to an average BIMA rate in CABG of 63% over the last ten years with a clear trend towards a further increasing utilization rate (78.1% in 2021). Despite this strategy, SVG is still applied in selected patients and particular clinical circumstances at our center. We herein aimed to retrospectively identify reasons for SVG use at our center and compare short-term outcomes of patients undergoing CABG with either BIMA or LIMA plus SVG over the last nine years.

2. Patients and Methods

2.1. Ethical Statement. Data acquisition was performed anonymized and retrospectively. Therefore, in accordance with German law, no ethical approval is needed and informed patient consent was waived.

2.2. Patients and Definitions. Between 01/2013 and 12/2022, 4145 consecutive patients underwent isolated CABG at our center. Exclusion criteria were utilization of no internal mammary artery, utilization of BIMA plus SVG, single anastomosis and application of the radial artery. Overall, 2067 patients with BIMA use and 1206 patients with LIMA plus SVG use remained for analysis. Choice of surgical strategy (e.g., on-pump CABG vs. OPCAB) was left to operators' discretion.

A patient inclusion flowchart is shown in Figure 1.

Primary endpoint for this study is all-cause mortality. Secondary outcomes consist of adverse events during 30 days after the index procedure including postoperative myocardial infarction, major stroke, acute renal failure (kidney disease improving global organization: KDIGO > 3), re-revascularization (percutaneous coronary intervention or surgical revision due to (combination of) significant changes in the ECG, rising troponin levels, wall motion abnormalities, hemodynamic instability), re-sternotomy for bleeding, number of transfused red blood cell (RBC) units, length of intensive care unit (ICU) and hospital stay, and post-operative wound infection.

Complete revascularization was defined as revascularization of all coronary segments with a stenosis of $\geq 50\%$ supplying viable myocardium [11]. DSWI was defined as postoperative infection involving the sternum and mediastinal space.

2.3. Statistical Analyses. Continuous variables are reported as mean \pm standard deviation or median with interquartile range. Categorical variables are presented as proportions. Baseline differences between patients undergoing CABG using BIMA and LIMA plus SVG were detected using the Student's *t*-test for normally distributed continuous variables, the Mann-Whitney test for non-normally distributed continuous variables and the Fisher's exact test for categorical variables. The effect of the second bypass graft was

analyzed in a univariable model and subsequently with propensity score matching analysis. The propensity score was estimated using a nonparsimonious logistic regression model, including age, sex, myocardial infarct, number of diseased coronary arteries, extracardiac arthropathy, chronic obstructive lung disease, previous transient ischemic attack or stroke, left ventricular ejection fraction (LVEF) < 35%, insulin-dependent diabetes mellitus, emergency procedure and pre-operative GFR < 60 ml/min. One-to-one propensity score matching was performed using the nearest-neighbor method and a caliper width of 0.2 of the standard deviation of the logit of the propensity score. Balance between propensity score-matched groups was assessed by evaluation of standardized differences which was considered nonsignificant < 0.10. The Student's *t*-test for continuous variables and the McNemar test for dichotomous variables were used to evaluate differences in baseline characteristics and adverse events of propensity score-matched pairs. Post hoc power analysis presented an adequate sample size for detection of differences in the primary endpoint.

All tests were two tailed and $p < 0.05$ was considered statistically significant. All statistical analyses were performed using the statistical software SPSS (IBM SPSS Statistics for Windows, Version 27.0, IBM Corp., Armonk, NY, USA).

3. Results

3.1. Baseline Demographics. Patients undergoing CABG with utilization of BIMA (group 1) presented with pronounced differences in baseline parameters compared to patients with application of LIMA and SVG (group 2). In particular, group 2 showed higher age (group 1: 65 [58–71] vs. group 2: 76 [71–79] years; $p < 0.001$), less male patients (1782/2067, 86.2% vs. 917/1206, 76.0%; $p < 0.001$), more patients with acute coronary syndrome including NSTEMI and STEMI (587/2067, 28.3% vs. 439/1206, 36.4%; $p < 0.001$) and a significantly higher prevalence of common comorbidities involving chronic obstructive pulmonary disease, extracardiac arthropathy, kidney damage, s/p stroke, and severely reduced left ventricular function. Overall, this resulted in a higher risk profile in group 2 as reflected by EuroSCORE II (1.2 [0.9–1.7] vs. 2.1 [1.5–3.38]; $p < 0.001$). Furthermore, patients in group 2 more often underwent CABG as urgent or emergency procedure (243/2067, 11.8% vs. 301/1206, 25.0%; $p < 0.001$).

After propensity score matching, 646 patients in each patient group remained for further analysis. Significant differences between matched groups persisted regarding age, BMI > 30 kg/m², and EuroSCORE II.

Detailed patient demographics of unmatched and matched groups are summarized in Table 1.

3.2. Peri-procedural Data. In the unmatched patient cohorts, significant differences in peri-procedural data were found regarding procedure time (255 [220–300] vs. 237 [196–285] min; $p < 0.001$), rates of procedures conducted in on-pump beating heart fashion (46/2067, 2.2% vs. 87/1206, 7.2%;

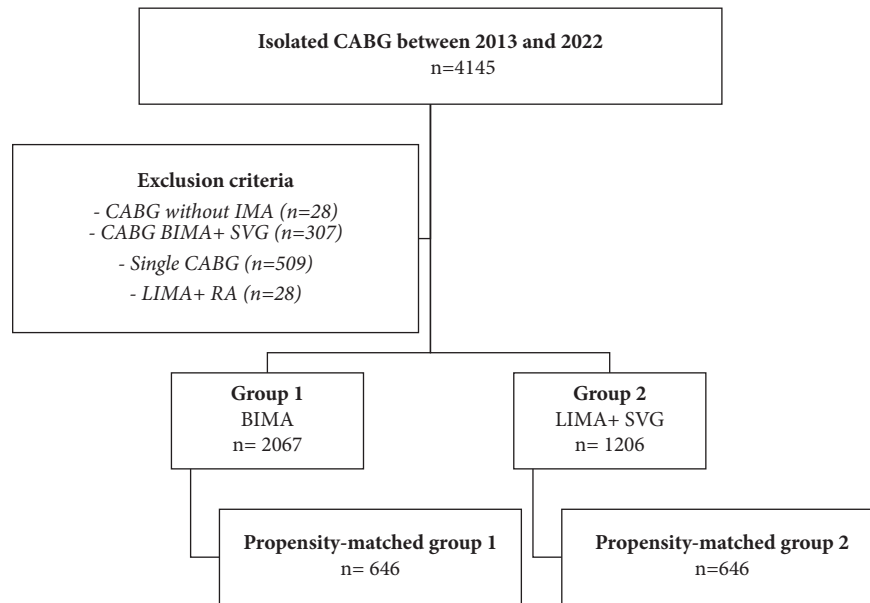


FIGURE 1: Patient inclusion flowchart. CABG, coronary artery bypass grafting; IMA, internal mammary artery; BIMA, bilateral internal mammary artery; SVG, saphenous vein graft; LIMA, left internal mammary artery; RA, radial artery.

$p < 0.001$), and a higher amount of bypasses in group 2. Also, in the propensity score-matched patient groups, group 2 demonstrated a higher proportion of patients provided with the on-pump beating heart technique during CABG, while OPCAB was more frequently performed in group 1. The number of performed bypasses presented higher in patients receiving LIMA and SVG after matching.

Detailed perioperative data are summarized in Table 2.

3.3. 30-Day Outcome Parameters. In unadjusted analysis, patients receiving LIMA and SVG during CABG presented with adverse 30-day outcomes compared to patients receiving BIMA. In particular, group 2 showed a higher mortality (18/2067, 0.9% vs. 34/1206, 2.8%; $p < 0.001$), a higher rate of surgical bypass revision (52/2067, 2.5% vs. 50/1206, 4.1%; $p < 0.001$), more stroke (20/2067; 1.0% vs. 33/1206, 2.7%; $p < 0.001$), a higher frequency of postoperative renal failure (17/2067, 0.8% vs. 27/1206, 2.2%; $p = 0.001$) as well as a longer ICU and hospital stay and a higher rate of postoperative wound healing disorders but not DSWI.

However, after adjustment for differing baseline characteristics, 30-day outcome parameters between groups were comparable. Remaining differences were prolonged ventilation and catecholamine administration in group 2, a longer ICU stay in group 2, more administered RBC units in group 2, and a trend towards a higher frequency of DSWI in group 1 (18/646, 2.8% vs. 7/646, 1.2%; $p = 0.041$). When comparing only patients after propensity matching who suffered from preoperative NSTEMI/STEMI (212/646, 32.8% vs. 196/646, 30.3%; $p = 0.369$) still no difference in 30-day mortality was found (4/212, 1.9% vs. 4/196, 2.0%; $p = 1.0$). When comparing mortality in group 1 between patients with and without acute coronary syndrome (7/434, 1.6% vs. 4/212, 1.9%; $p = 0.75$) and group 2 between patients with and

without acute coronary syndrome (8/450, 1.7% vs. 4/196, 2.0%; $p = 0.76$) no differences were found.

Detailed 30-day outcome parameters are summarized in Table 3. The distribution of key 30-day outcome parameters for matched patient cohorts is shown in Figure 2.

4. Discussion

Main findings of the herein conducted study are: (I) differing baseline characteristics of patients provided with BIMA or LIMA and SVG suggesting that main reasons for utilization of vein grafts at our center are higher age, female gender, acute coronary syndrome with an urgent or emergency CABG procedure and prevalence of comorbidities with an overall higher surgical risk profile, (II) outcomes of both groups were excellent with low rates of mortality, stroke, renal failure and DSWI, and (III) when comparing groups after adjustment for baseline characteristics no significant differences in 30-day outcomes were found suggesting a safe applicability of BIMA even in patients with acute coronary syndrome undergoing urgent or emergency CABG.

Commonly, SVG use in CABG is considered to present certain drawbacks such as high failure rates in the mid and long term, rapid progression of intermediate stenoses, limitations in applicability of percutaneous intervention in SVG stenoses, and an even higher rate of graft failure when providing multiple vessel targets with SVG compared to single SVG bypass [12, 13]. Although these drawbacks are described in several studies and guidelines for myocardial revascularization clearly recommend use of BIMA or the radial artery instead of SVG, vein grafts are still the most frequently used bypass grafts worldwide [1, 14]. Described reasons for application of SVG in CABG consist of female gender, obesity, older age, and presence of diabetes [15]. While association of SVG use and operation time with

TABLE 1: Baseline data of unmatched and propensity score-matched patients.

	Before propensity score matching				After propensity score matching			
	Group 1: BIMA (n = 2067)		Group 2: IMA + SVG (n = 1206)		Group 1: BIMA (n = 646)		Group 2: IMA + SVG (n = 646)	
Age, median (IQR)*	65 (58–71)	76 (71–79)	72 (67–75)	73 (66–77)				
BMI > 30, n (%)	580 (28.1%)	319 (26.5%)	150 (23.3%)	192 (29.8%)				0.135
Male, n (%)	1782 (86.2%)	917 (76.0%)	522 (80.8%)	526 (81.4%)				0.148
NSTEMI/STEMI, n (%)	587 (28.3%)	439 (36.4%)	212 (32.8%)	196 (30.3%)				0.015
No. of diseased vessels, median (IQR)	3 (2–3)	3 (3–3)	3 (3–3)	3 (3–3)				0.054
Extracardiac arteriopathy [§] , n (%)	350 (16.9%)	291 (24.2%)	132 (20.4%)	140 (21.7%)				0.032
COPD [§] , n (%)	104 (5.0%)	119 (9.9%)	51 (7.9%)	48 (7.4%)				0.019
Stroke/TIA, n (%)	152 (7.4%)	136 (11.3%)	67 (10.4%)	70 (10.8%)				0.013
LVEF <35%, n (%)	83 (4.0%)	89 (7.4%)	40 (6.2%)	37 (5.7%)				0.021
IDDM, n (%)	192 (9.3%)	141 (11.7%)	68 (10.5%)	64 (9.9%)				0.020
GFR <60 ml/min, n (%)	368 (17.8%)	460 (38.1%)	191 (29.6%)	169 (26.2%)				0.076
EuroScore II, median (IQR)	1.2 (0.9–1.7)	2.1 (1.5–3.38)	1.56 (1.22–2.14)	1.7 (1.30–2.47)				0.040
Urgent/emergency procedure, n (%)	243 (11.8%)	301 (25.0%)	134 (20.7%)	112 (17.3%)				0.087
								0.013
								0.008
								0.831
								0.369
								0.670
								0.633
								0.834
								0.857
								0.814
								0.783
								0.192
								0.020
								0.137

BIMA, bilateral internal mammary artery; IMA, internal mammary artery; SVG, saphenous vein graft; BMI, body mass index; NSTEMI, non-ST-elevation myocardial infarction; STEMI, ST-elevation myocardial infarction; COPD chronic obstructive pulmonary disease; TIA, transient ischemic attack; LVEF, left ventricular ejection fraction; IDDM, insulin-dependent diabetes mellitus; GFR, glomerular filtration rate; EuroSCORE II, European System for Cardiac Operative Risk Evaluation II; [§]extracardiac arteriopathy; [§]COPD, according to EuroSCORE definitions. Variables included for propensity score matching: age, sex, NSTEMI/STEMI, number of diseased vessels, extracardiac arteriopathy, COPD, TIA/stroke, LVEF <35%, IDDM, emergency procedure, GFR <60 ml/min.

TABLE 2: Perioperative data of unmatched and propensity score-matched patients.

	Before propensity score matching			After propensity score matching		
	Group 1: BIMA (<i>n</i> = 2067)	Group 2: IMA + SVG (<i>n</i> = 1206)	<i>p</i> value	Group 1: BIMA (<i>n</i> = 646)	Group 2: IMA + SVG (<i>n</i> = 646)	<i>p</i> value
Procedure duration, median (IQR)	255 (220–300)	237 (196–285)	<0.001	255 (215–290)	245 (205–295)	0.099
Skeletonized IMA harvesting, <i>n</i> (%)	1727 (83.6%)	1031 (85.5%)	0.163	524 (81.1%)	555 (85.9%)	0.024
On-pump arrested heart, <i>n</i> (%)	1238 (59.9%)	626 (51.9%)	<0.001	341 (52.8%)	372 (57.6%)	0.093
On-pump beating-heart, <i>n</i> (%)	46 (2.2%)	87 (7.2%)	<0.001	20 (3.1%)	41 (6.3%)	0.008
Off-pump, <i>n</i> (%)	783 (37.9%)	493 (40.9%)	0.095	285 (44.1%)	233 (36.1%)	0.004
Complete revascularization, <i>n</i> (%)	1609 (77.8%)	905 (75.0%)	0.071	484 (74.9%)	493 (76.3%)	0.604
Number of bypasses, median (IQR)	2 (2–3)	3 (2–3)	<0.001	2 (2–3)	3 (2–3)	0.009
Central anastomosis, <i>n</i> (%)	13 (0.7%)	506 (44.9%)	<0.001	6 (1.0%)	306 (50.5%)	<0.001

BIMA, bilateral internal mammary artery; IMA, internal mammary artery; SVG, saphenous vein graft.

regards to economization of clinical resources is not well investigated, reluctance in application of BIMA in diabetic patients may be related to describe higher incidences of DSWI with BIMA [9]. Furthermore, SVG use in predominantly female patients may be connected to anatomical considerations regarding smaller target vessel diameters [16]. The herein presented data from a BIMA first center largely confirms previously described reasons for SVG use in CABG, although SVG is overall significantly less utilized over a period of nine years compared to describe utilization rates. In addition, our investigated data suggest that patients with acute coronary syndrome undergoing urgent or emergency CABG are more likely to receive SVG for intended fast and sufficient reestablishment of coronary blood flow by sparing preparation of a second arterial graft. However, although this strategy is plausible, there is no data comparing BIMA and LIMA plus SVG use in the setting of acute coronary syndrome. The herein presented outcome data of baseline-adjusted groups indicate that utilization of BIMA even in patients undergoing emergent CABG in acute coronary syndrome may be safe and feasible. On the other hand, utilization of LIMA and SVG may be advantageous in the short term in older and frailer patients due to the reduced operative trauma and less DSWI as herein shown. A patient-specific approach should be established to weigh possible long-term benefits of BIMA utilization against short-term benefits of SVG.

Although clear drawbacks in outcomes of the LIMA and SVG group were seen in unadjusted analysis, it needs to be emphasized that outcomes of both groups were excellent with low rates of mortality, stroke, revascularization, and renal failure which are in line or even lower when compared to national and international registries [17, 18]. Therefore, strategy for graft choice should be based not only on the clinical setting but also on surgeons' expertise, experience in utilization of BIMA and graft quality. Whenever SVG is used key factors for prolonged graft patency should be taken into consideration including intraprocedural measures such as applying SVG to target vessels with a larger diameter, implementing a no

touch harvesting technique [19], and avoid bypassing of hemodynamically insignificant stenosis [20] as well as postoperative management including administration of dual antiplatelet therapy [21].

In this study, a trend towards a higher incidence of DSWI in patients receiving BIMA after adjustment for baseline differences was seen. However, DSWI after CABG is a multifactorial process including impact of the patient's nutritional status, technique of IMA harvesting (skeletonized vs. pedicled), and/or presence of metabolic syndrome and obesity [22–24]. Since not all risk factors for DSWI were investigated in the context of this study and CABG using BIMA still results in decreased hospital mortality, cerebrovascular events, and re-revascularization rates, especially in patients with reduced left ventricular function and DM [25], BIMA should be considered the first line grafting strategy in the majority of patients, and complete revascularization should be the goal in every patient.

4.1. Limitations. Limitations are inherent in the retrospective, single-center study design with limited patient numbers: patients were not randomized to a specific treatment; therefore, patient preselection with hidden confounders may apply, especially in terms of selection bias regarding surgeons' choice of LIMA vs. BIMA and on-pump CABG vs. OPCAB. Furthermore, no data were available on how many patients were converted from OPCAB to on-pump CABG or beating heart procedures. Also, a propensity score matching approach was applied to adjust for baseline differences; differences regarding BMI and EuroSCORE II persisted after matching, suggesting imbalances between patients receiving BIMA or SVG which may hamper comparability. However, major differences in outcome parameters before and after matching suggest at least a mostly sufficient abolishment of major baseline imbalances. Furthermore, operative strategies were different between groups, suggesting an imbalance of operating surgeons between groups, and NSTEMI/STEMI patients were merged to one subgroup, which may hamper interpretation of results.

TABLE 3: 30-day outcome parameter of unmatched and propensity score-matched patients.

	Before propensity score matching			After propensity score matching			<i>P</i> value
	Group 1: BIMA (<i>n</i> = 2067)	Group 2: IMA + SVG (<i>n</i> = 1206)	<i>P</i> value	Group 1: BIMA (<i>n</i> = 646)	Group 2: IMA + SVG (<i>n</i> = 646)	<i>P</i> value	
All cause mortality, <i>n</i> (%)	18 (0.9%)	34 (2.8%)	<0.001	11 (1.7%)	12 (1.9%)	1.000	
Bypass revision, <i>n</i> (%)	52 (2.5%)	50 (4.1%)	0.012	17 (2.6%)	26 (4.0%)	0.214	
Emergent PCI, <i>n</i> (%)	17 (0.8%)	13 (1.1%)	0.454	4 (0.6%)	6 (0.9%)	0.753	
Myocardial infarction, <i>n</i> (%)	35 (1.6%)	29 (2.4%)	0.190	12 (1.9%)	15 (2.3%)	0.698	
Major stroke, <i>n</i> (%)	20 (1.0%)	33 (2.7%)	<0.001	10 (1.5%)	17 (2.6%)	0.243	
Acute renal failure (KDIGO3), <i>n</i> (%)	17 (0.8%)	27 (2.2%)	0.001	9 (1.4%)	12 (1.9%)	0.661	
Prolonged catecholamine use >24h, <i>n</i> (%)	37 (1.8%)	74 (6.1%)	<0.001	15 (2.3%)	30 (4.6%)	0.033	
Prolonged ventilation >24h, <i>n</i> (%)	54 (2.6%)	69 (5.7%)	<0.001	21 (3.3%)	37 (5.7%)	0.043	
Rethoracotomy for bleeding, <i>n</i> (%)	74 (3.6%)	54 (4.5%)	0.224	23 (3.6%)	31 (4.8%)	0.270	
ICU stay, day, median (IQR)	2 (1-3)	2 (1-4)	<0.001	2 (1-3)	2 (2-3)	0.045	
Hospital stay, median (IQR)	7 (6-8)	7 (6-10)	<0.001	7 (6-8)	7 (6-9)	0.162	
RBC unit, median (IQR)	0 (0-0)	0 (0-2)	<0.001	0 (0-1)	0 (0-2)	0.001	
Wound healing disorder, <i>n</i> (%)	80 (3.9%)	26 (2.2%)	0.008	27 (4.2%)	14 (2.2%)	0.056	
DSWI, <i>n</i> (%)	35 (1.7%)	13 (1.2%)	0.226	18 (2.8%)	7 (1.2%)	0.041	

BIMA, bilateral internal mammary artery; IMA, internal mammary artery; SVG, saphenous vein graft; PCI, percutaneous coronary intervention; ICU, intensive care unit; RBC, red blood cells; DSWI, deep sternal wound infection.

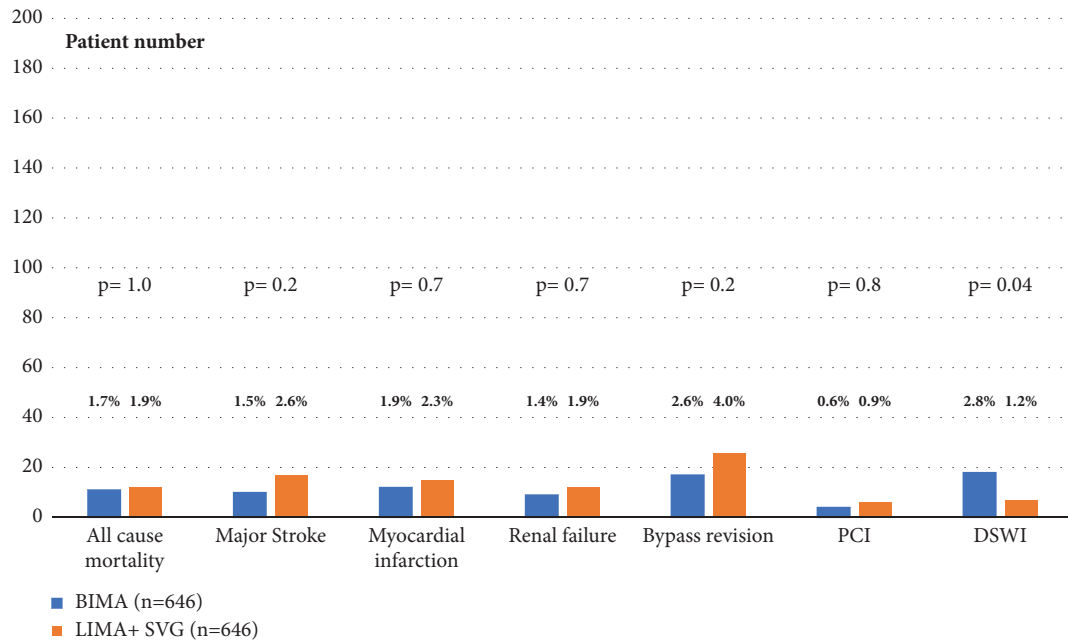


FIGURE 2: Key outcomes of patients undergoing CABG with BIMA or LIMA plus SVG in matched patient cohorts. CABG, coronary artery bypass grafting; BIMA, bilateral internal mammary artery; LIMA, left internal mammary artery; SVG, saphenous vein graft; PCI, percutaneous coronary intervention; DSWI, deep sternal wound infection.

5. Conclusions

After adjustment for baseline characteristics no differences in outcomes were found between groups suggesting a safe applicability of BIMA even in patients with acute coronary syndrome undergoing urgent/emergency CABG. Differing baseline characteristics of patients provided with BIMA or LIMA and SVG suggesting that main reasons for utilization of vein grafts in our center are higher age, female gender, acute coronary syndrome with an urgent or emergency CABG procedure, and prevalence of comorbidities with an overall higher surgical risk profile. Utilization of LIMA and SVG may be advantageous in older and frailer patients due to the reduced operative trauma and less DSWI as herein shown. When taking the higher rate of DSWI in patients provided with BIMA into consideration, a patient-specific approach should be established to weigh possible long-term benefits of BIMA utilization against short-term benefits of SVG.

Abbreviations

BIMA:	Bilateral internal mammary artery
CABG:	Coronary artery bypass grafting
CAD:	Coronary artery disease
DM:	Diabetes mellitus
DSWI:	Deep sternal wound infection
ICU:	Intensive care unit
LIMA:	Left internal mammary artery
LVEF:	Left ventricular ejection fraction
OPCAB:	Off-pump coronary artery bypass
RBC:	Red blood cells
RIMA:	Right internal mammary artery

SVG: Saphenous vein graft

SYNTAX: Synergy between percutaneous coronary intervention with TAXUS and cardiac surgery

WHD: Wound healing disorder.

Data Availability

The data used to support the findings of this study are available from the corresponding author upon reasonable request.

Ethical Approval

Data acquisition was performed anonymized and retrospectively. Therefore, in accordance with German law, no ethical approval is needed.

Consent

Informed patient consent was waived.

Conflicts of Interest

The authors declare that they have no conflicts of interest.

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