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Evolution of Bilateral Mammary Arterial Grafting Program in Veterans Affairs Medical Center

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Abstract

Background: Coronary revascularization with bilateral internal mammary arteries is associated with increased long-term survival, but underutilized due to sternal wound infection concerns. Dedicated bilateral mammary grafting programs are typically high-volume academic or private practices, rather than lower-volume federal institutions whose results are not captured in the Society of Thoracic Surgeons database. Our institution used only single internal mammary arterial grafting in the year prior to implementing a dedicated bilateral grafting program using skeletonized technique. We describe our experience transitioning to bilateral mammary grafting and its impact on sternal wound infection.

Methods: Retrospective cohort study at San Francisco Veterans Affairs Medical Center in 200 patients undergoing first-time isolated, multi-vessel coronary artery bypass from August 2014 to October 2017. Sternal wound infection was defined broadly to include any patient receiving antibiotics for suspicion of sternal infection. Patients were followed for wound complications until 3 post-operative months.

Results: Of 200 total patients, 45.5% (n=91) were diabetic, 44% (n=88) had BMI >30, and 61.5% (n=123) underwent bilateral mammary grafting. Bilateral mammary grafting population had 2.4% (n=3/123) deep sternal wound infection with 1.6% (n=2/123) requiring sternal reconstruction while single mammary population had 1.3% (n=1/77, p=1.0). Bilateral mammary grafting population had 6.5% (n=8/123) superficial sternal wound infection compared to 5.2% (n=4/77, p=0.77) in single mammary grafting population.

Conclusions: Transitioning to high rates of bilateral mammary utilization was possible in a year with low rates of complications. Based on our experience, surgeons should consider adopting a skeletonized bilateral mammary grafting approach given potential long-term survival benefit.

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Introduction

Bilateral internal mammary artery (BIMA) grafting is associated with increased long-term survival compared to single internal mammary artery (SIMA) grafting based on retrospective observational data[1–7]. Although presented long-term randomized trial data not yet published suggests no difference in survival between BIMA vs SIMA with saphenous vein or radial artery grafting [8], both European and American surgical societies have put forth Class IIa recommendations in favor of BIMA grafting[9, 10]. In 2014, European Association for Cardio-Thoracic Surgery (EACTS) recommended BIMA grafting in patients <70 years of age.[10] Society of Thoracic Surgeons (STS) in 2011 and 2016 recommended BIMA grafting could and should be performed safely in most patients, endorsing skeletonized grafts, smoking cessation, and glycemic control to offset risks of sternal wound infections (SWI)[9, 11].

Nevertheless, BIMA grafting remains underutilized, with 2016 STS database reporting BIMA utilization at 5.5% in the US[12]. In Synergy between PCI with Taxus and Cardiac Surgery (SYNTAX) trial, BIMA grafting in US patients was significantly lower than in European patients (10% vs 25%, respectively)[13]. Japan was notable for 36% BIMA utilization [14] . BIMA grafting has been considered more technically challenging and time consuming, which coupled with concerns regarding increased incidence of deep sternal wound infections (DSWI), have likely hampered BIMA utilization[2]. Centers for Medicare and Medicaid Services' (CMS) decision to not cover hospitalization costs for mediastinitis likely further disincentivized surgeons from BIMA usage[14]. Although one-year safety data from Arterial Revascularization Trial (ART) noted a 1.3% increase in rate of SWI complication after BIMA grafting in comparison to SIMA grafting[15], further analysis demonstrated that harvesting the IMA using a skeletonized technique decreased risk of SWI by preserving sternal blood flow[16, 17].

In order to provide potential long-term survival benefit to maximum number of patients, we initiated a BIMA grafting program using the skeletonized harvesting technique at San Francisco Veterans Affairs Medical Center (SFVAMC). Unlike BIMA programs from high-volume academic or private practices, results from lower volume federal institutions are unknown, since outcomes are not captured in the STS national database. Our objective was therefore to describe the evolution of a VA program committed to providing BIMA coronary artery bypass grafting (CABG) and examine its impact on SWI.

Patients and Methods

Patients and Data Acquisition

This study was approved by Committee on Human Research at University of California San Francisco and the Institutional Review Board of SFVAMC. We retrospectively reviewed 255 CABG operations involving one or more IMA grafts at SFVAMC, a tertiary referral center for cardiac surgery during the study period starting with program initiation in August 2014 to October 2017. We excluded patients with previous cardiac surgery or concomitant surgery. We performed demographic and outcomes analysis on remaining 200 multi-vessel, isolated first-time CABG patients to reduce heterogeneity. To understand the impact of a dedicated BIMA program on rates of multiple arterial revascularization, we reviewed an additional 79 isolated, multi-vessel CABG operations from the year prior to the study period (August 2013-August 2014). All BIMA harvesting was performed using skeletonized technique to preserve sternal vascularity and reduce risk of SWI[16, 17].

Study variables

Patient demographics and perioperative data was collected from the VA Computerized Patient Record System and stored using a modified version of STS Adult Cardiac Surgery Data Collection form v2.73. We used STS definitions for variables unless an alternate definition is listed below.

We defined DSWI to include infection of the fascia, muscle, bone, or mediastinum occurring within 3 post-operative months, unlike STS definition of 30 days. DSWI involved tissue excision, positive tissue cultures, or discovery of a deep abscess. In contrast, superficial sternal wound infection (SSWI) involved only skin and subcutaneous tissue. We defined SWI broadly to include any patient receiving antibiotics for suspected or documented sternal infection.

Statistical analysis

We examined statistical differences between SIMA and BIMA groups. Continuous variables were expressed as mean±SD or as median (IQR) and evaluated using student's t-test or Wilcoxon rank-sum test depending on distribution. Categorical variables were expressed as the frequency of their group and compared using $\chi 2$ or Fisher's exact tests, with 2-tailed $p<0.05$ considered statistically significant. Analysis was performed using Stata 14.2 (StataCorp).

Results

In the year prior to implementing our program, we performed 100% SIMA grafting. Only 8% (n=6/79) of CABG operations involved multiple arterial revascularization through the LIMA and radial artery or sequential LIMA grafting. Following program implementation, BIMA grafting comprised 61.5% (n=123/200) of multi-vessel, isolated CABG operations. In the first 6 months of BIMA grafting, 28% (9/32) of CABG cases used BIMA grafting. Prevalence of BIMA grafting increased to 45.7% (16/35) in the next 6 month period (6–12 months after program initiation), and continued to increase to 80% (25/31) of CABG cases by the following 6 month period (12–18 months after program initiation). Frequency of BIMA grafting settled at approximately >70% of isolated, multi-vessel CABG operations after the program's initial year (Figure 1).

Patient demographics, comorbidities, and operative characteristics for SIMA (n=77) and BIMA (n=123) are summarized in Table 1. In our overall patient population, 45.5% (n=91/200) were diabetic and 44% (n=88/200) had BMI >30. Patient population was entirely male. In the SIMA cohort, 55% (n=42/77) of patients had BMI>30 compared to 37% (n=46/123) of BIMA patients (p=0.017) (Figure 2). Diabetes was present in 55% (n=42/77) of SIMA patients compared to 39% (n=49/123) of BIMA patients (p=0.042). Median pre-operative hemoglobin A1c (hgbA1c) was 6.3 (IQR 5.5–7.7; range 4.4–10.1) for SIMA vs.

5.8 (IQR 5.5–6.7; range 4.6–9.2) in BIMA. Median hgbA1c in BIMA patients progressively increases during consecutive 6-month periods from the first skeletonized BIMA operation (Figure 3). Overall frequency of off-pump CABG was 60% (n=46/77) in SIMA patients compared to 41% (n=50/123) in BIMA patients (p=0.009). Furthermore, on-pump CABG with aortic cross-clamp was 25% (n=19/77) in SIMA compared to 38% (n=47/123) in BIMA (p = 0.048).

Examining infection outcomes, BIMA population had 2.4% (n=3/123) DSWI with 1.6% (n=2/123) requiring sternal reconstruction while SIMA population had 1.3% (n=1/77, p=1.0). BIMA population had 6.5% (n=8/123) SSWI compared to 5.2% (n=4/77, p=0.77) in SIMA population. Treatment for SSWI involved antibiotics only for 75% (n=6/8) of cases in BIMA patients, with the remaining SSWI necessitating placement of a wound vac. Infection outcomes are summarized in Table 2 and post-operative outcomes in Table 3.

Discussion

We report our experience during a step-wise implementation program committed to arterial revascularization using skeletonized BIMA. Transitioning from 100% SIMA use to approximately 70% BIMA utilization in a year was possible with low rates of complications. Furthermore, adopting BIMA grafting allowed us to increase our rate of dual arterial revascularization nearly tenfold, from 7.6% to 70%. Further increasing to total arterial revascularization may be particularly beneficial for diabetic patients[18].

Development of BIMA Program and Surgical Paradigm

To provide potential of enhanced long-term survival benefit to the maximum number of patients, we chose to perform BIMA whenever possible as a commitment to the technique. We initially maintained strict hgbA1c and body mass index (BMI) requirements for BIMA. Although we did not have absolute contraindications for hgbA1c limits for BIMA, we avoided hgbA1c>10 and aimed for optimization of <8 for elective cases. Insulin drips for strict post-operative glucose control <180 were routine for the first 48 hours following surgery. We initially avoided performing BIMA grafting in patients with BMI >35. As infection rates remained low, we gradually liberalized the upper range for hgbA1c and BMI to those of SIMA patients as the program continued.

BIMA grafting can be technically challenging upon initiation. Our implementation deliberately opted for greater on-pump CABG in the BIMA group to minimize failures due to technical error. As the program progressed and surgeons gained confidence with the technique, proportion of off-pump BIMA increased. In the first 100 patients, frequency of off-pump BIMA cases was 20% (n=10/51), which rose to 55% (n=40/72) in the second 100 patients.

In regard to graft orientation, skeletonized right internal mammary artery (RIMA) was used as an *in situ* graft primarily to the right coronary artery (RCA), ramus or high obtuse marginal arteries, or taken as a free graft to the posterior descending or obtuse marginal arteries. LIMA was nearly always anastomosed to the LAD.

Survival benefit

Large observational studies[1–6] have led to recommendations in favor of BIMA in the latest US and European CABG guidelines[9, 10]. Patients with life expectancy greater than 5–10 years can potentially benefit from survival advantage associated with BIMA grafting. Based on long-term outcome analyses, many patients >70 years old at time of cardiac surgery were still alive after 15 years and likely received increasing benefit from BIMA grafting with time[2].

However, BIMA is underutilized in the US and conflicting data exists regarding BIMA and survival advantage. An observational study in the VA population between 1991–1998 showed no significant difference in survival with BIMA versus SIMA grafting. In the intervening 20 years since this study period, medical therapy and overall survival following CABG have greatly improved[19] and the study was limited by lack of power (n=66)[19]. Of note, the recent interim 5-year ART trial results showed no difference in survival,[20] but several confounding factors may contribute to equivalence in mortality at the 5-year mark. As saphenous vein graft failure occurs more prominently in the 7–10 year range, trial data is likely too early to detect mortality differences and lack of difference at 5 years has also been noted in observational studies. In the ART trial, 23% of SIMA group also involved multiple arterial revascularization using the radial artery. The ART patients demonstrated high medication compliance, which may also contribute to lower rates of saphenous vein graft failure and mortality[20].

Risk of infection

Concern for sternal wound infections with BIMA grafting hinders greater adoption of the technique. When analyzing ART results by graft harvesting techniques, risk of SWI complications was equal between skeletonized BIMA grafting and SIMA grafting,[16] while pedicled BIMA was associated with increased rates of infection. These observations persisted even in higher risk patients, including high BMI, insulin-dependent diabetes mellitus (IDDM), and women[17],[21]. These findings are reassuring given Veterans Affairs Surgical Quality Improvement Program (VASQIP) demonstrates a progressive increase in prevalence of obese and diabetic patients undergoing CABG from 1997 to 2011[22]. Despite increased infection risk with diabetes, diabetic patients may benefit more significantly from multiple arterial grafts using BIMA due to their diffuse multi-vessel disease, accelerated atherosclerosis, and increased propensity for graft failure[23]. In our study, we used skeletonized harvesting technique for BIMA and DSWI remained low.

Our BIMA population included 39% (n=49/123) diabetic patients, with 27% (n=33/123) non-insulin dependent (NIDDM) and 12% (n=15/125) insulin dependent (IDDM). In comparison, the ART trial included 23.9% diabetic patients, 17.8% NIDDM and 6.1% IDDM. DSWI requiring sternal reconstruction occurred in 1.6% of cases (n = 2/123), similar to 1.9% of sternal reconstruction rate reported in ART[15, 20]. We did exclude one additional BIMA patient who developed mediastinitis after emergent sternal reentry in the ICU for tamponade. Given the unsterile nature of the sternal reopening, we felt the circumstances more than the type of IMA harvesting likely contributed to DSWI in that particular case. The other two remaining BIMA patients who developed DSWI had A1c ~8 with normal BMI, but both patients were non-compliant with their routine 2- and 6-week post-operative follow-up. As we aggressively treated SSWI with wound vacuum treatment and/or antibiotics, lack of follow-up until late DSWI presentation was felt to be a major contributing factor. Rates of SSWI were comparable between SIMA and BIMA groups.

Limitations of the study

As a small retrospective study, we are underpowered to develop risk models for sternal infection. Our purpose was, instead, to focus on the adoption and growth of BIMA grafting at a lower volume federal VA institution, whose results are not represented in the STS database. As a pilot outcomes study for our dedicated BIMA program initiation, we demonstrated low incidence of DWSI and SSWI in a program transitioning to 70% BIMA grafting. We hope to serve as a model for other federal institutions and smaller volume practices to address under-utilization of BIMA grafting in the US.

This study provides useful data on SWI outcomes of BIMA vs SIMA grafting in a male veteran population with a higher percentage of diabetes (by 15%) than previously reported clinical trials in the community. However, female sex is a risk factor for DSWI[17] and applicability in this important demographic is limited, as is generalizability outside a VA population.

In addition, surgeons were not blinded to the operation performed. Increased concern for SSWI in BIMA patients did lead to early, potentially premature diagnosis of SSWI from sternal wound erythema or drainage with aggressive management with antibiotics. Future directions for this study include follow-up for long-term graft patency data and survival between SIMA and BIMA.

Conclusions

By modeling the transition to a dedicated BIMA program with the skeletonized technique in a VA population with high rates of obesity and diabetes, we encourage other federal and civilian institutions to overcome barriers to BIMA grafting and offer the potential benefits of increased patient survival. We encourage gradual liberalization of exclusion criteria (BMI and hgbA1c) and use of cardiopulmonary bypass to address the technical challenge as surgeons develop experience with the technique.

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Glossary of Abbreviations:

BIMA	Bilateral internal mammary artery
SIMA	Single internal mammary artery
EACTS	European Association for Cardio-Thoracic Surgery

STS	Society of Thoracic Surgeons
SYNTAX	Synergy between PCI with Taxus and Cardiac Surgery
SWI	Sternal Wound Infections
DSWI	Deep Sternal Wound Infections
SSWI	Superficial Sternal Wound Infections
CMS	Centers for Medicare and Medicaid Services
ART	Arterial Revascularization Trial (ART)
SFVAMC	San Francisco Veterans Affairs Medical Center
LIMA	Left Internal Mammary Artery
RIMA	Right Internal Mammary Artery
NIDDM	Non-Insulin Dependent Diabetes Mellitus
IDDM	Insulin Dependent Diabetes Mellitus
CABG	Coronary Artery Bypass Grafting
HgbA1c	Hemoglobin A1c

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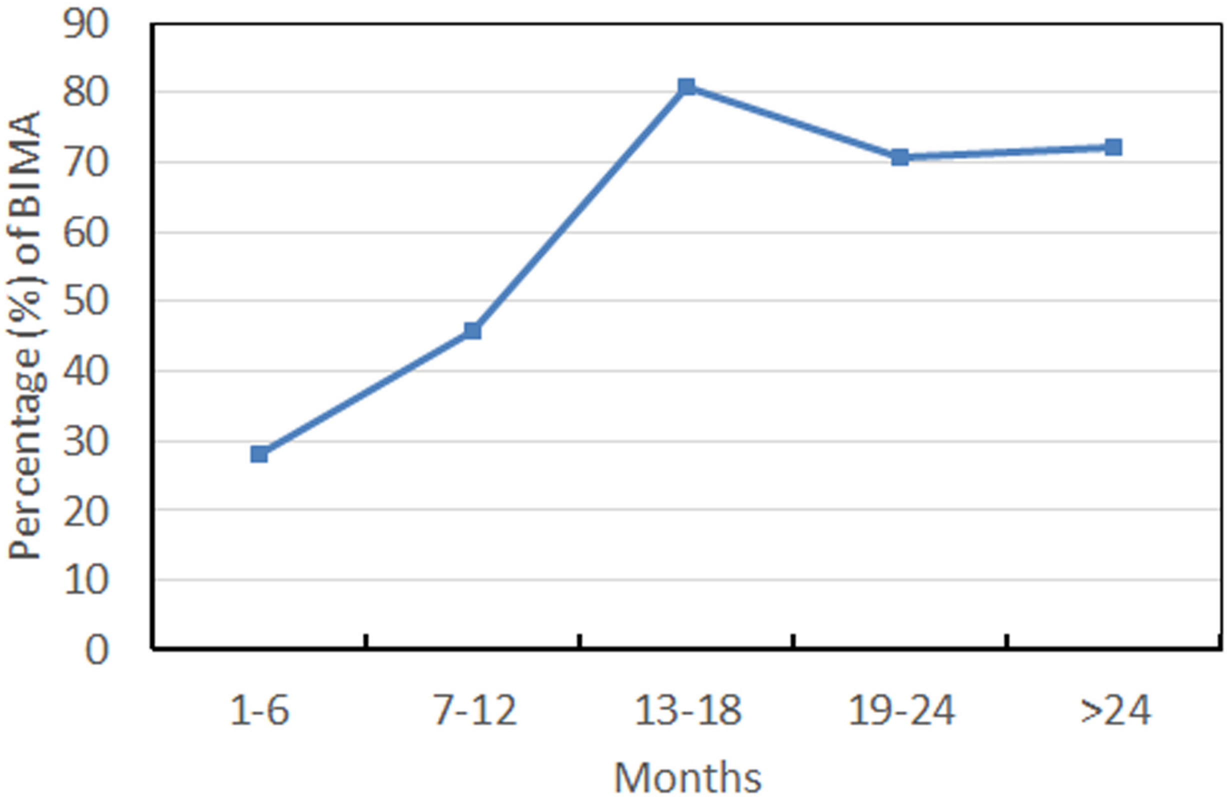

Figure 1:

Proportion of BIMA cases increased until reaching approximately 70% as more cases were performed after adopting a dedicated BIMA program.

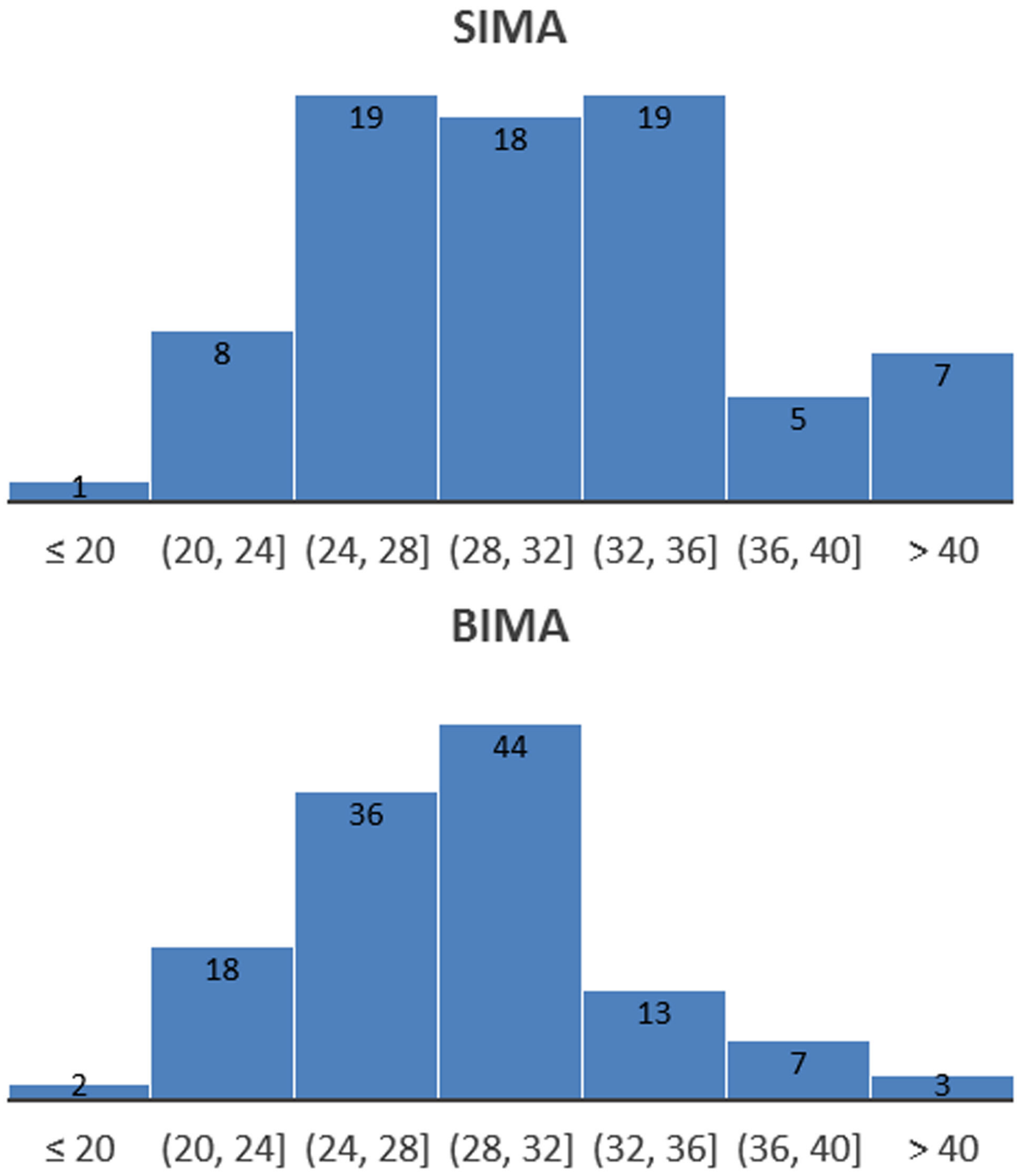

Figure 2A-B:
BMI in patients undergoing SIMA (A) and BIMA (B) grafting.

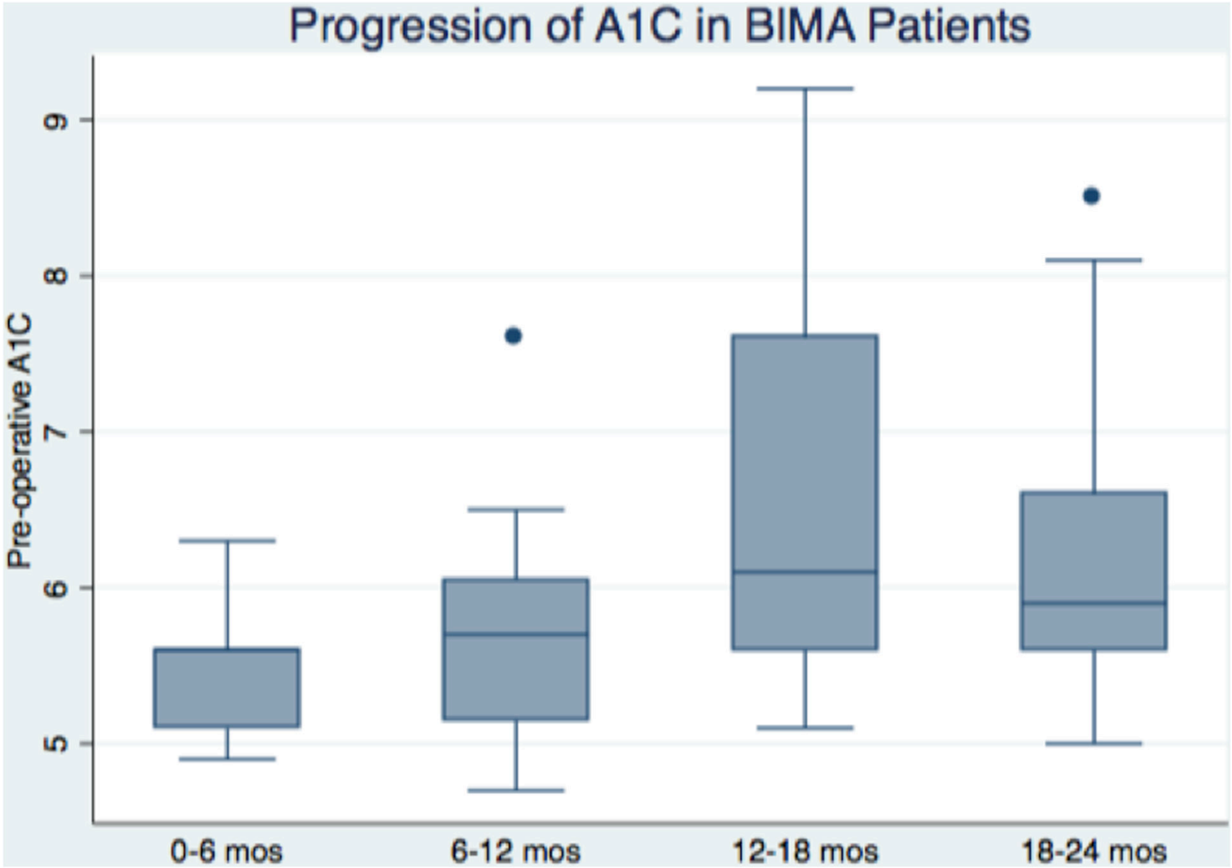

Figure 3:

Median hgbA1c for bilateral internal mammary artery (BIMA) patients in 6-month intervals following program initiation. $p < 0.05$

TABLE 1.

Patient characteristics and operative data by IMA graft status

Graft status	SIMA (n= 77)	BIMA (n= 123)	P-value
Patient demographics			
Age, mean±SD	66.9±7.0	66.9±6.8	0.97
Ethnicity - no. (%)			
White	51 (66)	92 (75)	0.43
African	10 (13)	7 (6)	
Hispanic	3 (4)	5 (4)	
Asian	3 (4)	6 (5)	
Other or unavailable	10 (13)	13 (11)	
Risk factors			
BMI, median (IQR)	31.0 (27.2–33.7)	28.2 (25.5–31.0)	0.003*
Absolute range	19.1–42.7	19.3–40.3	
Diabetes	42 (55)	49 (40)	0.042*
HgbA1C (last preoperative, IQR)	6.3 (5.5–7.7)	5.8 (5.5–6.7)	0.0195*
Absolute range	4.4–10.1	4.6–9.2	
Dyslipidemia	73 (95)	109 (88)	0.137
Dialysis	3 (4)	1 (1)	0.139
Hypertension	71 (92)	107 (87)	0.25
Tobacco use			
Never	25 (33)	41 (33)	0.96
Former	8 (10)	14 (11)	
Current	44 (57)	68 (55)	
Chronic lung disease	24 (31)	25 (20)	0.083
Sleep apnea	23 (30)	24 (20)	0.093
Depression	13 (17)	20 (16)	0.908
Liver disease	6 (8)	4 (3)	0.152
Immunocompromised	2 (3)	5 (4)	0.583
History of CVA	6 (8)	10 (8)	0.932
Cardiac history			
Previous PCI	20 (26)	24 (20)	0.283
History of MI	22 (29)	39 (32)	0.639
LVEF <45%	12 (16)	12 (10)	0.217
Left Main disease >50%	19 (25)	33 (27)	0.74
Three or more vessel disease	62 (81)	115 (94)	0.07
CABG characteristics			
Number of grafts	3.0±0.9	3.3±0.9	0.007
Pump strategy			

Graft status	SIMA (n= 77)	BIMA (n= 123)	P-value
Off pump bypass	46 (60)	50 (41)	0.009
On pump w/ ACC	19 (25)	47 (38)	0.048
On pump w/o ACC	12 (16)	26 (21)	0.33
Bypass time (min)	124 (81–139)	101 (76–130)	0.167
Clamp time (min)	78 (58–93)	63 (50–84)	0.21

[*] p-value <0.05

TABLE 2.

Infection outcomes by graft status in isolated, multi-vessel CABG

Graft status	SIMA (n= 77)	BIMA (n= 123)	p value
Superficial sternal infections			
All cases - no. (%)	4 (5)	8 (6.5)	0.77
Treated with antibiotics only	2 (3)	6 (4.9)	0.713
Treated with wound vac	2 (3)	2 (1.6)	0.64
Deep sternal infections	1 (1)	3 (2.4)	1.00

*p-value < 0.05

TABLE 3.

Post-operative outcomes by graft status

Graft status	SIMA (n= 77)	BIMA (n= 123)	P-value
LOS after surgery, median (IQR)	8 (6–10)	7 (6–10)	0.49
Ventilation time (hours), (IQR)	6.6 (5.0–9.2)	6.5 (4.5–9.4)	0.56
Complications			
Stroke	2 (3)	2 (2)	0.64
Dialysis or ultrafiltration	0 (0)	1 (1)	0.42
Mortality	0 (0)	2 (2)	0.26
Atrial fibrillation	21 (27)	26 (21)	0.378
Reoperation	1 (1)	5 (4)	0.41
Pleural effusion with intervention	4 (5)	4 (3)	0.714
Unplanned readmission	6 (8)	10 (8)	1.00

*p-value < 0.05