

## Staged percutaneous coronary intervention and minimally invasive valve surgery: Results of a hybrid approach to concomitant coronary and valvular disease

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**Background:** We compared a hybrid approach combining staged percutaneous coronary intervention (PCI) and minimally invasive valve surgery with concurrent valve surgery plus bypass via a median sternotomy approach.

**Methods:** We retrospectively evaluated 65 consecutive patients with coronary disease and surgical valvular heart disease who underwent planned PCI followed within 60 days by minimally invasive valve surgery, and we compared them with 52 matched control patients who underwent conventional bypass grafting and valve surgery.

**Results:** There were no in-hospital deaths in the hybrid group, compared with 2 (3.8%) observed in the matched group ( $P = .11$ ). Death, renal failure, or stroke occurred in 1 (1.5%) in the hybrid group versus 15 (28.8%) in the conventional group ( $P = .001$ ). The median number of days between PCI and surgery was 24 (interquartile range, 2.5-37). At surgery, 23 hybrid patients were receiving both aspirin and clopidogrel; 18, clopidogrel alone; 4, aspirin alone; and 22 stopped the antiplatelet agents 5 days before the operation. Intensive care unit hours and total hospital length of stay, including PCI stay for the hybrid group, were less in the hybrid group ( $P = .001$  for both comparisons). In the hybrid group, average blood use was  $1.6 \pm 1.6$  U per patient versus  $1.9 \pm 2.4$  U per patient with conventional surgery ( $P = .35$ ). There were no reoperations for postoperative bleeding in the hybrid group compared with 2 (3.8%) in the conventional group ( $P = .43$ ).

**Conclusions:** Staged PCI with minimally invasive valve surgery may offer an alternative to coronary bypass grafting with concurrent valve surgery and should be tested prospectively. (*J Thorac Cardiovasc Surg* 2012;144:634-9)

Coronary artery bypass graft (CABG) with concomitant valve surgery has a higher mortality than does isolated valve surgery or isolated CABG.<sup>1-3</sup> Typically, patients are sicker, operative times are longer, and morbidity and mortality are increased. Thus, some groups have begun exploring a strategy to dissociate the procedures into 2 smaller, staged procedures—minimally invasive valve surgery and percutaneous coronary intervention (PCI). When compared with a standard median sternotomy approach, the potential benefits of minimally invasive valve surgery include less trauma and faster recovery time, possibly leading to improved outcomes.<sup>4-14</sup> Inasmuch as PCI has a mortality of less than 1% in elective settings and minimally invasive valve procedures have a mortality between 0.7% and 2%,<sup>15,16</sup> a hybrid approach that

combines PCI with minimally invasive valve surgery is worthy of consideration.<sup>16-20</sup> We report our experience using this staged method in a nonrandomized, but consecutive, case series.

### METHODS

After obtaining approval from the institutional review board, we retrospectively reviewed the medical records of 65 consecutive patients with concomitant coronary and valvular disease who underwent staged PCI followed, within 60 days, by minimally invasive valve surgery between February 2009 and June 2011. Their outcomes were compared with a matched control group of 52 patients who underwent simultaneous conventional CABG and valve surgery, necessarily by median sternotomy, between March 2005 and June 2011. Excluded were patients who underwent aortic root replacement, had active endocarditis, had left main coronary artery disease, or underwent emergency surgery. All median sternotomy operations were performed by a group of 6 surgeons. All minimally invasive operations were performed by 1 of the 6 surgeons. The median sternotomy control group was matched on the basis of decade age, number of diseased coronary vessels, gender, creatinine level, type of valve surgery, and heart failure. The definitions and variables selected were based on The Society of Thoracic Surgeons Database definitions. Composite surgical complications were defined as the presence of postoperative renal failure, stroke, myocardial infarction, or death. The hybrid patients were evaluated in the outpatient setting 30 days after the operation.

### Patient Selection

In all patients the coronary and valvular lesions were documented by diagnostic catheterization and echocardiography. The patients were selected

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### Abbreviations and Acronyms

CABG	= coronary artery bypass grafting
IQR	= interquartile range
PCI	= percutaneous coronary intervention

to undergo a staged approach at the discretion of the referring cardiologist and/or by the surgeon.

### Procedural Staging

Once the treatment plan was established, the interventional cardiologist proceeded with PCI and possible stent placement of the coronary artery lesion or lesions. In all patients receiving stents, a loading dose of 600 mg of clopidogrel and 325 mg of aspirin was administered at the time of stent placement, followed by clopidogrel 75 mg/day and aspirin 325 mg/day thereafter. Management of antiplatelet therapy between the PCI and the operation was at the discretion of the interventional cardiologist.

### Technique for Minimally Invasive Valve Surgery

All patients were placed in the supine position and underwent anesthetic induction and intubation with a single-lumen endotracheal tube and a bronchial blocker. A roll was placed underneath the right scapula in patients undergoing a minimally invasive mitral valve procedure. Every patient had a Swan-Ganz catheter (Edwards LifeSciences, Irvine, Calif) and a radial arterial line placed. A transesophageal echocardiogram Doppler probe was placed intraoperatively to evaluate the diseased valves, as well as to assess the postoperative results.

In all cases except 1, a femoral platform was used to establish cardiopulmonary bypass. A 2- to 3-cm incision was made in the inguinal crease. A 5-0 Prolene polypropylene purse-string suture (Ethicon, Inc, Somerville, NJ) was placed on the femoral artery and vein. After heparinization, a Seldinger technique was used to cannulate the femoral vessels. The femoral artery was cannulated with a 16F to 18F arterial cannula (Edwards LifeSciences), and the femoral vein. Transesophageal echocardiography was used to aid in placement of the venous cannula in the superior vena cava.

For the mitral valve procedures, a 4- to 5-cm skin incision was made in the fourth to fifth intercostal space at the site of the anterior axillary line. The same incision was made for patients having double valve surgery involving the mitral and tricuspid valves. For the mitral valve repair and replacements, the mitral valve was accessed through the Waterston groove and then through the atrial septum into the left atrium. A specially designed atrial lift retractor and atrial exposure device was used for visualization of the mitral valve. Mitral valve repair or replacement was carried out in the standard fashion. A 4-0 Prolene polypropylene suture was used to close the left atrium.

In the patients undergoing mitral valve surgery with a history of CABG, we used moderate-to-deep hypothermia (24°C-26°C) and fibrillatory arrest. Cardioplegic solution was not delivered at all. Air was removed via a vent placed through the atriotomy, mitral valve, and into the left ventricle. If significant peripheral vascular disease was present in patients undergoing mitral valve procedures, then axillary artery cannulation was performed, as was the case in 1 patient of our study.

For aortic valve procedures, a 4- to 5-cm transverse parasternal incision was made over the second to third intercostal space. This incision was extended to 6 to 7 cm in those undergoing combined aortic and mitral valve surgery. In all aortic valve procedures, the second or third costochondral cartilage was transected to allow adequate exposure of the aorta. At the completion of the operation, the rib was reattached to the sternum with a 1-cm metal plate (Synthes, West Chester, Pa) and a fiber wire was placed in a figure-of-8 fashion. In all cases, the pericardium was opened above the phrenic nerve and over the aorta to facilitate exposure. A transverse

aortotomy was performed for exposure of the aortic valve. Valve replacement was carried out under direct vision by standard techniques. In aortic valve procedures, a left ventricular vent was inserted into the left ventricle via a purse-string suture in the right superior pulmonary vein.

In patients undergoing aortic valve replacement who have a previous CABG and a patent left internal thoracic graft, we use moderate hypothermia (28°C) with one induction dose of antegrade cardioplegic solution. Thereafter, cardioplegic solution is delivered retrogradely at 20-minute intervals. We do not dissect the left internal thoracic artery pedicle. In the setting of a patent left internal thoracic artery, we prefer the native left anterior descending artery to be totally occluded. This diminishes a constant stream of blood return from the left main coronary artery obscuring the operative field. If the left anterior descending artery is patent, we place a No. 10F red rubber catheter, connected to a pump suction, into the left main coronary artery to aspirate the blood. If significant peripheral vascular disease had been present, then central aortic cannulation would have been performed, but this was not the case in any of the patients.

With transesophageal echocardiography guidance, a retrograde coronary sinus catheter was directly inserted through the incision, and a purse-string suture was placed in the right atrium. Cardiopulmonary bypass was initiated at 32°C to 36°C using a closed membrane oxygenator and roller pump. Venous drainage was augmented with vacuum assistance applying negative pressures of 30 to 70 mm Hg as needed to decompress the right side of the heart. Transincisional direct aortic crossclamping was performed with a flexible and retractable shaft crossclamp (Novare Surgical Systems, Cupertino, Calif). One dose of antegrade cold blood cardioplegia was given to establish electromechanical arrest of the heart. Thereafter, retrograde cold blood cardioplegia was given throughout the procedure at 20- to 25-minute intervals. If retrograde cardioplegia was not possible, a cannula was left in the ascending aorta to deliver antegrade cardioplegia, or the heart was fibrillated. All procedures were performed with specially designed long-shafted minimally invasive instruments (Geister, Tuttlingen, Germany). Carbon dioxide was infused into the operative field during the entire procedure. Air was removed from the heart with a needle in the root of the aorta and under transesophageal echocardiographic guidance. The heart was not directly manipulated during deairing maneuvers. If needed, external compression of the chest wall was performed to aid in deairing. With the heart empty, both atrial and ventricular pacing wires were placed. After cardiopulmonary bypass had been discontinued and protamine administered, decannulation was performed. The purse-string sutures were tied, and the femoral artery was directly repaired with 5-0 Prolene polypropylene suture. A single chest tube was left in the pleural space. For pain relief, all patients had an On-Q pain relief system inserted (I-Flow Corporation, Lake Forest, Calif). Two catheters were placed in the intercostal space to deliver 0.25% bupivacaine for 72 hours. The thoracotomy incision was closed in the routine fashion.

### Statistical Analysis

All continuous variables are expressed as the means  $\pm$  1 standard deviation. Nonparametric variables were expressed as medians and interquartile ranges (IQRs, or 25% to 75%). An independent *t* test was used to compare continuous variables between groups that had a normal distribution. Nonparametric variables were compared with a Mann-Whitney *U* test. All dichotomous variables were compared by  $\chi^2$  analysis. The statistical analyses were done using SPSS version 17 (SPSS, Inc, Chicago, Ill).

### RESULTS

From February 2009 to June 2011, 65 patients underwent staged PCI followed by elective minimally invasive valve surgery. There were 37 (57%) men and 28 (43%) women with a mean age of  $75.4 \pm 8$  years. The baseline

TABLE 1. Patient baseline characteristics

Variables	Hybrid group (n = 65)	Conventional group (n = 52)	P value
Variables			
Age (mean ± 1 SD)	75.4 ± 8	73.8 ± 8.2	.3
Gender (male)	37 (57%)	29 (55%)	.9
EF (mean ± 1 SD)	53.9 ± 12.5%	50 ± 12.6%	.036
Prior MI	19 (29%)	11 (21.2%)	.32
BMI (mean ± 1 SD)	27.8 ± 4.6	27.2 ± 4.5	.46
Diabetes mellitus	25 (38%)	15 (28.8%)	.28
Hypertension	55 (85%)	49 (94%)	.1
COPD	16 (25%)	16 (30.8%)	.46
CHF	24 (37%)	26 (50%)	.15
CVA	11 (17%)	5 (9.6%)	.25
Preoperative creatinine level (mean ± 1 SD)	1.21 ± 1.1	1.16 ± 0.49	.56
Previous CABG surgery	5	1	.16
Previous AVR	2	0	.06
EuroSCORE (mean ± 1 SD)	10 ± 8.45%	8.9 ± 4.84%	.7
Preoperative medications			
Aspirin	43%	44%	.7
Clopidogrel	64%	17%	<.001
ACE inhibitors/ARB	67%	42%	.003
Nitrates	5%	7%	.76
Beta-blockers	67%	73%	.24
Statins	71%	64%	.49
Warfarin	10%	23%	.04

SD, Standard deviation; EF, ejection fraction; MI, myocardial infarction; BMI, body mass index; COPD, chronic obstructive pulmonary disease; CHF, congestive heart failure; CVA, cerebrovascular accident; CABG, coronary artery bypass grafting; AVR, aortic valve replacement; ACE, angiotensin converting enzyme; ARB, angiotensin II receptor blocker.

characteristics were similar between the hybrid and conventional groups, with the exception that the ejection fraction was slightly lower in the conventional group (53.9% ± 12.5% vs 50% ± 12.6%; *P* = .036) and there were more patients with a history of cardiac surgery in the hybrid group than in the conventional group (7 [10.7%] vs 1 [1.9%], although the difference did not reach statistical significance; *P* = .06). The EuroSCORE predicted operative mortality was 10% ± 8.45% and 8.9% ± 4.84% for the hybrid and the conventional groups, respectively (*P* = .7; Table 1). There was also no significant difference in the number of diseased vessels of the hybrid group versus the conventional group (Table 2).

All hybrid patients were clinically stable for both PCI and surgery, except for 2 patients whose PCI was

TABLE 2. Comparison of the number of diseased vessels between the hybrid and the conventional group

No. of diseased vessels	Hybrid group (n = 65)	Conventional group (n = 52)	P value
1	36 (55.3%)	29 (42%)	.56
2	15 (23.1%)	29 (42%)	.48
3	14 (21.5%)	11 (16%)	.96

TABLE 3. Antiplatelet therapy of hybrid patients at time of cardiac valve surgery

N=65(%)	
Antiplatelet agents stopped 5 days before surgery 20 (30.7%)	
Aspirin alone	4 (6.1%)
Clopidogrel alone	18 (27.7%)
Aspirin and clopidogrel	123 (35.4%)
Any clopidogrel	41 (63%)

performed in the setting of an ST-elevation myocardial infarction and underwent minimally invasive surgery electively later. Of the 7 patients with a history of cardiac surgery, 5 had previous CABG and underwent mitral valve repair for severe functional mitral regurgitation and 2 had a history of aortic valve replacement with CABG and now had severe paravalvular aortic insufficiency needing repeat aortic valve replacement.

**Description of PCI**

In the hybrid arm, 36 (55.3%) patients underwent 1-vessel, 15 (23.1%) underwent 2-vessel, and 14 (21.5%) underwent 3-vessel PCI. Drug-eluting stents were placed in 36 (55.5%), bare metal stents in 25 (38.5%), and balloon angioplasty was performed in 4 (6.2%). The anatomic locations of the lesions treated with PCI were as follows: 21 (32.3%) proximal left anterior descending coronary artery, 40 (61.5%) mid-left anterior descending coronary artery, 26 (40%) right coronary artery, and 21 (32.3%) circumflex coronary artery. There were 2 post-PCI procedural complications. A femoral arteriovenous fistula, which needed repair, developed in 1 patient, and a groin infection, which was treated with antibiotics, developed in the other. The median number of days between PCI and surgery was 24 (IQR, 2.5-37).

**Description of Surgery**

At the time of surgery in the hybrid group, 23 (35.4%) patients were receiving both aspirin and clopidogrel, 18 (27.7%) were taking clopidogrel alone, 4 (6.1%) were taking aspirin alone, and 20 (30.7%) patients had their antiplatelet agents stopped 5 days before surgery (Table 3). All patients were placed on their preoperative anticoagulation regimen on day 1 or 2 postoperatively. The type of valve surgery performed was not significantly different between the 2 groups, except that there were 10 (15.3%) double valve operations in the hybrid group and none in the conventional group, with the difference in the numbers of aortic valve replacements with mitral valve repairs reaching statistical significance (*P* = .025; Table 4).

In the hybrid group, of the 31 patients who had aortic valve replacement, 29 (93.5%) were operated on for severe aortic stenosis and 2 (6.4%) for prosthetic aortic valve regurgitation. Of the 24 patients who had mitral valve surgery,

TABLE 4. Type of valve surgery performed

	Hybrid (n = 65)	Conventional (n = 52)	P value
Aortic valve replacement alone	31 (47.7%)	32 (61.5%)	.14
Mitral valve repair alone	14 (21.5%)	14 (28.8%)	.37
Mitral valve replacement alone	10 (15.4%)	5 (9.6%)	.36
Aortic valve replacement plus mitral valve repair	6 (9.2%)	0	.025
Aortic valve replacement plus mitral valve replacement	4 (6.2%)	0	.07

13 (54.1%) had functional mitral regurgitation, 6 (25%) had myxomatous degeneration, and 5 (20.8%) had regurgitation. The 10 patients who had aortic valve replacement with mitral valve repair or replacement consisted of patients with severe aortic stenosis, 6 of whom had mitral regurgitation owing to calcific degeneration of the mitral valve and 4, functional mitral regurgitation.

The median aortic crossclamp and cardiopulmonary bypass times for the hybrid group were 84.5 minutes (IQR, 71-108) and 115 minutes (IQR, 96-135), respectively; for the conventional group they were 64 minutes (IQR, 47-92) and 95 minutes (IQR, 78-115),  $P = .001$  and  $P = .004$ , respectively.

### Clinical Outcomes

There were no deaths in the hybrid group, whereas the in-hospital mortality for the conventional group was 2 (3.8%;  $P = .11$ ). Of the 2 patients who died in the conventional group, 1 did so from pneumonia/sepsis and the other died of acute renal failure that was followed by an acute myocardial infarction. Composite postoperative complications (renal failure, stroke, myocardial infarction, or death) occurred significantly less frequently in the hybrid group than in the control group: 1 (1.5%) versus 16 (30.8%) ( $P = .001$ ). The incidence of prolonged intubation was 7 (10.7%) in the hybrid group and 22 (42.3%) in the median sternotomy group ( $P < .001$ ). The mean number of packed red blood cells transfused in the hybrid group was  $1.6 \pm 1.6$  units and in the conventional group,  $1.9 \pm 2.4$  units ( $P = .35$ ). There was 1 (1.5%) reoperation for postoperative bleeding in the hybrid arm compared with 2 in the conventional group ( $P = .43$ ) (Table 5).

In the hybrid group, there were 41 patients taking clopidogrel at the time of surgery and 24 who were not. Those receiving clopidogrel required a mean of  $1.9 \pm 1.8$  units of transfused packed red blood cells, whereas those not receiving clopidogrel required a mean of  $1.4 \pm 1.5$  units ( $P = .36$ ).

### Resource Use

The median length of stay in the intensive care unit was 50 hours (IQR, 38-92) for the hybrid group and 98 hours

TABLE 5. Operative results

Variables	Hybrid group (n = 65)	Conventional group (n = 52)	P value
In-hospital mortality	0	2 (3.8%)	.11
Composite complications	1 (1.5%)	16 (38.8%)	.001
ICU length of stay (h, median, IQR)	50 (38-92)	98 (66-138)	.001
Length of hospital stay (d, median, IQR)	9 (7-12)	15 (10-20)	.001
Units of PRBCs transfused (mean $\pm$ 1 SD)	$1.6 \pm 1.6$	$1.9 \pm 2.4$	.35
Aortic crossclamp time (min, median, IQR)	84.5 (71-108)	64 (47-92)	.001
CPB time (min, median, IQR)	115 (96-135)	95 (78-115)	.004
Prolonged ventilation	7 (10.7%)	22 (42.3%)	<.001
Postoperative renal failure	1 (1.5%)	9 (17.3%)	.002
Bleeding requiring reoperation	1 (1.5%)	2 (3.8%)	.43
Postoperative CVA	0	2 (3.8%)	.11

Composite complications: mortality, renal failure, myocardial infarction, and cerebrovascular accidents. Hybrid group hospital length of stay includes the length of stay for the percutaneous coronary intervention. ICU, Intensive care unit; IQR, interquartile range; PRBCs, packed red blood cells; SD, standard deviation; CPB, cardiopulmonary bypass; CVA, cerebrovascular accident.

(IQR, 66-138) for the control group ( $P = .001$ ). The total length of hospital stay, which included the hospital days for the PCI interventions, was shorter in the hybrid group, with a median of 9 days (IQR, 7-12) versus 15 days (IQR, 10-20) for the control group ( $P = .001$ ).

### DISCUSSION

A hybrid procedure that changes a conventional CABG with concurrent valve surgery into a PCI with isolated minimally invasive valve surgery is an appealing way to parse and minimize the risk of complex heart surgery. Our report of a consecutive series of patients undergoing staged PCI and minimally invasive valve surgery demonstrates a low cumulative complication rate for the hybrid approach, coupled with a short length of intensive care unit and overall hospital stay. Indeed, a comparison with matched historical controls at the same institution demonstrated the superiority of the hybrid approach.

This hybrid approach was first evaluated by Byrne and colleagues<sup>16</sup> in a study of 26 patients with acute coronary syndrome who underwent PCI followed by valve surgery within a median of 5 days. The operative mortality was 3.8%, which was much lower than the 22% mortality predicted by the Society of Thoracic Surgeons Database. Because of the use of dual antiplatelet therapy, a high incidence of bleeding occurred, with 22 (85%) of the 26 patients requiring blood transfusions. In an attempt to reduce the incidence of bleeding, Brinster and colleagues<sup>20</sup> performed the PCI the day of, or evening before, the scheduled

minimally invasive aortic valve replacement in 18 patients. There were no reoperations for bleeding, and only 8 (44%) patients required blood transfusions. The hybrid patients in our study had a lower number of blood transfusions than the conventional group, but the difference did not reach statistical significance. However, our study differs from the previously mentioned studies in that we had a significant variation on the use of antiplatelet agents, which is a reflection of the different practice patterns among the interventional cardiologists. We noted no difference in the need for blood transfusions between the patients taking clopidogrel and those who were not taking it. On the basis of our preliminary results, we recommend continuing dual antiplatelet agents on the hybrid patients when they undergo minimally invasive valve surgery. The current guidelines for antiplatelet management in patients with a bare metal coronary stent who require surgery within 6 weeks of stent placement is to continue aspirin and clopidogrel in the perioperative period, as well as in those who have had a drug-eluting stent who require surgery within 12 months of stent placement.<sup>21</sup>

As more hybrid PCI/valve procedures are being performed, many questions remain unanswered, including the optimal order for the procedures, their timing, the management of dual antiplatelet therapy, and the optimal costs and logistics of the procedures.<sup>22</sup> It would be reasonable to hypothesize that the 1-stop approach proposed by Brinster and colleagues<sup>20</sup> not only reduces bleeding but also is more convenient for the patient and more cost effective than a 2-stage approach. This approach requires a high degree of coordination between the interventional cardiologist and the cardiothoracic surgeon, which may be facilitated by the presence of a “hybrid” operating room designed for performing both procedures.<sup>22</sup> However, our experience suggests that a hybrid approach combining PCI with minimally invasive valve surgery can be done safely without these special rooms.

Given the trends toward increases in minimally invasive cardiac surgery, the broad applicability of the hybrid approach described here may be particularly appealing. Gammie and colleagues<sup>23</sup> reported that from 2004 to 2008 the percentage of mitral valve operations that were done via a minimally invasive approach increased from 11.9% to 20.1% ( $P < .0001$ ). With this progression, it is most likely that a hybrid approach will increase as well. On the other hand, the short-term benefits of a hybrid approach are not without potential long-term hazards. Clinical trials suggest that, in many instances, full revascularization with coronary surgery may be superior to partial revascularization with PCI. Moreover, the long-term intervention-free survival of a left internal thoracic graft to the left anterior descending coronary artery is probably superior to the best currently available drug-eluting stent. Thus, the results of this short-term, single-center study should be viewed as supporting

a prospective randomized controlled clinical trial to compare a hybrid (staged) PCI and minimally invasive valve surgery with the conventional median sternotomy approach.

### Study Limitations

This was a single-center, retrospective study of a heterogeneous group of patients. All minimally invasive operations were performed by a single surgeon (J.L.). Selection of patients for PCI was based on favorable anatomy for this procedure, which is an important selection bias. The follow-up of the patients was limited to 30 days, and thus no statement may be made regarding long-term differences in outcomes, as might be expected when comparing PCI and CABG. Also, the control group and the study cohort were not concurrent in terms of the time frames of the procedures performed. The length of hospital stay in the conventional patients was high at 15 days, which reflected patient recovery times and clinical practice. These are uncontrollable confounders, and in view of this, the results can only be interpreted as hypothesis-generating.

### CONCLUSIONS

In selected sites with a surgical team comfortable with minimally invasive surgery, a staged approach of PCI followed by minimally invasive valve surgery may be an effective approach for selected patients with suitable coronary and valvular anatomy.

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