

Left Main PCI in Interventional Labs Without On-Site Surgery: When is High Risk Too High?

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There are many interventional labs in the United States that operate without the benefit of on-site surgery, with agreements in place for emergency transfers and other safety procedures as outlined in the 2014 Society for Cardiovascular Angiography and Interventions (SCAI) consensus document on percutaneous coronary intervention (PCI) in labs without surgery on site (SOS).¹ As PCI technique progresses and new aspects of stenting, chronic total occlusion (CTO) procedures, and complex interventions become more routine for large, full-service centers, many experienced operators are bringing their expertise to labs without SOS. This expansion in sites of care prompted a revision of the 2014 SCAI consensus statement, released this month, headed by chairperson Dr. Cindy Grines and co-chair Dr. Arnold Seto.²

The issue of what constitutes safe practice in the no-SOS labs is not trivial. Before I present a summary of the revised consensus statement, I thought I would stimulate our thinking by providing a real case from our lab, what my colleagues said about the case, and the issues around the no-SOS lab transfer approach.

The Case

A 72-year-old patient with stable exertional angina on appropriate medical therapy was brought to the cath lab after a positive preoperative screening stress test (electrocardiogram [ECG] ST depressions) for cataracts. (Usually, cataract surgery doesn't get screening stress tests, but sometimes it is done.) On angiography, we found an 80% irregular, ulcerated-appearing left main artery narrowing and total right coronary artery (RCA) with left-to-right collaterals (Figure 1). Echocardiography showed a left ventricular ejection fraction (LVEF) of 45%. After discussions with the patient and surgical colleagues at our nearby referring hospital, we planned to transfer this patient urgently after the procedure for coronary artery bypass graft (CABG) surgery. However, there were no beds available for surgery at any of our three potential referral sites. This delay in needed care could be a bigger problem if the patient destabilizes and needs urgent revascularization. Fortunately, and for a majority of our patients, we are able to treat the patient conservatively with heparin and anti-ischemic meds until a bed opens up.

While transfer is a standard approach for many

sites without SOS, in these post-COVID days of tight bed availability, transfer for CABG is often not timely.

My question to the group was, what to do now that there are no beds available?

1. Do you admit for observation following the procedure while awaiting transfer?
2. Although the patient is entirely asymptomatic for the last week, do you insert an intra-aortic balloon pump (IABP)? His blood pressure, heart rate (HR), and sats are normal after the procedure. I doubt anyone would place an Impella (Abiomed) left ventricular assist device at this juncture.
3. Should we proceed with high-risk PCI without surgical standby?

Before we hear about what we did and what our expert cath lab colleagues said, let's review the guidelines and consensus statements information on PCI in centers without SOS.

Outpatient PCI in 2014?

In 2014, most PCI patients were still observed overnight, sometimes for clinical reasons, sometimes for billing reasons. Concerns about the femoral access

and late bleeding might have contributed to the situation. Outpatient PCI was not reimbursed at the same rate as short stay or full admission status. These scenarios and recommendations for outpatient PCI and for centers with no SOS were summarized in the SCAI consensus document.¹ Since the publication of the 2014 consensus statement, same-day discharge after elective PCI has increased (29% of all PCIs).³ Forty percent of radial access PCI procedures in the United States underwent same-day discharge by 2017.³ The volume and complexity of PCI in no-SOS sites have also increased, with many interventional cardiologists performing PCI in ambulatory surgery centers (ASCs). Several studies from around the world subsequently demonstrated that PCIs at no-SOS centers have low rates of complications, with similar outcomes compared to PCIs performed at centers with SOS. Fast forward to 2023.

PCI of Complex Lesions in No-SOS Centers

The 2023 SCAI consensus document² reviews the state of the art and provides data regarding patient selection criteria based on patient risk, operator experience, and facility capabilities and administrative lab requirements. Although a detailed and expert report, there are limited data regarding PCI outcomes for high-risk lesion subsets in outpatient settings. Several large datasets are cited. The Victorian Cardiac Outcomes Registry in Australia reported that 19% of unprotected left main procedures were undertaken in no-SOS centers.^{2,4} Of interest, patients treated at no-SOS sites had a higher prevalence of left ventricular dysfunction, ST-elevation myocardial infarction (STEMI), and/or cardiogenic shock or required intubation, and had higher mortality and major adverse cardiac event (MACE) rates. Many of these patients, of course, are not elective interventions, but rather potentially life-saving emergencies. Importantly, on-site cardiac surgery was not independently associated

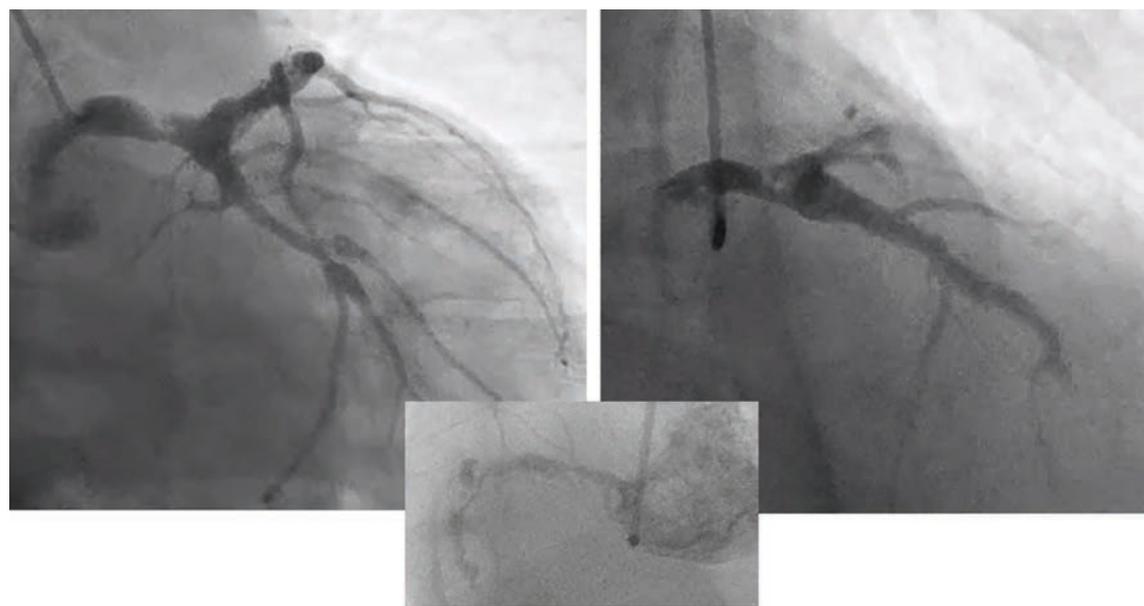


Figure 1. Frames from cine coronary angiography of left coronary artery in right anterior oblique (RAO) caudal (left) and RAO cranial (right) projections showing ulcerated severe left main narrowing. Insert below shows chronic total occlusion of right coronary artery.

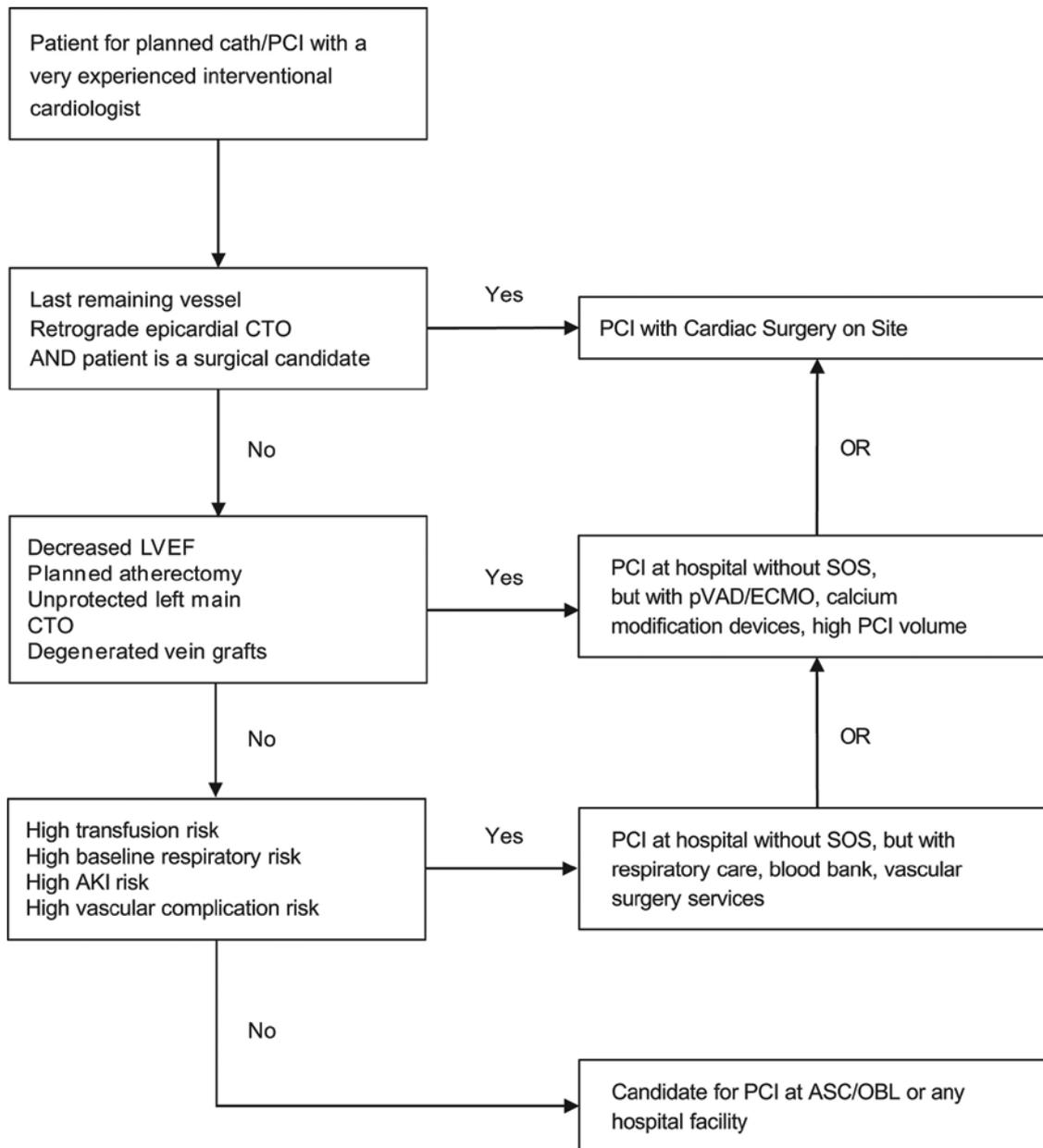


Figure 2. Simplified algorithm for case selection for elective PCI at different facilities, assuming an experienced interventional cardiologist. AKI, acute kidney injury; ASC, ambulatory surgery centers; CTO, chronic total occlusions; ECMO, extracorporeal membrane oxygenation; LVEF, left ventricular ejection fraction; OBL, office-based laboratories; PCI, percutaneous coronary intervention; pVAD, percutaneous ventricular assist device; SOS, surgery on site.

Reprinted from Grines CL, Box LC, Mamas MA, et al. *JACC Cardiovasc Interv.* 2023 Jan 24; S1936-8798(22)02297-X. doi: 10.1016/j.jcin.2022.12.016 ©2023 the Author(s). Published by Elsevier Inc on behalf of Society for Cardiovascular Angiography and Interventions Foundation and American College of Cardiology. An open access article under the Cc By-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

with in-hospital mortality or 30-day mortality. In the United Kingdom, a series of 40,744 left main PCIs reported 37% were performed at no-SOS centers. There was no association between surgery backup and risk of death, major adverse cardiac and cerebrovascular events (MACCE), or emergency CABG. Noteworthy was that bleeding complications were lower at no-SOS centers (probably in large part due to use of the radial approach).

There have been no comparative studies in other complex subgroups such as CTO and atherectomy; however, observational data suggests that CTO procedures are feasible with experienced operators, but with higher complication rates than with other anatomic subsets.

The 2023 consensus document makes a strong case for judicious patient selection for the safe performance of ambulatory PCI. The difference among these settings is compared in Table 1. Ambulatory centers do not generally receive high-risk acute coronary syndrome (ACS) patients, but hospital-based labs with no SOS can manage STEMI and other ACS patients. Patient comorbidities, particularly those that would favor the hospital setting, are shown on Table 2. The personnel and facility requirements for PCI programs without on-site surgical backup are summarized in Table 3. Requirements for primary PCI and emergency CABG at hospitals without on-site cardiac surgery are also provided in Table 4.

PCI with no surgery on site (SOS) is as safe as PCI at centers with on-site surgery. Adequate operator experience, appropriate clinical judgment and case selection, and facility preparation are essential to a successful PCI program with no SOS.

Our Left Main Patient

Our lab is a hospital-based PCI/electrophysiology lab without SOS. Here is what we did. Although the patient was very stable after the angiogram, given the ulcerated image of the left main (LM), we had concern that urgent surgery was needed (flow chart, Figure 2). We found that we could not transfer the patient that day due to lack of outside bed availability. We admitted him to the intermediate monitored care unit, initiated heparin infusion, and continued his home medications while awaiting a surgical bed at one of our referral CABG facilities. It took 2 days to transfer the patient. He then had his surgery without any complications and was discharged home.

As for the risk for PCI at our no-SOS center, we use the same criteria as described in the SCAI expert consensus document of 2023,² but an unprotected LM with RCA CTO was deemed too high risk for us. We cannot risk our program on a complication in a patient like this. As for the question about need for IABP, since he remained rock stable and never changed clinical status, we saw no indication.

My colleagues (below) agreed with management and commented on the challenges of transfer of patients to tertiary referral centers.



Chris White, New Orleans, Louisiana:

Just a comment on transfers during the pandemic being slow. The knock-on effect has been the increases in labor costs (agency nursing), resulting in many hospitals not being able

to afford to staff all of their beds. There are plenty of beds, but not enough nurses to open them. We are currently experiencing a contraction of available beds from pre-pandemic levels, so I would expect that transfer delays may get worse will be with us for a while.



Kirk Garratt, Newark, Delaware: I

heard a healthcare economist recently say we are currently short 400k RNs nationwide. The really bad news: things are expected to worsen, with a shortage of 450k expected by 2025.

Table 1. Table of differences among types of PCI centers.

| | ASC/OBL | Level 1 No-SOS Hospital | Level 2 No-SOS Hospital | Cardiac Surgery Facility |
|--|--|---|--|---|
| Typical characteristics | No ICU, Code team, blood bank | Low volume (<200 PCI) cath lab | Experienced interventional cardiologists Well-staffed team (4/room) Well-resourced Often multiple cath labs and ORs 24/7 ICU/anesthesia/radiology/OR support | Experienced interventional cardiologists High-volume cath lab Structural heart procedures Well-staffed, resourced, on-call cath lab team Multiple operating rooms On-call cardiac surgeon and perfusionist Shock team |
| Rescue/support capabilities | IABP | IABP | IABP pVAD or ECMO Vascular/thoracic surgery | IABP pVAD Cardiopulmonary bypass +/- ECMO +/- RVAD +/- LVAD +/- transplant |
| Plaque modification devices | Often cutting balloon or IVL | Often cutting balloon or IVL | Rotational atherectomy Orbital atherectomy IVL | Rotational atherectomy Orbital atherectomy IVL |
| Cases that may be higher risk to avoid | High transfusion risk, Calcified lesions, Atherectomy, Low EF, CTO, Unprotected left main, Degenerated vein grafts | Calcified lesions, Atherectomy, Low EF, CTO, Unprotected left main, Degenerated vein grafts | Epicardial retrograde CTO Last remaining vessel/conduit | |

Abbreviations: PCI, percutaneous coronary intervention; ASC, ambulatory surgical center; OBL, office-based laboratory, SOS, surgery on site; ICU, intensive care unit, OR, operating room; IABP, intra-aortic balloon pump; pVAD, percutaneous ventricular assist device; ECMO, extracorporeal membrane oxygenation; RVAD, right ventricular assist device; LVAD, left ventricular assist device; IVL, intravascular lithotripsy; CTO, chronic total occlusion; EF, ejection fraction.

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Bonnie Weiner, Worcester, Massachusetts: Thanks, Kirk. These numbers don't really surprise me. What concerns me, though, is the sense I have that just like physician workforce issues, the need here is for "bedside"

nurses and the trend recently has been for increasing specialization and "advancement" to advance practice and administrative roles. A lower percentage of nurses are actually doing or staying in direct patient care roles. Not sure we have the tools to change the trend.



Kirk Garratt, Newark, Delaware: You're absolutely right, Bonnie. The bedside and some specialty nurses seem to be in shortest supply, so they are getting really mind-bending compensation offers. I heard an unsubstantiated rumor that some OR RNs are getting \$300/hour. RNs often work 36 hours/week. At 1872 work hours/year, that comes out to a salary competitive with an interventional cardiologist!! I might be an outlier here, but I also feel part of our overall workforce problem is our failure to use the advanced practice clinicians (APCs) properly. Too many APCs

function as handmaidens and manservants to the doctors. That's totally wrong and financially backwards. We talk about having APCs work at top of license, but we fail all too often, contributing further to excess cost. APCs are here to stay and talented RNs will continue to move in that direction. If we use APCs to work in team-based models and improve care efficiency, we have a shot at containing costs, which will help (among other things) sustain physician salaries. Without changes like this, physician compensation will suffer.



Bonnie Weiner, Worcester, Massachusetts: Thanks, Kirk. I agree with your comments about the APCs as well. Too often, I hear of them "waiting for the attending" to do consults or stress tests, for example. They

should be quite capable of doing these things in the majority of cases. Knowing that an MD is going to follow after or is available for questions, they should be freeing up time for MDs to do more complex activities and other things such as teaching or research, where appropriate. It's definitely not always happening that way.

Table 2. Comorbidities favoring in-hospital patient management.

| |
|--|
| 1. Decompensated heart failure/severe left ventricular dysfunction |
| 2. Respiratory compromise (hypoxia at rest) |
| 3. High risk of blood transfusion |
| 4. At risk for acute kidney injury |
| 5. History of severe contrast allergy |
| 6. Critical valvular heart disease |
| 7. Any condition likely to require overnight observation |

The Bottom Line

PCI with no SOS is as safe as PCI at centers with on-site surgery. Adequate operator experience, appropriate clinical judgment and case selection, and facility preparation are essential to a successful PCI program with no SOS. The expert consensus statement summarizes the evidence supporting PCI with no SOS and provides the community

Table 3. Personnel and facility requirements for percutaneous coronary intervention (PCI) programs without on-site surgical backup.

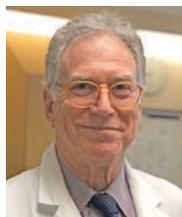
| | |
|---|--|
| • | Experienced, interventional trained nursing/technologist staff comfortable in treating acutely ill patients with hemodynamic and electrical instability. |
| • | On-call operation of laboratory 24 hours/day, 365 days/year. |
| • | Experienced coronary care unit nursing staff comfortable monitoring hemodynamics, and management of temporary pacemaker and intra-aortic balloon pumps (IABPs). |
| • | Personnel capable of airway management (endotracheal intubation, ventilator) both on site and during transfer. |
| • | Full support from hospital administration in fulfilling the necessary institutional requirements and appropriate support services (eg, respiratory care, blood bank). |
| • | Written emergency transfer agreements for patients to a facility with cardiac surgery. Transport protocols should be developed and tested a minimum of 2 times per year. |
| • | Well-equipped and maintained cardiac catheterization laboratory with high-resolution digital imaging capability and IABP equipment compatible with ambulance transport. The capability for real-time transfer of images and hemodynamic data (via T-1 transmission line), as well as audio and video images to review terminals for consultation at the facility providing surgical backup support is ideal. |
| • | Appropriate inventory of interventional equipment (including covered stents, temporary pacemakers, and pericardiocentesis trays. Pressure wire device and intravascular ultrasound equipment are optimal, but not mandatory. Rotational or other atherectomy devices should be used cautiously in these facilities because of the greater risk of perforation. |
| • | Meticulous clinical and angiographic selection criteria for PCI. |
| • | Performance of primary PCI as the treatment of first choice for ST-elevation myocardial infarction to ensure streamlined care paths and increased case volumes. Door-to-balloon times should be tracked, and >90-minute outlier cases should be carefully reviewed for process improvement opportunities. |
| • | On-site rigorous data collection, outcomes analysis, benchmarking, quality improvement, and formalized periodic case review. |
| • | Participation in a national data registry where available, such as the American College of Cardiology's National Cardiovascular Data Registry in the United States. |

Modified from Table 5. Grines CL, Box LC, Mamas MA, et al. *JACC Cardiovasc Interv.* 2023 Jan 24; S1936-8798(22)02297-X. doi: 10.1016/j.jcin.2022.12.016 ©2023 the Author(s). Published by Elsevier Inc on behalf of Society for Cardiovascular Angiography and Interventions Foundation and American College of Cardiology. An open access article under the Cc By-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

with the guidance necessary for this transition. Lastly, many other centers like ours will have to accept the fact that transfers during the triple pandemic will be slow. ■

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Disclosures: Dr. Morton Kern reports he is a consultant for Abiomed, Abbott Vascular, Philips Volcano, ACIST Medical, and Opsens Inc.

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Table 4. Requirements for primary percutaneous coronary intervention (PCI) and emergency coronary artery bypass graft surgery (CABG) at hospitals without on-site cardiac surgery.

Avoid intervention in patients with:

- >50% diameter stenosis of left main artery proximal to infarct-related lesion, especially if the area in jeopardy is relatively small and overall left ventricular function is not severely impaired.
- Long, calcified, or severely angulated target lesions at high risk for PCI failure with TIMI flow grade 3 present during initial diagnostic angiography.
- Lesions in other than the infarct artery (unless they appeared to be flow-limiting in patients with hemodynamic instability or ongoing symptoms).
- Lesions with TIMI flow grade 3 that are not amenable to stenting in patients with left main or 3-vessel disease that will require coronary bypass surgery.
- Culprit lesions in more distal branches jeopardizing only a modest amount of myocardium when there is more proximal disease that could be worsened by attempted intervention.

Transfer emergently for coronary bypass surgery patients with:

- High-grade left main or 3-vessel coronary disease with clinical or hemodynamic instability after successful or unsuccessful PCI of an occluded vessel and preferably with intra-aortic balloon pump (IABP) support.
- Failed or unstable PCI result and ongoing ischemia, with IABP support during transfer.

Modified from Table 7. Grines CL, Box LC, Mamas MA, et al. *JACC Cardiovasc Interv.* 2023 Jan 24; S1936-8798(22)02297-X. doi: 10.1016/j.jcin.2022.12.016 ©2023 the Author(s). Published by Elsevier Inc on behalf of Society for Cardiovascular Angiography and Interventions Foundation and American College of Cardiology. An open access article under the Cc By-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

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