As seen in Cath Lab Digest

Cardiac Cath Procedural Labs: Positioning Yourself for the Future

By Lorraine Buck

Cath lab program expansion is usually accompanied by questions regarding whether to expand by adding additional labs or expand by widening the scope of clinical offerings. Often organizations considering expansion find themselves already successfully managing significant procedural volumes in their cardiac cath labs. But will these high procedural volumes continue into the future? Understanding if the market exists to support any additional programming is only one piece of the puzzle, and making the determination can be quite difficult, as additional factors must be identified and understood. To begin to answer these questions, it is best to start by understanding the following:

- Cath lab volume trends — are they increasing or decreasing?
- What changes are occurring in clinical care and technology that can impact patient flow through procedural labs?
- How will ambulatory care centers (ASC) impact inpatient procedural volumes?
- If adding "new" clinical service offerings, does the organization have the ability to support program expansion financially, clinically, and operationally?

Cardiac Cath Lab Volume Trends

Coronary Artery Disease: Revascularization Volumes

From 2005 to 2014, there was an industry-wide decrease in both percutaneous coronary intervention (PCI) and coronary artery bypass grafting (CABG) procedure volumes. The procedural volume decreases started post COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial, which failed to demonstrate a reduction in death, myocardial infarction, or other major cardiovascular events with revascularization for patients with stable coronary artery disease (CAD). During this time, continued improvements in primary and secondary prevention also took place. The decrease in coronary revascularization became consistent as compared to other registries, including the Washington State Cardiac Care Outcomes Program, as well as volumes reported by Medicare and the National Cardiovascular Data Registry (NCDR CathPCI registry). Another factor that appeared to contribute to the decrease in PCI and CABG volumes was the implementation of the Appropriate Use Criteria (AUC) program starting in 2009-2010, which placed defined restrictions on indications for revascularization (Table 1).

Table 1. TRENDS in CAD Revascularization Volumes

	2005 - 2017	
COURAGE Trial	CABG PCI	↓ 22.6% ↓ 2.9%
	2010 - 2013	
Washington State Cardiac Care Outcomes Program	Elective PCI	↓ 43%
	2008 - 2012	
Medicare	CABG Total PCI	↓ 13.1% ↓ 5.3%
	2008 - 2012	
National Cardiovascular Data Registry	CABG Non-Acute PCI	↓ 15.2% ↓ 33.8%

However, 2013 to 2017 saw a 30% increase in CAD revascularization volumes from elective PCI. During this period, it is interesting to note that there were no accompanying or recent clinical trials that suggested PCI was superior to medical therapy or that CABG for chronic CAD was the best choice for treatment. Additionally, no new AUC statements were released or updated to specifically encourage an increase in PCI procedures. The increase in procedural volume is considered to be multi-factorial. Financially, there was the expansion of Medicaid. In addition, there was technical progress in addressing unprotected left main (LM) disease, and chronic total occlusions (CTO). Was the resulting increase in complex PCI procedures enough to explain a 30% increase in elective PCI procedures? The answer is, simply, no. Unprotected LM procedures were at approximately 1% of elective PCI procedures, not significantly different from the 0.7% to 1.3% seen between the years of 2009 to 2016. CTO procedures were also unlikely to account for the increase. From 2012 to 2015, only 5.7% of all elective PCI cases included CTO procedures. So what did contribute to the increase? The spike in elective PCI cases appears to

coincide with the evolution of transcatheter aortic valve replacement (TAVR), as PCI is frequently pursued pre TAVR. During this same time period, 2011 to 2015, 19% of the 72,417 aortic valve replacements were TAVR.[1]

Key takeaway: *If you are a center currently performing TAVR procedures (or considering starting a TAVR program), it would be important to account for PCI volume increase, especially as the indications for TAVR have expanded to allow for those that are considered low-risk.*

Technology Changes: Rise of Non-Invasive Imaging

In 2019, based on recent studies, the European Society of Cardiology published guidelines on the diagnosis and management of chronic coronary syndrome (CCS), which classified coronary computed tomography angiography (CCTA) as a Class 1 recommendation for diagnosing CAD in symptomatic patients.2 Unless obstructive CAD can be excluded based on clinical evaluation alone, either non-invasive functional imaging or anatomical imaging (CCTA) should be used to rule out a diagnosis of CCS. The 2019 guidelines target patients with a lower range of clinical likelihood of CAD, no previous CAD, and characteristics associated with good image quality.

The VERDICT trial (Very EaRly vs Deferred Invasive Computerized Tomography) results released in 2018 evaluated the use of CCTA versus invasive coronary angiography for non-ST elevated myocardial infarctions (NSTEMI). Out of 1023 patients, 263 (26%) went straight to CCTA and had negative results. As a comparison, all of these patients went to invasive coronary angiography and only 2% (24) out of the total number of patients had positive results. There were 758 (74%) of patients were sent to invasive coronary angiography. Of those, 92 (9%) out of the total number of patients were found to have no significant stenosis.

Although results of the VERDICT trial were promising, additional studies need to be done incorporating the measurement of fractional flow reserve (FFR) and to further understand the role of high troponin levels. Studies comparing the use of non-invasive imaging to invasive coronary angiography continue, and will likely change treatment pathways. This includes, for example, the use of CCTA along with FFR (FFRCT), which involves the application of computational fluid dynamic techniques to CCTA and has been shown to correlate well with invasive FFR.

Key takeaway: *In the future, the use of CCTA may have an impact on the flow of patients bypassing your cath lab, as the non-invasive approach will "rule out" the need for invasive coronary angiography. The volume impact could be as much as a 25-30% decrease.*

Ambulatory Surgery Centers (ASC)

In 2016, the Centers for Medicare and Medicaid Services (CMS) added pacemaker implants, loop recorders, and defibrillators to a list of approved procedures for reimbursement in the ASC. In 2019, diagnostic cardiac catheterization procedures were added, followed by PCI (angioplasty and stenting) in 2020. Procedures offered in the ASC setting have resulted in a better patient experience, higher provider satisfaction and improvements in population health, lower rates of post-procedure infections, and a lower cost of care.3

As these highly profitable services move out of the hospital, there are huge financial implications to hospitals that use the revenue generated from these procedures to support other services. Although patients may experience higher co-pays in the ASC, they typically pay the higher amount for the convenience. There are currently seven 'early adopter' states that have shifted these procedures to the ASC with another eleven approvals on the horizon (Figure 1).

Key takeaway: *Corazon anticipates that a trend toward ASCs is likely to continue over the next five to ten years, with some studies estimating a shift upwards of approximately 65% of procedures within a year and about 80% over the next five years. Depending on state regulations, the shift in procedures from the inpatient to the outpatient setting may already be occurring. And if not, changes will likely become visible in your area within the next five years.*

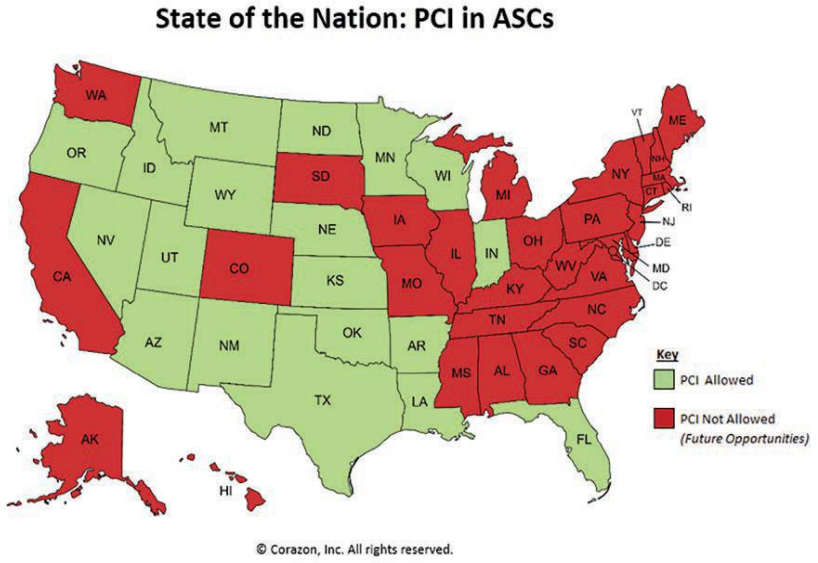

Figure 1. Percutaneous coronary intervention (PCI) in an ambulatory surgical center (ASC) has been/ will be approved (green states) in 19 states in the U.S. as of 2021.

Conclusion

What does all of this mean for the cardiac cath lab as we evaluate the movement of advanced services into our own communities? Rapidly changing clinical developments that may permit patients to bypass invasive coronary angiography through the use of new technology, rising patient expectations, and providers favoring a push to the outpatient setting all will have a significant impact on the hospital procedural lab. For example, for two cardiac cath labs running at 80% capacity, a shift in those procedures to the outpatient area, if permitted in your particular state, by Year 1 can result in a capacity need of 55%. And by Year 5, a capacity need of only 33%.

If such a reduction were to occur, what could backfill the available space in the cath lab? Corazon believes neurointervention cases are a viable option. Since the lower volume of neurointerventions will typically not require a separate lab, shared interventional space can be ideal.

As the incidence of stroke continues to rise, hospitals will need to consider what level of service is offered to the community at large. For organizations that already offer best-practice care to stroke patients as a Primary Stroke Center, the transition to offering interventional services such as thrombectomy-capable and/or comprehensive stroke care can be a natural progression. Challenges of offering a higher level of service can be lessened by use of the existing infrastructure and administrative leadership, as well as current cardiac cath lab staffing. We have seen many organizations cross-train their cardiac cath lab staff to care for complex neurointerventional patients, as the standards of care and clinical program requirements are very similar.

Although the idea of integrating neurointerventional capabilities into a fully functional cath lab may be received with initial skepticism, with the proper planning, installation of appropriate equipment, recruitment of physicians and advanced practice providers, and trained staff, all coupled with strong administrative leadership, an organization can build an extraordinary service.

No doubt the incidence of stroke will continue to rise and hospitals will need to consider the addition of programs to address the needs of their community. A traditional cardiac cath lab setting does hold the potential flexibility to incorporate an expansion of services. With the proper planning and support, financially and clinically, hospitals can work to capitalize on the success of their cardiac cath labs by addressing potential volume decreases impacted by continued research, technology, and the push to the ASCs. This can be offset by evolving into offering a new model of care with the addition of neurointerventions.

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