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EDITORIAL

Fall and Rise of Coronary Intervention

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In this issue of the *Journal of the American Heart Association* (*JAHA*), Kataruka et al analyze 12 years of data from a broadly inclusive Washington State registry that captures all percutaneous coronary intervention (PCI) (N=178 474) and coronary artery bypass grafting (CABG) (N=36 592) performed in nonfederal hospitals from 2005 to 2017.[1] The authors examined the risk profile, procedural volumes, and early outcomes of patients undergoing PCI and isolated CABG. The contemporary nature of the data provides a new observation: after a long and steady decline, PCI volumes are increasing (2013–2017), including a 30% increase in elective PCI. How can we explain the recent increase of PCI?

See Article by Kataruka et al.

RECENT TRENDS IN CORONARY ARTERY DISEASE REVASCULARIZATION VOLUMES

The overall results of this temporal trends study are as expected: overall coronary revascularization volumes have decreased in the post-COURAGE (Clinical Outcomes Utilizing Revascularization and Aggressive Drug Evaluation) trial era.[2] In the current study, annual CABG volume decreased by 22.6% from 2005 to 2017, whereas PCI volume decreased by 2.9% over the same period. The decrease in coronary revascularization seen in Washington is generally consistent with other temporal trend studies in coronary revascularization (Table): for example, nonfederal hospitals in Massachusetts had a 39% decrease in total revascularization from 2003 to 2012, with elective PCI volume decreasing nearly by half.[3] Similarly, an earlier data analysis from the Washington State registry noted that elective PCI volume declined by 43% from 2010 to 2013.[4] These state-wide trends have been replicated in national registries as well: (1) total PCI volume for Medicare recipients decreased by 5.2% from 2008 to 2012, whereas CABG volume decreased by 13.1%[5]; and (2) PCI volume decreased by 15.2% from 2010 to 2014 at NCDR (National Cardiovascular Data Registry)–participating centers, largely driven by a 33.8% decrease in nonacute PCI volumes.[6] The explanations for this decrease in revascularization volumes are continued improvement in primary and secondary prevention as well as 2 trials, BARI 2D (Bypass Angioplasty Revascularization Investigation 2 Diabetes)[7] and COURAGE,[2] that failed to demonstrate clear benefits of revascularization for patients with coronary artery disease (CAD). Finally, widespread implementation of appropriateness use criteria starting in 2009 to 2010[4,6] placed formal restrictions on revascularization indications that may have changed practice.

All of these studies noting decline in PCI and coronary revascularization focused their enrollment on the period from 2003 to 2014. There is a general consistency to these population trends, including the current Washington State registry: CABG declined steadily over time by at least 10% in each study. Are the PCI trends similarly consistent and downward? One begins to see some change to this pattern in a more recent cohort: among 85 024 veterans treated at federal hospitals between 2009 and 2015, there

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Table. Recent Trends in Coronary Revascularization in the United States

Study Name (Publication Date)	Enrollment (Time Period)	Study Population	Temporal Volume Trends	Other Key Observations
Washington Cardiac Care Outcomes Program[1] (2020)	N=178 474 PCIs N=36 592 CABGs (2005–2017)	All revascularization procedures at nonfederal hospitals in Washington State	PCI volume decreased by 2.9% CABG volume decreased by 22.6%	Risk-adjusted hospital mortality increased for PCI and decreased for CABG 2013–2017: 30.3% increase in elective PCI
VA-CART[8] (2018)	N=85 024 PCIs (2009–2015)	All patients undergoing PCI at VA hospitals for any indication	PCI volume was unchanged over the study period	NCDR risk score increased from 14 to 18 without an increase in mortality
NCDR[6] (2016)	N=2 685 683 PCIs (2009–2014)	All patients undergoing PCI at NCDR centers for any indication	PCI volume decreased by 15.2% from 2010 to 2014	2010–2014: Nonacute PCI declined by 33.8%
Medicare[5] (2015)	N=2 104 333 PCIs N=663 674 CABGs (2008–2012)	All revascularization procedures among Medicare population	PCI volume declined by 5.2% CABG volume declined by 13.1%	PCI mortality increased from 1.67% in 2008 to 1.94% in 2012
Massachusetts Registry[3] (2015)	N=132 039 PCIs N=39 663 CABGs (2003–2012)	All revascularization procedures at nonfederal hospitals in Massachusetts	PCI volume declined by 37.1% CABG declined by 44.2%	2003–2012: Elective PCI decreased by 47.1%
Washington Cardiac Care Outcomes Program[4] (2015)	N=51 872 PCIs (2010–2013)	All PCI procedures at nonfederal hospitals in Washington	PCI volume declined by 6.8%	2010–2014: Elective PCI declined by 43%

CABG indicates coronary artery bypass grafting; NCDR, National Cardiovascular Data Registry; and PCI, percutaneous coronary intervention; VA, Veterans Administration; and VA-CART, Veterans Administration Cardiovascular Assessment, Reporting and Tracking..

was no decrease in PCI volumes.[8] If one looks at the overall declining PCI volumes noted in the current Washington registry, a new trend becomes clear. By analyzing the study in an earlier post-COURAGE trial period (2005–2012) versus a contemporary era (2013–2017), the PCI findings highlight an important new trend: *"A unique finding from our analysis was an increase in volume of PCI in the recent era from 2013 to 2017 with a 20.0% increase in overall PCI and 30.3% increase in elective PCI."*[1]

TEMPORAL TRENDS AND NEW INDICATIONS FOR PCI

How can we understand the recent increase of PCI? Of note, there are no recent clinical trials (2013–2017) suggesting that PCI is superior to medical therapy or CABG for chronic stable CAD.[2,9] There are also no new guideline or appropriate use statements that would generally encourage more PCI. Furthermore, this increase does not reflect a generic trend toward more coronary revascularization: CABG volumes steadily declined throughout the entire study period. Thus, the increase of PCI in general and elective PCI in particular is likely multifactorial and not driven by randomized trials proving the superiority of PCI. In fact, the PCI strategy continued a recent history of negative comparative trials when the FREEDOM (Future Revascularization Evaluation in Patients With Diabetes Mellitus: Optimal Management of Multivessel Disease) trial (published in 2012) showed CABG was superior to PCI for patients with multivessel CAD and diabetes mellitus[10]; these randomized clinical trial findings were not completely ignored. PCI for patients with diabetes mellitus and multivessel CAD in Washington State steadily declined over time (from 66.7% to 54.1% of revascularization procedures; $P<0.0001$) with a concomitant increase in CABG in this group.

Thus, understanding the recent increase in PCI requires the examination of factors beyond comparative efficacy, clinical trials, or guideline statements. Financial factors may be important, including the expansion of Medicaid.[11] In addition, technical progress in addressing complex PCI should be considered: namely, unprotected left main PCI and chronic total occlusion PCI. Increasing operator facility with complex PCI because of advances in percutaneous techniques[12] allows patients who were previously treated surgically or with medications to opt for PCI. Is the increase in complex PCI procedures enough to explain the 30% increase in elective PCI procedures described in this registry? In a 2019 study by Valle et al using the NCDR,[13] unprotected left main PCI procedures represented 1.0% of all PCI procedures, modestly increasing from 0.7% to 1.3% from 2009 through 2016. Only 16.5% of interventional operators and 53.7% of facilities performed an average of ≥1 unprotected left main PCIs annually. Similarly, increased use of atherectomy and chronic total occlusion volume would be unlikely to fully account for increase of PCI volume. A recently published large French registry

study (2012–2015) demonstrated that only 5.7% of all elective PCIs included a chronic total occlusion PCI.[14]

On the other hand, the period of increase in elective PCI (2013–2017) coincides with a particular revolution of interventional cardiology: US Food and Drug Administration approval of transcatheter aortic valve replacement (TAVR). CAD and aortic stenosis frequently coexist, with a reported prevalence of concomitant CAD and aortic stenosis >50% in multiple registries.[15] For patients not having surgical aortic valve replacement with concomitant CABG, PCI is frequently pursued pre-TAVR after discussions between the patient and the Heart Team. The Washington State registry cannot provide the granularity needed to fully understand the increase of elective PCI. However, there are lines of evidence that are consistent with a combination of enhanced high-risk and pre-TAVR PCI driving this new trend:

1. There is a temporal correlation between increasing PCI volume and expanding TAVR volume since 2013.
2. In the Washington State cohort, there is a greater prevalence over time of several comorbidities among patients undergoing revascularization, including diabetes mellitus, renal failure requiring dialysis, and prior myocardial infarction, reflecting trends seen in the general population. These factors may favor a less invasive strategy for revascularization.
3. The risk profile of Washington State revascularization patients (calculated using the NCDR CathPCI mortality risk) increased only for patients undergoing PCI, whereas it simultaneously decreased for patients undergoing isolated CABG over the span of the study. This again suggests a shift toward less invasive strategy on the basis of risk profiles.
4. The worsening risk profile and prevalence of comorbidities in patients undergoing PCI noted in this registry has been broadly observed in other national and international registries, such as NCDR,[16] VA-CART (Veterans Administration Cardiovascular Assessment, Reporting, and Tracking),[8] Medicare,[5] NIS (Nationwide Inpatient Sample),[17] and SCAAR (Swedish Coronary Angiography and Angioplasty Registry).[18]
5. Washington State noted an increase in observed to expected mortality risk with PCI. This might partially reflect the increasing risk of PCI patients and difficulty in adjusting for these risks using older mortality models. Emerging factors, such as cardiac arrest, cardiogenic shock, calcified left main disease, and concomitant aortic stenosis, may be driving the increase in observed to expected mortality risk.

The authors of this broadly inclusive registry are to be congratulated for observing this significant new trend in revascularization. More work is needed before concluding that the increase of PCI will continue indefinitely. Two recent randomized clinical trials, ORBITA (Objective Randomized Blinded Investigation With Optimal Medical Therapy of Angioplasty in Stable Angina)[19] and ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches),[20] have tempered the expected benefits of PCI in elective cases. The competing impact of trial data versus practical advances in complex PCI in patients both with and without aortic stenosis will have an unclear effect on overall population trends in revascularization. Furthermore, well-established registries may need to implement new data collection tools to understand and adjust to new forces (ie, pre-TAVR PCI) impacting clinical practice. The landscape of coronary revascularization is rapidly changing, and continued evolution of contemporary registries is crucial in shedding much needed light on powerful trends shaping the care of patients with CAD.

ARTICLE INFORMATION

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Disclosures

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REFERENCES

1. Kataruka A, Maynard CC, Kearney KE, Mahmoud A, Bell S, Doll JA, McCabe JM, Bryson C, Gurm HS, Jneid H, et al. Temporal trends in percutaneous coronary intervention and coronary artery bypass grafting: insights from the Washington Cardiac Care Outcomes Assessment Program. *J Am Heart Assoc*. 2020;9:e015317. DOI: 10.1161/JAHA.119.015317.
2. Boden WE, O'Rourke RA, Teo KK, Hartigan PM, Maron DJ, Kostuk WJ, Knudtson M, Dada M, Casperson P, Harris CL, et al. Optimal medical therapy with or without PCI for stable coronary disease. *N Engl J Med*. 2007;356:1503–1516.
3. Yeh RW, Mauri L, Wolf RE, Romm IK, Lovett A, Shahian D, Normand SL. Population trends in rates of coronary revascularization. *JAMA Intern Med*. 2015;175:454–456.
4. Bradley SM, Bohn CM, Malenka DJ, Graham MM, Bryson CL, McCabe JM, Curtis JP, Lambert-Kerzner A, Maynard C. Temporal trends in percutaneous coronary intervention appropriateness: insights from the clinical outcomes assessment program. *Circulation*. 2015;132:20–26.
5. Culler SD, Kugelmass AD, Brown PP, Reynolds MR, Simon AW. Trends in coronary revascularization procedures among Medicare beneficiaries between 2008 and 2012. *Circulation*. 2015;131:362–370; discussion 370.
6. Desai NR, Bradley SM, Parzynski CS, Nallamothu BK, Chan PS, Spertus JA, Patel MR, Ader J, Soufer A, Krumholz HM, et al. Appropriate use criteria for coronary revascularization and trends in utilization, patient selection, and appropriateness of percutaneous coronary intervention. *JAMA*. 2015;314:2045–2053.
7. BARI Investigators. The final 10-year follow-up results from the BARI randomized trial. *J Am Coll Cardiol*. 2007;49:1600–1606.
8. Waldo SW, Gokhale M, O'Donnell CI, Plomondon ME, Valle JA, Armstrong EJ, Schofield R, Fihn SD, Maddox TM. Temporal trends

in coronary angiography and percutaneous coronary intervention: insights from the VA clinical assessment, reporting, and tracking program. *JACC Cardiovasc Interv*. 2018;11:879–888.
9. De Bruyne B, Pijls NH, Kalesan B, Barbato E, Tonino PA, Piroth Z, Jagic N, Mobius-Winkler S, Rioufol G, Witt N, et al. Fractional flow reserve-guided PCI versus medical therapy in stable coronary disease. *N Engl J Med*. 2012;367:991–1001.
10. Farkouh ME, Domanski M, Sleeper LA, Siami FS, Dangas G, Mack M, Yang M, Cohen DJ, Rosenberg Y, Solomon SD, et al. Strategies for multivessel revascularization in patients with diabetes. *N Engl J Med*. 2012;367:2375–2384.
11. Charles EJ, Johnston LE, Herbert MA, Mehaffey JH, Yount KW, Likosky DS, Theurer PF, Fonner CE, Rich JB, Speir AM, et al. Impact of Medicaid expansion on cardiac surgery volume and outcomes. *Ann Thorac Surg*. 2017;104:1251–1258.
12. Lee PH, Ahn JM, Chang M, Baek S, Yoon SH, Kang SJ, Lee SW, Kim YH, Lee CW, Park SW, et al. Left main coronary artery disease: secular trends in patient characteristics, treatments, and outcomes. *J Am Coll Cardiol*. 2016;68:1233–1246.
13. Valle JA, Tamez H, Abbott JD, Moussa ID, Messenger JC, Waldo SW, Kennedy KF, Masoudi FA, Yeh RW. Contemporary use and trends in unprotected left main coronary artery percutaneous coronary intervention in the United States: an analysis of the National Cardiovascular Data Registry Research to Practice Initiative. *JAMA Cardiol*. 2019;4:100–109.
14. Boukantar M, Loyeau A, Gallet R, Bataille S, Benamer H, Caussin C, Garot P, Livarek B, Varenne O, Spaulding C, et al. Angiography and percutaneous coronary intervention for chronic total coronary occlusion in daily practice (from a Large French Registry [CARDIO-ARSIF]). *Am J Cardiol*. 2019;124:688–695.
15. Cao D, Chiarito M, Pagnotta P, Reimers B, Stefanini GG. Coronary revascularisation in transcatheter aortic valve implantation candidates: why, who, when? *Interv Cardiol*. 2018;13:69–76.
16. Vora AN, Dai D, Gurm H, Amin AP, Messenger JC, Mahmud E, Mauri L, Wang TY, Roe MT, Curtis J, et al. Temporal trends in the risk profile of patients undergoing outpatient percutaneous coronary intervention: a report from the National Cardiovascular Data Registry's CathPCI Registry. *Circ Cardiovasc Interv*. 2016;9:e003070.
17. Agarwal S, Sud K, Thakkar B, Menon V, Jaber WA, Kapadia SR. Changing trends of atherosclerotic risk factors among patients with acute myocardial infarction and acute ischemic stroke. *Am J Cardiol*. 2017;119:1532–1541.
18. Fokkema ML, James SK, Albertsson P, Akerblom A, Calais F, Eriksson P, Jensen J, Nilsson T, de Smet BJ, Sjogren I, et al. Population trends in percutaneous coronary intervention: 20-year results from the SCAAR (Swedish Coronary Angiography and Angioplasty Registry). *J Am Coll Cardiol*. 2013;61:1222–1230.
19. Al-Lamee R, Thompson D, Dehbi HM, Sen S, Tang K, Davies J, Keeble T, Mielewczik M, Kaprielian R, Malik IS, et al. Percutaneous coronary intervention in stable angina (ORBITA): a double-blind, randomised controlled trial. *Lancet*. 2018;391:31–40.
20. Maron DJ, Hochman JS, Reynolds HR, Bangalore S, O'Brien SM, Boden WE, Chaitman BR, Senior R, Lopez-Sendon J, Alexander KP, et al. Initial invasive or conservative strategy for stable coronary disease. *N Engl J Med*. 2020;382:1395–1407.