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Original Research

Use of Calcium Modification During Percutaneous Coronary Intervention After Introduction of Coronary Intravascular Lithotripsy

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ABSTRACT

Background: Calcified coronary lesions are a challenge for percutaneous coronary interventions (PCIs). Coronary intravascular lithotripsy (IVL) is a novel calcium modification technology approved for commercial use in February 2021, but little is known about its uptake in US clinical practice.

Methods: We described trends in use of calcium modification strategies, variation in use across hospitals, and predictors of calcium modification and IVL use in PCI. We included National Cardiovascular Data Registry CathPCI Registry patients who underwent PCI between April 1, 2018, and December 31, 2022. We examined trends and hospital variation in calcium modification and IVL use. We used multivariate hierarchical logistic regression to identify predictors of calcium modification and IVL use at hospitals in 2022.

Results: Of 2,733,494 PCIs across 1676 hospitals over 4.75 years, 11.4% were performed with calcium modification. Coronary IVL use increased rapidly from 0% of PCIs in Q4 2020 to 7.8% of PCIs in Q4 2022, which was accompanied by an overall increase in use of all calcium modification strategies (11.1%-16.0%) during this period with a slight corresponding decrease in coronary atherectomy use (5.4%-4.4%). In 2022, there was wide variation in IVL use across hospitals (median, 3.86%; IQR, 0%-8.19%), with IVL being the most common calcium modification strategy in 48% of hospitals. The treating hospital was the strongest predictor of calcium modification (median odds ratio [OR], 2.49; 95% CI, 2.40-2.57) and IVL use (median OR, 2.89; 95% CI, 2.74-3.04).

Conclusions: IVL has rapidly changed the landscape of calcium modification use for PCI, although there remains wide variation across hospitals.

Introduction

Calcified coronary lesions are challenging to treat with percutaneous coronary intervention (PCI) and are associated with worse outcomes than noncalcified lesions.[1] Patients undergoing PCI in current clinical practice more frequently have diabetes, advanced age, and renal insufficiency, which likely contribute to an increasing prevalence and severity of coronary calcification over time.[2–4] Heavy calcium can make delivery of equipment for interventional procedures challenging and, if not adequately addressed, can lead to stent underexpansion, which is associated with stent thrombosis and in-stent restenosis (ISR).[5]

A variety of treatment options exist for modification of calcium in coronary lesions during PCI, including cutting balloons, scoring balloons, and rotational or orbital atherectomy.[6–10] More recently, intravascular lithotripsy (IVL), a novel approach using acoustic shockwaves in a balloon-based delivery system to transmit energy to calcified coronary lesions, has been approved by the US Food and Drug Administration for use in coronary arteries.[11] IVL is easier for operators to use compared with atherectomy and has been shown to be safe and effective in facilitating stent implantation and expansion in severely calcified lesions.[12]

Despite increasing prevalence of risk factors leading to calcified coronary lesions and growing options to treat them, limited data exist on use of calcium modification strategies during PCI. A prior report from the National Cardiovascular Data Registry (NCDR) CathPCI Registry found that use of coronary atherectomy in PCI was infrequent between

Abbreviations: CBA, cutting or scoring balloon angioplasty; ISR, in-stent restenosis; IVL, intravascular lithotripsy; MOR, median odds ratio; NCDR, National Cardiovascular Data Registry; OA, orbital atherectomy; PCI, percutaneous coronary intervention; RA, rotational atherectomy.

Keywords: atherectomy; calcified coronary lesions; calcium modification; intravascular lithotripsy; percutaneous coronary intervention.

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2009 and 2016, although use did increase from 1.1% to 3.0% during this period.[13] However, little is known about trends in use of atherectomy beyond this period and how introduction of new calcium modification strategies that are procedurally easier to use, such as IVL, may have affected treatment of calcified coronary lesions in real-world practice.

This study leverages the NCDR CathPCI Registry to describe contemporary treatment of calcified lesions on a national scale. Specifically, we examined trends in use of calcium modification strategies over time, variation in use across hospitals, and predictors of using calcium modification strategies for PCI. These results provide valuable information on the contemporary use of calcium modification strategies for PCI and shed light on temporospatial dissemination and disparities in use of novel technologies in interventional cardiology more broadly.

Methods

Study population

We included all patients in the NCDR CathPCI Registry who underwent PCI between April 1, 2018, and December 31, 2022. The NCDR CathPCI Registry is a voluntary registry that captures standardized data elements regarding all PCIs at over 2000 participating US hospitals. The registry has data quality monitoring and annual audits for data accuracy, and patient and procedural characteristics have strong agreement with similarly ascertained variables in clinical trials.[14,15] The analysis was conducted entirely using version 5.0 of the CathPCI Registry, which was routinely implemented starting April 2018. We excluded patients with ST-segment elevation myocardial infarction, cardiogenic shock, cardiac arrest within 24 hours, or salvage PCI. We additionally excluded patients from sites with <10 PCI each year or with less than 4 quarters of data. Multiple visits to the catheterization laboratory for the same patient during the study period (including the same hospitalization) were counted as separate observations. PCI of multiple vessels or lesions during the same catheterization laboratory visit were counted as the same observation.

Variables

The primary outcome was any use of a calcium modification strategy on any lesion during PCI. Calcium modification strategies considered included cutting or scoring balloon angioplasty (CBA), rotational atherectomy (RA), orbital atherectomy (OA), IVL, and any combination of these techniques. Additionally, among those that received calcium modification, we examined the use of IVL (alone or in conjunction with other therapies) on any lesion during PCI specifically.

Predictor variables included demographics (age, sex, race, or Hispanic ethnicity), medical history (presence of hypertension, dyslipidemia, diabetes mellitus, dialysis use, prior myocardial infarction, prior PCI, tobacco use, cerebrovascular disease, peripheral arterial disease, chronic lung disease, and prior coronary artery bypass grafting), clinical presentation (body mass index, glomerular filtration rate, heart failure, frailty, preprocedural statin use, and presence of acute coronary syndrome), procedural/lesion characteristics (PCI vessel, PCI urgency status, chronic total occlusion, graft lesion, bifurcation lesion, AHA-ACC class C lesion, ISR, lesion length, and surgical turndown), and hospital characteristics (annual PCI volume, ownership/type, region, teaching status, and presence of onsite cardiac surgery). Frailty was measured according to the Canadian Study of Health and Aging Clinical Frailty Scale. Surgical turndown was defined as a patient for whom surgery was consulted in decision making for PCI, but surgery was declined. Presence of onsite cardiac surgery was defined as the presence of any cardiac surgery procedure documented among patients reported to the CathPCI Registry in 2022. Other procedural characteristics examined, but not included in prediction models, included procedure time, temporary pacemaker use, and access site.

Statistical analysis

We described temporal trends in the use of calcium modification strategies for PCI graphically over the entire study period. We then described variation in use of calcium modification strategies and use of coronary IVL in particular in 2022 (the most recent year available) and in the first year of our cohort (Q2 2018-Q1 2019) and in 2020 (the year before IVL introduction). Among those who received calcium modification for PCI in 2022, we examined the proportion of IVL use by hospital.

We examined use of calcium modification strategies according to baseline patient, procedural, and hospital characteristics over the entire study period. Standardized differences were calculated in comparing those who received any calcium modifying strategy vs those who did not, with a threshold of at least 10% used to define a meaningful difference.[16]

We then performed multivariate hierarchical (to account for the clustering of patients within sites) logistic regression with use of any calcium modification strategy as the binary dependent variable and patient, procedural, and hospital characteristics as independent predictors. All aforementioned variables were included in prediction models with the exception of procedure time, temporary pacemaker use, and access site because these procedural characteristics would be influenced by calcium modification use.

We quantified the variability in calcium modification use across hospitals by calculating the median odds ratio (MOR), which quantifies the average difference in the likelihood that 2 statistically identical patients would receive calcium modification at one random hospital compared with that at another. An MOR of 1.5 would mean that a patient would have 50% higher odds of receiving calcium modification if they received PCI at one hospital compared with that at another.

Next, we repeated our regression analysis among patients at a hospital with IVL receiving PCI with any calcium modification in 2022 to evaluate the association of baseline characteristics with use of IVL, relative to other calcium modification techniques.

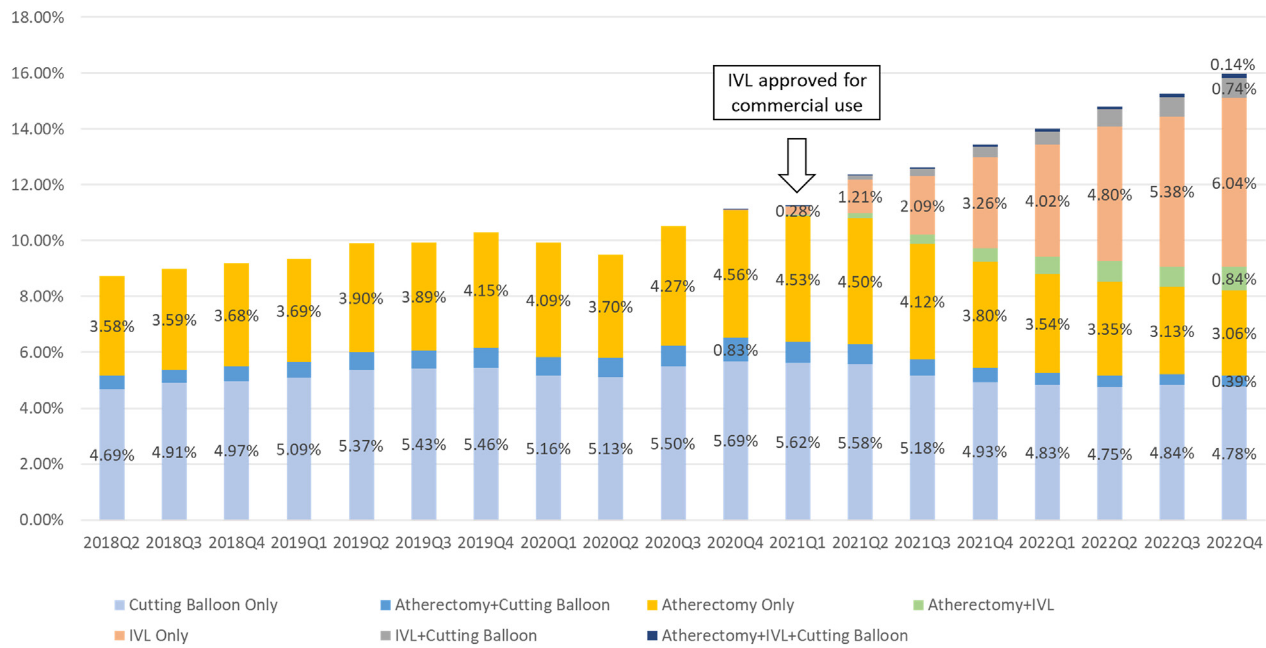
All statistical tests were 2-sided with a P value <.05 considered statistically significant. All analyses were performed using SAS version 9.4 (SAS Institute).

Supplemental analysis

As a robustness check, we repeated all analyses among the subgroup of PCIs with any lesion classified by operators as severely calcified. We did not include lesion calcification as part of the inclusion criteria for the primary analysis given the potential for subjectivity and interoperator variability in assessing calcium severity. We additionally examined trends in procedure success, perforation, significant dissection, and in-hospital mortality overall and stratified by use of calcium modification. Procedure success was defined as postprocedural stenosis of <50%, Thrombolysis in Myocardial Infarction (TIMI) grade 3 flow, and absence of death, myocardial infarction, or stroke.

Results

Of 3,448,322 PCIs performed between April, 2018, and December, 2022, 2,733,494 PCIs were included in our final study cohort (Supplemental Figure S1). The most common reasons for exclusion were STEMI (n = 587,798), lack of information regarding calcium modification devices (n = 53,627), and shock (n = 35,463). A total of 312,186 PCIs (11.4% of our sample) were performed using calcium modification.



Central Illustration.
Trends in use of calcium modification strategies among patients undergoing PCI. Cutting balloon categories include both cutting and scoring balloons; atherectomy includes both rotational and orbital atherectomy. IVL, intravascular lithotripsy; PCI, percutaneous coronary intervention.

Trends in calcium modification use

Use of calcium modification during PCI increased slightly from 8.7% in Q2 of 2018 to 11.1% in Q4 of 2020 (Central Illustration). After commercial introduction of IVL in the first quarter of 2021, use of calcium modification increased rapidly to 16.0% in fourth quarter of 2022. During this period, IVL use increased from 0% to 7.8%, whereas any atherectomy use (alone or in combination with other strategies) decreased from 5.4% to 4.4% (19% decrease).

After the introduction of IVL, there was a slightly greater decrease in use of OA (19% decrease from 1.7% to 1.4%) compared with RA (16% decrease from 3.4% to 2.8%) (Figure 1). In Q4 of 2022, there was over 3 times greater use of IVL in combination with RA compared with OA (RA, 0.73%; OA, 0.22%), which was out of proportion to overall rates of utilization of RA alone versus OA alone in this population (RA, 2.1%; OA, 1.2%; RA use 1.8× that of OA).

Hospital variation in calcium modification use in 2022

In 2022, the median hospital use of calcium modification was 10.2% of PCI cases (25th percentile, 4.8%; 75th percentile, 17.6%) (Figure 2A). Nearly 9% of hospitals did not use any calcium modification strategy at all, whereas the highest 5% of calcium modification using hospitals used these strategies in 31% of cases. This was a substantial increase from the first year of the study period (Q2 2018 - Q1 2019), in which the median hospital used calcium modification in 5.2% of PCI cases (25th percentile: 1.8%, 75th percentile: 10.3%) and 13.3% of hospitals did not use

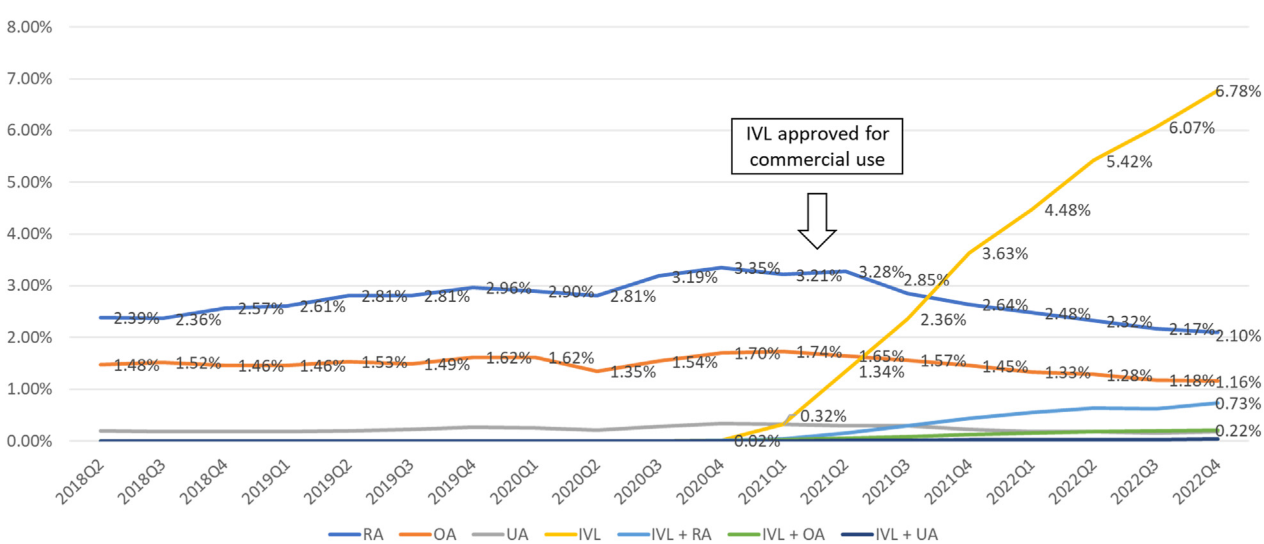


Figure 1.
Trends in use of type of atherectomy and IVL among patients undergoing PCI. Categories include combination use with cutting/scoring balloons. IVL, intravascular lithotripsy; OA, orbital atherectomy; PCI, percutaneous coronary intervention; RA, rotational atherectomy; UA, unspecified atherectomy (rotational or orbital).

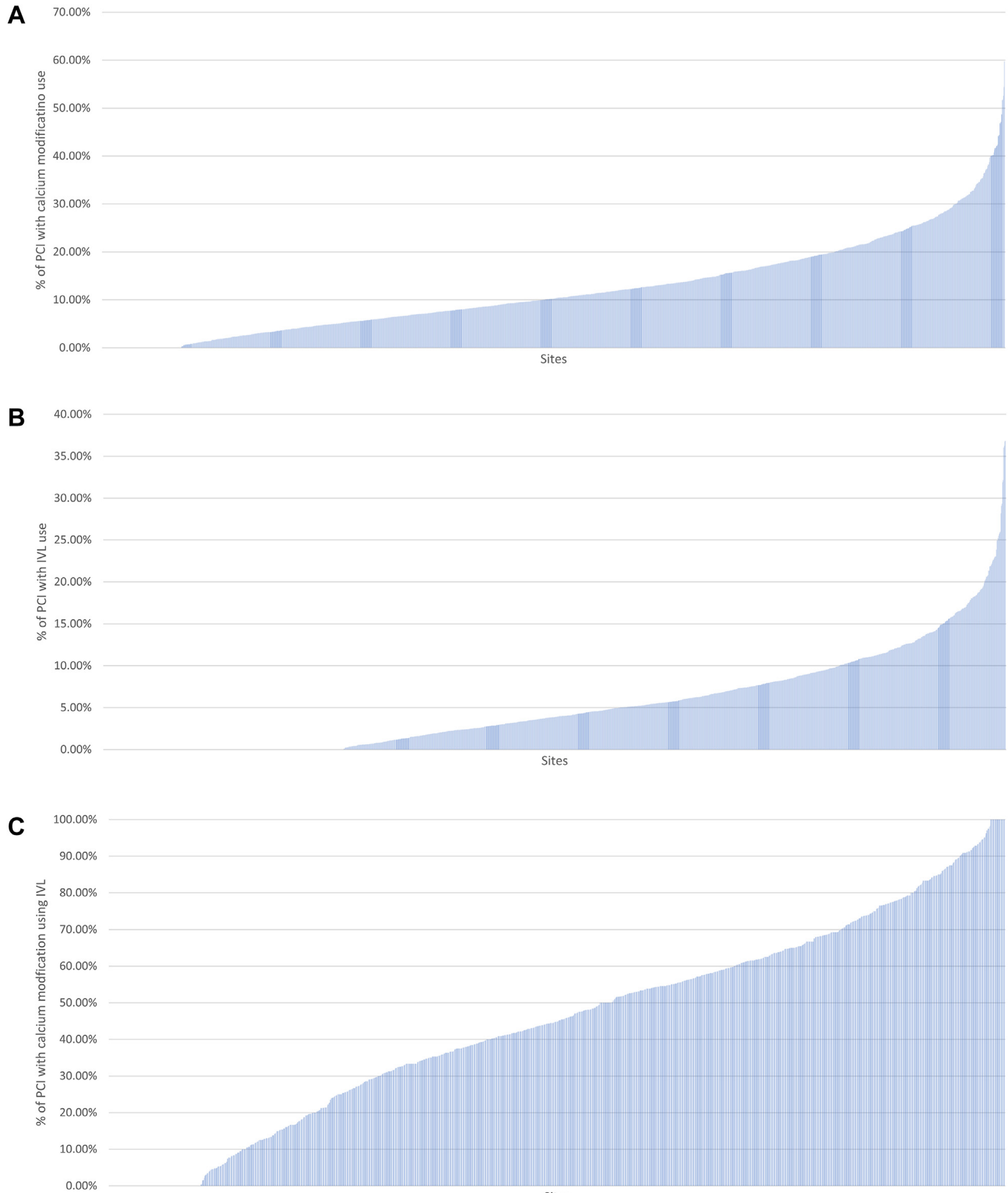


Figure 2.

Variation in calcium modification use for PCI across hospitals in 2022. (**A**) Hospital variation in use of calcium modification. (**B**) Hospital variation in use of IVL. (**C**) Hospital variation in use of IVL among patients undergoing PCI with calcium modification. IVL, intravascular lithotripsy; PCI, percutaneous coronary intervention.

any calcium modification strategies, with the increase in calcium modification use occurring primarily after IVL was introduced (after 2020) (Figure 3).

In 2022, the median hospital use of IVL was in 3.9% of PCI cases (25th percentile, 0%; 75th percentile, 8.19%) (Figure 2B). Over 26% of hospitals did not use any IVL at all, whereas the top 5% of hospitals used IVL in 17% of cases.

Among PCIs in which calcium modification was used, the median hospital used IVL in 44.8% of cases (Figure 2C). Additionally, IVL was the most common calcium modification strategy in 47.7% of hospitals.

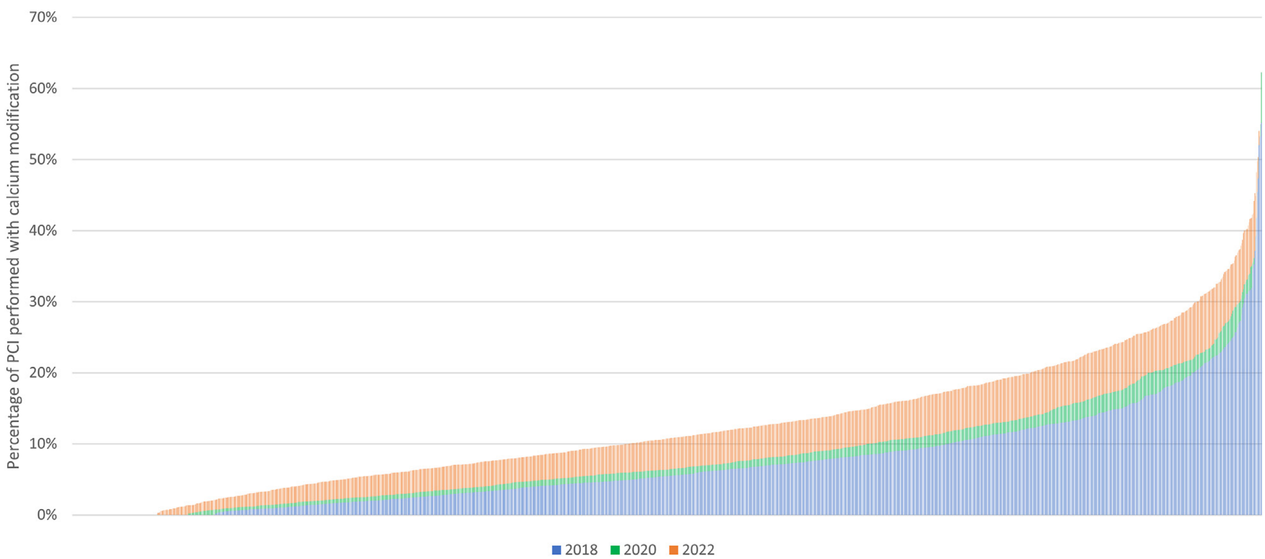


Figure 3.

Hospital variation in use of calcium modification for PCI over time. Growth of calcium modification between 2018 and 2020 (pre-IVL) is represented by the green area. Growth of calcium modification use between 2020 and 2022 (after introduction of IVL) is represented by the orange area. The introduction of coronary IVL in 2021 has made the use of calcium modification for PCI more widespread (orange area is greater than green area). Hospitals sorted separately for each year. 2018 includes Q2-Q4 of 2018 and Q1 of 2019. IVL, intravascular lithotripsy; PCI, percutaneous coronary intervention.

Baseline characteristics and calcium modification use

Patients who underwent PCI with use of a calcium modification strategy were older (mean age, 71 vs 67 years), more likely to have comorbidities (hypertension, dyslipidemia, prior myocardial infarction, prior PCI, cerebrovascular disease, peripheral artery disease, chronic lung disease, diabetes, and dialysis use), on statin preprocedure (84% vs 75%), and have heart failure (36% vs 26%). Patients who underwent PCI using calcium modification were more likely to present electively (56% vs 47%), be moderately or severely frail (67% vs 62%), and be turned down for surgery (9.8% vs 3.3%) and were less likely to present with acute coronary syndrome (35% vs 46%) (Table 1, Supplemental Table S1).

The average procedure time was longest with multiple techniques (119 minutes), followed by atherectomy (100 minutes), IVL (90 minutes), CBA (75 minutes), and no calcium modification (60 minutes). PCI with use of atherectomy, IVL, or multiple techniques was more likely to be for a class C, left main, or bifurcation lesion and less likely to be for a graft lesion compared with the use of CBA or no calcium modification strategy. CBA was much more likely to be used for ISR (40%) compared with other strategies (19% IVL, 18% multiple techniques, 11% no calcium modification, and 5.8% atherectomy). Compared with other strategies, use of atherectomy or multiple techniques was more commonly performed at a hospital with surgical backup (95% atherectomy and multiple, 88% IVL and CBA, and 83% no modification), with a concomitant temporary wire (17% atherectomy, 15% multiple, 1.5% IVL, 1% CBA, and no calcium modification) and less commonly performed with radial access site (36% atherectomy and multiple, 47% CBA, 51% IVL, and 55% no calcium modification).

Predictors of calcium modification use

In multivariate analysis, calcium modification was more likely to be used in patients who were older (adjusted odds ratio [OR], 1.29 for 10-year increment; 95% CI, 1.29-1.30), Asian (OR, 1.12; 95% CI, 1.09-1.14), or Hispanic (OR, 1.06; 95% CI, 1.04-1.08) and were less likely among patients who were female (OR, 0.95; 95% CI, 0.94-0.96) or Black (OR, 0.97; 95% CI, 0.96-0.99; Table 2).

In adjusted analyses, calcium modification was used more frequently in patients treated with dialysis (OR, 1.78; 95% CI, 1.74-1.81) and those with previous coronary artery bypass grafting (OR, 1.28; 95% CI, 1.27-1.30) and was used less frequently in those with acute coronary syndrome (OR, 0.78; 95% CI, 0.77-0.79). Calcium modification was used more frequently in left main lesions (OR, 1.61; 95% CI, 1.55-1.67) and surgical turndown cases (OR, 2.2; 95% CI, 2.16-2.23) and less frequently in chronic total occlusion (OR, 0.79; 95% CI, 0.77-0.80) and graft (OR, 0.39; 95% CI, 0.38-0.40) lesions. Calcium modification use was less likely at rural (OR, 0.79; 95% CI, 0.77-0.80) and suburban (OR, 0.92; 95% CI, 0.91-0.93) hospitals and at hospitals without onsite cardiac surgery (OR, 0.70; 95% CI, 0.69-0.71). The MOR was 2.49 (95% CI, 2.40-2.57), indicating a 2.5-fold difference in the odds of patients undergoing PCI receiving calcium modification at one random hospital vs those at another.

Predictors of IVL use

Predictors of IVL use were examined among patients who underwent PCI with calcium modification at hospitals with at least 1 use of IVL in 2022. Among 80,713 PCIs meeting these criteria, 36,889 (46%) were performed with IVL (Table 3). Relative to other calcium modification strategies, IVL use was less likely among women (OR, 0.94; 95% CI, 0.91-0.97) and Black (0.88; 95% CI, 0.83-0.93), Asian (OR, 0.83; 95% CI, 0.77-0.89), or Hispanic patients (OR, 0.93; 95% CI, 0.87-0.99) in adjusted analyses. IVL was used more in patients on dialysis (OR, 1.26; 95% CI, 1.18-1.34), with previous CABG (OR, 1.11; 95% CI, 1.06-1.15), on statins preprocedure (OR, 1.11; 95% CI, 1.06-1.15), and with class C lesions (OR, 1.4; 95% CI, 1.34-1.45) but less in patients with chronic total occlusions (OR, 0.89; 95% CI, 0.83-0.96), graft lesions (OR, 0.62; 95% CI, 0.56-0.68), or ISR (OR, 0.87; 95% CI, 0.83-0.90). IVL use was more likely to be used at teaching (OR, 1.09; 95% CI, 1.05-1.12), rural (OR, 1.2; 95% CI, 1.14-1.27), and suburban hospitals (OR, 1.16; 95% CI, 1.12-1.20) and hospitals without onsite surgery (OR, 1.27; 95% CI, 1.21-1.34). The MOR was 2.89 (95% CI, 2.74-3.04), indicating an almost 3-fold difference in the odds of patients undergoing PCI with calcium modification receiving IVL relative to another technique at one random hospital versus those at another.

Table 1. Baseline characteristics

	Total (N = 2,733,494)	No calcium modification (n = 2,421,308)	Atherectomy (n = 105,373)	Intravascular lithotripsy (n = 38,479)	Cutting or scoring balloon (n = 140,983)	Multiple techniques (n = 27,351)
Demographics						
Age, y	67.4 ± 11.4	67.0 ± 11.5	72.8 ± 9.7	72.2 ± 9.8	68.3 ± 11.0	72.3 ± 9.8
Male sex	1,880,383 (68.8)	1,661,387 (68.6)	73,711 (70.0)	27,074 (70.4)	98,433 (69.8)	19,778 (72.3)
Race						
White	2,310,237 (87.2)	2,049,089 (87.2)	89,373 (87.9)	32,798 (88.1)	116,301 (85.9)	22,676 (86.9)
Black	232,569 (8.8)	207,845 (8.8)	7347 (7.2)	2878 (7.7)	12,554 (9.3)	1945 (7.5)
Asian	92,442 (3.5)	79,581 (3.4)	4335 (4.3)	1377 (3.7)	5871 (4.3)	1278 (4.9)
Native American	17,597 (0.7)	15,419 (0.7)	741 (0.7)	213 (0.6)	1011 (0.7)	213 (0.8)
Pacific Islander	6860 (0.3)	5866 (0.2)	343 (0.3)	130 (0.3)	415 (0.3)	106 (0.4)
Hispanic ethnicity	201,134 (7.4)	177,125 (7.3)	7642 (7.3)	2773 (7.2)	11,576 (8.2)	2018 (7.4)
Insurance type						
Any private insurance	1,792,303 (65.6)	1,586,313 (65.5)	69,408 (65.9)	26,111 (67.9)	92,383 (65.5)	18,088 (66.1)
Medicare, no private	651,313 (23.8)	569,374 (23.5)	29,464 (28.0)	9996 (26.0)	35,076 (24.9)	7403 (27.1)
Medicaid/low income state plan, no private	155,094 (5.7)	141,909 (5.9)	3313 (3.1)	1156 (3.0)	7827 (5.6)	889 (3.3)
Other Insurance	43,209 (1.6)	38,815 (1.6)	1540 (1.5)	621 (1.6)	1828 (1.3)	405 (1.5)
None	91,575 (3.4)	84,897 (3.5)	1648 (1.6)	595 (1.5)	3869 (2.7)	566 (2.1)
Medical history						
Hypertension	2,402,298 (87.9)	2,112,764 (87.3)	98,001 (93.0)	35,784 (93.0)	130,115 (92.3)	25,634 (93.7)
Dyslipidemia	2,292,291 (83.9)	2,010,272 (83.0)	94,679 (89.9)	34,942 (90.8)	127,349 (90.3)	25,049 (91.6)
Diabetes mellitus	1,195,804 (43.7)	1,040,882 (43.0)	52,025 (49.4)	19,453 (50.6)	68,965 (48.9)	14,479 (52.9)
Current dialysis	98,890 (3.6)	78,503 (3.2)	8207 (7.8)	2677 (7.0)	7235 (5.1)	2268 (8.3)
Previous myocardial infarction	806,444 (29.5)	693,687 (28.6)	31,254 (29.7)	13,049 (33.9)	58,765 (41.7)	9689 (35.4)
Previous PCI	1,200,516 (43.9)	1,027,774 (42.4)	43,790 (41.6)	19,762 (51.4)	95,173 (67.5)	14,017 (51.2)
Tobacco use	1,575,132 (57.6)	1,389,877 (57.4)	63,010 (59.8)	22,490 (58.4)	83,509 (59.2)	16,246 (59.4)
Cerebrovascular disease	435,228 (15.9)	372,029 (15.4)	22,558 (21.4)	8264 (21.5)	26,509 (18.8)	5868 (21.5)
Peripheral arterial disease	352,375 (12.9)	295,359 (12.2)	21,107 (20.0)	6975 (18.1)	23,547 (16.7)	5387 (19.7)
Chronic lung disease	454,943 (16.6)	395,971 (16.4)	20,711 (19.7)	7384 (19.2)	25,661 (18.2)	5216 (19.1)
Previous CABG	465,639 (17.0)	399,366 (16.5)	19,282 (18.3)	7545 (19.6)	33,431 (23.7)	6015 (22.0)
Clinical presentation						
Body mass index, kg/m^2	30.4 ± 64.8	30.5 ± 68.8	29.3 ± 7.0	29.6 ± 6.8	30.1 ± 7.7	29.4 ± 7.8
Frailty						
Not frail	1,015,007 (37.2)	913,706 (37.8)	33,424 (31.8)	11,526 (30.0)	48,241 (34.3)	8110 (29.7)
Intermediate frailty	1,480,731 (54.3)	1,302,896 (53.9)	58,784 (55.9)	22,633 (58.9)	80,481 (57.2)	15,937 (58.4)
Severely frail	231,652 (8.5)	199,325 (8.3)	12,948 (12.3)	4256 (11.1)	11,900 (8.5)	3223 (11.8)
Preprocedural statin use	2,085,333 (76.3)	1,823,436 (75.3)	89,629 (85.1)	33,061 (86.0)	115,452 (81.9)	23,755 (86.9)
Heart failure	748,475 (27.4)	634,895 (26.2)	40,632 (38.6)	15,234 (39.6)	46,272 (32.8)	11,442 (41.8)
Acute coronary syndrome	1,216,058 (44.5)	1,107,101 (45.8)	31,823 (30.2)	12,712 (33.1)	55,833 (39.7)	8589 (31.4)
Procedural/lesion characteristics						
PCI vessel						
Left anterior descending	1,861,700 (68.1)	1,651,636 (68.2)	71,653 (68.0)	25,526 (66.3)	94,610 (67.1)	18,275 (66.8)
Left circumflex	310,653 (11.4)	256,805 (10.6)	19,611 (18.6)	7097 (18.4)	21,004 (14.9)	6136 (22.4)
Right coronary artery	985,249 (36.0)	873,219 (36.1)	38,883 (36.9)	13,912 (36.2)	48,832 (34.6)	10,403 (38.0)
Ramus	81,690 (3.0)	72,322 (3.0)	2661 (2.5)	980 (2.5)	4887 (3.5)	840 (3.1)
Left main	120,387 (4.4)	82,489 (3.4)	16,525 (15.7)	5432 (14.1)	10,583 (7.5)	5358 (19.6)
PCI urgency						
Elective	1,305,173 (47.7)	1,130,699 (46.7)	62,477 (59.3)	22,176 (57.6)	73,902 (52.4)	15,919 (58.2)
Urgent	1,372,200 (50.2)	1,237,407 (51.1)	42,249 (40.1)	15,978 (41.5)	65,314 (46.3)	11,252 (41.1)
Emergent	55,049 (2.0)	52,261 (2.2)	611 (0.6)	317 (0.8)	1689 (1.2)	171 (0.6)
Chronic total occlusion	105,055 (3.8)	90,492 (3.7)	4900 (4.7)	1585 (4.1)	6341 (4.5)	1737 (6.4)
Any lesion in graft	142,620 (5.2)	132,006 (5.5)	1074 (1.0)	848 (2.2)	8162 (5.8)	530 (1.9)
Bifurcation lesion	354,399 (13.0)	296,935 (12.3)	21,083 (20.0)	7003 (18.2)	23,097 (16.4)	6281 (23.0)
Any class C lesion	1,765,021 (64.6)	1,525,965 (63.0)	93,068 (88.3)	31,269 (81.3)	90,688 (64.3)	24,031 (87.9)
In-stent restenosis	333,777 (12.2)	258,878 (10.7)	6144 (5.8)	7458 (19.4)	56,276 (39.9)	5021 (18.4)
Lesion length, mm	33.4 ± 24.7	32.5 ± 23.9	47.9 ± 30.9	42.2 ± 29.0	32.9 ± 25.0	49.6 ± 32.5
Surgical turndown	110,558 (4.0)	80,029 (3.3)	15,629 (14.8)	4072 (10.6)	6558 (4.7)	4270 (15.6)
Temporary pacemaker use	38,129 (1.4)	14,446 (0.6)	17,693 (16.8)	566 (1.5)	1356 (1.0)	4068 (14.9)
Radial access site	1,468,193 (53.7)	1,335,029 (55.1)	37,689 (35.8)	19,759 (51.4)	65,857 (46.7)	9859 (36.0)
Procedure time, min	63.1 ± 36.5	59.7 ± 33.2	100.1 ± 49.8	90.0 ± 44.0	75.2 ± 41.0	118.5 ± 58.8
Hospital characteristics						
Annual PCI volume	789.6 ± 540.2	773.5 ± 523.6	932.8 ± 618.1	834.7 ± 509.8	906.2 ± 670.5	998.9 ± 724.9
Teaching hospital	1,413,844 (51.7)	1,228,449 (50.7)	63,659 (60.4)	22,446 (58.3)	82,159 (58.3)	17,131 (62.6)
Hospital type						
Government	35,762 (1.3)	32,453 (1.3)	947 (0.9)	361 (0.9)	1770 (1.3)	231 (0.8)
Private/community	2,375,937 (86.9)	2,119,664 (87.5)	85,972 (81.6)	32,447 (84.3)	116,297 (82.5)	21,557 (78.8)
University	321,782 (11.8)	269,178 (11.1)	18,454 (17.5)	5671 (14.7)	22,916 (16.3)	5563 (20.3)
Hospital location						
Rural	381,972 (14.0)	350,878 (14.5)	9034 (8.6)	4266 (11.1)	15,577 (11.0)	2217 (8.1)
Suburban	911,927 (33.4)	814,748 (33.6)	34,289 (32.5)	13,346 (34.7)	41,869 (29.7)	7675 (28.1)
Urban	1,439,582 (52.7)	1,255,669 (51.9)	62,050 (58.9)	20,867 (54.2)	83,537 (59.3)	17,459 (63.8)

(*continued on next page*)

Table 1. (*continued*)

	Total (N = 2,733,494)	No calcium modification (n = 2,421,308)	Atherectomy (n = 105,373)	Intravascular lithotripsy (n = 38,479)	Cutting or scoring balloon (n = 140,983)	Multiple techniques (n = 27,351)
Hospital region						
Midwest	684,486 (25.0)	607,980 (25.1)	26,468 (25.1)	9143 (23.8)	34,277 (24.3)	6618 (24.2)
Northeast	473,141 (17.3)	405,732 (16.8)	21,712 (20.6)	7562 (19.7)	31,471 (22.3)	6664 (24.4)
South	1,154,157 (42.2)	1,037,786 (42.9)	39,321 (37.3)	15,330 (39.8)	52,823 (37.5)	8897 (32.5)
West	421,710 (15.4)	369,810 (15.3)	17,872 (17.0)	6444 (16.7)	22,412 (15.9)	5172 (18.9)
Surgical backup center	2,282,402 (83.5)	1,999,344 (82.6)	99,665 (94.6)	33,933 (88.2)	123,622 (87.7)	25,838 (94.5)

CABG, coronary artery bypass grafting; PCI, percutaneous coronary intervention.

Supplemental analysis

Upon repeating analyses among the subgroup of 322,487 PCIs with any lesion classified by operators as severely calcified (11.8% of original sample), of which 133,871 (41.5%) used calcium modification, we found similar results overall. There was still rapid uptake in coronary IVL use for severely calcified lesions in the United States, which led to an overall increase in calcium modification with displacement of atherectomy (Supplemental Figure S2). We continued to find wide variation in calcium modification and IVL use across hospitals (Supplemental Figure S3). We found evidence of differences in use of calcium modification by race and sex, although such differences in use of IVL were attenuated. Treating hospital remained the strongest predictor of use (Supplemental Tables S2 and S3). Although PCIs using calcium modification had a lower rate of procedural success and higher rates of perforation, dissection, and in-hospital mortality, there were no apparent trends in these outcomes over the study period (Supplemental Figure S4).

Discussion

In this analysis of a large national registry of PCIs, we found an overall increase in use of calcium modification for PCI after commercial introduction of coronary IVL with displacement of atherectomy use. We additionally found wide variation in calcium modification use across hospitals and race and sex differences in the initial use of IVL. These results provide valuable insight into the use of calcium modification for PCI in contemporary practice and the dispersion of novel technologies in interventional cardiology more broadly.

The uptake in coronary IVL was rapid, accounting for 7.8% of PCI in less than 2 years after its commercial approval. By comparison, orbital atherectomy amounted to only 1% of all PCI 3 years after its initial approval in 2013.[13] This rapid uptake in IVL was likely driven by its ease of use,[12] which has made calcium modification with IVL as simple as balloon angioplasty. It was potentially further bolstered by Medicare's New Technology Add-on Payments and Transitional Pass-Through Payments, although these notably did not cover the full cost of the device during this period.[17] The increase in coronary IVL use led to an overall increase in calcium modification use, although was accompanied by a decrease in atherectomy use. Notably, there was substantially greater use of IVL in conjunction with RA compared with that with OA, suggesting greater IVL use at hospitals that use RA or a greater perceived synergy between IVL and RA among US operators.

There was wide variability in the use of calcium modification and IVL across hospitals, which was not explained by specific patient or hospital characteristics. Our results are consistent with a prior CathPCI study between 2009 and 2017, which found rates of atherectomy varied from 0% to 19% across hospitals.[13] Notably, treating hospital site itself was a stronger predictor of whether calcium modification or IVL was used than any other clinical, lesion, or identifiable hospital characteristic. This could reflect the selective launch of IVL to certain hospitals in its initial rollout or financial considerations and hospital price sensitivity to costly novel calcium modification technologies. Given the lack of rigorous data and guidance on the decision to use calcium modification for PCI,[18] variability in use of calcium modification for PCI may also be explained by differences in culture and comfort of operators with different calcium modification techniques at different hospitals, which remains a rich area for future inquiry.

The introduction of IVL has made use of calcium modification in PCI more widespread. We found that rural and suburban hospitals and those without onsite cardiac surgery were less likely to use calcium modification for PCI overall, but they were more likely to use IVL if calcium modification was pursued. This may reflect the ease of use of IVL relative to atherectomy because we found greater use of radial access, shorter procedure duration, and less frequent need for concomitant temporary pacing wire with IVL in comparison with atherectomy. Additionally, in contrast to atherectomy, which was previously only recommended at sites with surgical backup, there are no explicit advanced hospital capabilities required for use of IVL. The implications of having IVL as an option for hospitals that do not use atherectomy include fewer transfers to centers with cardiac surgical backup and the potential for improving stent expansion and PCI procedural success.

We found evidence of differences in use of calcium modification and IVL by sex, race, and ethnicity, despite extensive multivariate adjustment. Prior work has shown disparities in utilization of PCI by sex, race, ethnicity, and age.[19–21] In this study, we found that women and black patients were less likely to receive calcium modification for PCI, and among those who received calcium modification, were less likely to receive IVL despite adjustment for clinical, lesion, and hospital characteristics. These results may reflect underlying differences in the prevalence and characteristics of calcified lesions in these demographic subgroups that warrant different treatment strategies because some of these differences were attenuated when restricting our sample to patients defined by operators as having a severely calcified lesion. Notably, women have worse procedural outcomes with atherectomy compared with men but similar outcomes with IVL,[22] which is being further investigated in the prospective EMPOWER CAD study (NCT05755711). It is possible that differences could also reflect possible disparities in the use of calcium modification for PCI and in the initial rollout of IVL. Further research on mechanisms underlying these demographic differences in the rollout of IVL and whether they could reflect disparities will be important to inform the equitable rollout of novel technologies in interventional cardiology in the future.

Limitations

These results should be interpreted in the context of the following potential limitations. First, these results contain data only from hospitals participating in the CathPCI Registry and may not reflect nonparticipating hospitals. However, more than 90% of hospitals participate in the CathPCI Registry, and it is thought to be nationally representative.[23]

Table 2. Predictors of calcium modification use during PCI

Variable	Odds ratio (95% CI)	*P*
Demographics		
Age (10-y increment)	1.29 (1.29-1.3)	<.0001
Female sex	0.95 (0.94-0.96)	<.0001
Race (compared with White)		
Black race	0.97 (0.96-0.99)	.0005
Asian race	1.12 (1.09-1.14)	<.0001
Hispanic ethnicity	1.06 (1.04-1.08)	<.0001
Medical history		
Hypertension	1.2 (1.18-1.22)	<.0001
Dyslipidemia	1.19 (1.17-1.2)	<.0001
Diabetes mellitus	1.1 (1.09-1.11)	<.0001
Current dialysis use	1.78 (1.74-1.81)	<.0001
Previous myocardial infarction	1.02 (1.01-1.03)	<.0001
Previous PCI	1.14 (1.13-1.15)	<.0001
Tobacco use	1.06 (1.05-1.07)	<.0001
Cerebrovascular disease	1.03 (1.02-1.05)	<.0001
Peripheral arterial disease	1.15 (1.14-1.16)	<.0001
Chronic lung disease	1.02 (1.01-1.03)	.0008
Previous coronary artery bypass grafting	1.28 (1.27-1.3)	<.0001
Clinical presentation		
Body mass index	0.99 (0.99-0.99)	<.0001
Frailty (compared with no frailty)		
Intermediate frailty	1.08 (1.07-1.09)	<.0001
Severe frailty	1.05 (1.03-1.06)	<.0001
Preprocedure statin use	1.31 (1.3-1.33)	<.0001
Heart failure	1.18 (1.17-1.19)	<.0001
Acute coronary syndrome	0.78 (0.77-0.79)	<.0001
Procedural/lesion characteristics		
PCI vessel (compared with left anterior descending)		
Left circumflex	1.16 (1.13-1.18)	<.0001
Right coronary artery	1.05 (1.04-1.06)	<.0001
Ramus	0.78 (0.74-0.81)	<.0001
Left main	1.62 (1.56-1.68)	<.0001
Multivessel	1.11 (1.1-1.12)	<.0001
PCI urgency (compared with elective)		
Urgent	0.83 (0.82-0.84)	<.0001
Emergent	0.5 (0.48-0.52)	<.0001
Chronic total occlusion	0.77 (0.76-0.79)	<.0001
Any lesion in graft	0.39 (0.39-0.4)	<.0001
Bifurcation lesion	1.26 (1.24-1.27)	<.0001
Any class C lesion	1.58 (1.56-1.59)	<.0001
In-stent restenosis	2.32 (2.29-2.35)	<.0001
Lesion length (5-mm increment)	1.03 (1.03-1.03)	<.0001
Surgical turndown	2.2 (2.16-2.23)	<.0001
Hospital characteristics		
Teaching hospital	1.05 (1.05-1.06)	<.0001
Annual PCI volume (100-case increment)	1.02 (1.02-1.02)	<.0001
Hospital type (relative to private)		
Government	0.85 (0.84-0.86)	<.0001
University	1.08 (1.07-1.09)	<.0001
Hospital location (relative to urban)		
Rural	0.79 (0.77-0.8)	<.0001
Suburban	0.92 (0.91-0.93)	<.0001
Hospital region (relative to Northeast)		
Midwest	0.84 (0.83-0.85)	<.0001
South	0.8 (0.79-0.81)	<.0001
West	0.98 (0.96-0.99)	.0008
No onsite surgery	0.7 (0.69-0.71)	

PCI, percutaneous coronary intervention.

Table 3. Predictors of IVL use among those receiving calcium modification at hospitals with IVL in 2022

Variable	Odds ratio (95% CI)	*P*
Demographics		
Age (10-y increment)	1.17 (1.15-1.19)	<.0001
Female sex	0.94 (0.91-0.97)	.0004
Race (compared with White)		
Black race	0.88 (0.83-0.93)	<.0001
Asian race	0.83 (0.77-0.89)	<.0001
Hispanic ethnicity	0.93 (0.87-0.99)	.0199
Medical history		
Hypertension	1.01 (0.95-1.07)	.8310
Dyslipidemia	0.99 (0.93-1.04)	.6119
Diabetes mellitus	1.08 (1.05-1.11)	<.0001
Current dialysis use	1.26 (1.18-1.34)	<.0001
Previous myocardial infarction	1.01 (0.98-1.04)	.5945
Previous PCI	0.95 (0.92-0.98)	.0052
Tobacco use	1 (0.97-1.03)	.9860
Cerebrovascular disease	0.99 (0.95-1.02)	.4676
Peripheral arterial disease	1.01 (0.97-1.05)	.6717
Chronic lung disease	1.05 (1.01-1.09)	.0115
Previous coronary artery bypass grafting	1.11 (1.06-1.15)	<.0001
Clinical presentation		
Body mass index	1 (1-1.01)	.0003
Frailty (compared with no frailty)		
Intermediate frailty	1.01 (0.98-1.05)	.4750
Severe frailty	1.07 (1.01-1.13)	.0207
Preprocedure statin use	1.11 (1.06-1.15)	<.0001
Heart failure	1.08 (1.04-1.11)	<.0001
Acute coronary syndrome	0.98 (0.94-1.02)	.2930
Procedural/lesion characteristics		
PCI vessel (compared with left anterior descending)		
Left circumflex	1.18 (1.08-1.29)	.0002
Right coronary artery	1.16 (1.12-1.21)	<.0001
Ramus	0.8 (0.67-0.96)	.0135
Left main	1.27 (1.11-1.46)	.0005
Multivessel	1.14 (1.1-1.19)	<.0001
PCI urgency (compared with elective)		
Urgent	0.97 (0.93-1.01)	.1135
Emergent	0.87 (0.73-1.03)	.0974
Chronic total occlusion	0.89 (0.83-0.96)	.0016
Any lesion in graft	0.62 (0.56-0.68)	<.0001
Bifurcation lesion	0.98 (0.94-1.02)	.2549
Any class C lesion	1.4 (1.34-1.45)	<.0001
In-stent restenosis	0.87 (0.83-0.9)	<.0001
Lesion length (5-mm increment)	1 (1-1.01)	.0091
Surgical turndown	1.03 (0.98-1.09)	.2067
Hospital characteristics		
Teaching hospital	1.09 (1.05-1.12)	<.0001
Annual PCI volume (100-case increment)	0.97 (0.97-0.97)	<.0001
Hospital type (relative to private)		
Government	1.03 (0.98-1.09)	.2286
University	0.86 (0.83-0.89)	<.0001
Hospital location (relative to urban)		
Rural	1.2 (1.14-1.26)	<.0001
Suburban	1.16 (1.12-1.2)	<.0001
Hospital region (relative to Northeast)		
Midwest	0.91 (0.87-0.95)	<.0001
South	1.05 (1-1.1)	.0347
West	0.98 (0.93-1.03)	.4138
No onsite surgery	1.27 (1.21-1.34)	<.0001

IVL, intravascular lithotripsy; PCI, percutaneous coronary intervention.

Second, granular data on coronary calcification (arc of calcium, degree of calcification, and presence of nodules) or use of intravascular imaging was not available in the CathPCI database and could affect use of calcium modification strategies. However, results were similar when repeated among the subset of patients with severely calcified lesions. Finally, this study focused on patients who underwent PCI; however, the degree to which PCI was not attempted in patients with severe coronary calcification, or how the treatment rate of such lesions varied over time, could not be addressed.

Conclusions

The introduction of IVL has changed the landscape of calcium modification use for PCI. There was rapid uptake in use of coronary IVL after its commercial introduction in the United States, which primarily led to an overall increase in use of calcium modification for PCI with some displacement of atherectomy. Additionally, there remains wide variation in calcium modification and IVL use, and the strongest predictor of use was treating hospital site, which may reflect hospital price sensitivity to costly novel technologies or the selective rollout of IVL. Finally, we found evidence of race and sex differences in the use of calcium modification for PCI and the initial use of IVL, which lends insight into the prevalence of calcified lesions in these demographic subgroups and has implications for the equitable rollout of novel technologies in interventional cardiology in the future.

Declaration of competing interest

The views expressed in this manuscript represent those of the authors and do not necessarily represent the official views of Society for Cardiovascular Angiography & Interventions, Shockwave Medical, or the National Cardiovascular Data Registry or its associated professional societies identified at www.ncdr.com. The funder had no role in the design and conduct of the study; collection, management, analysis, and interpretation of the data; preparation, review, or approval of the manuscript; and decision to submit the manuscript for publication. The views expressed in this article are those of the authors and do not necessarily reflect the position or policy of the Department of Veterans Affairs, the US Government, or National Institutes of Health.

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Ethics statement and patient consent

The use of the CathPCI data set was granted a waiver of informed consent by Advarra.

Supplementary material

To access the supplementary material accompanying this article, visit the online version of the *Journal of the Society for Cardiovascular Angiography & Interventions* at 10.1016/j.jscai.2023.101254.

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