

# The Real-World Safety and Effectiveness of Coronary Intravascular Lithotripsy

Insights from the BMC2 Registry

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## BACKGROUND

- The complexity of percutaneous coronary intervention (PCI) has increased over time partly due to an increase in the presence of coronary calcification.
- Multiple devices exist for the management of coronary calcium during PCI, including a novel intravascular lithotripsy (IVL) device approved by the FDA in February 2021 (Shockwave Medical; Santa Clara, California).
- We examined the contemporary trends and outcomes of coronary intravascular lithotripsy (IVL) and atherectomy for the treatment of coronary artery calcification among patients who underwent percutaneous coronary intervention (PCI) in Michigan.

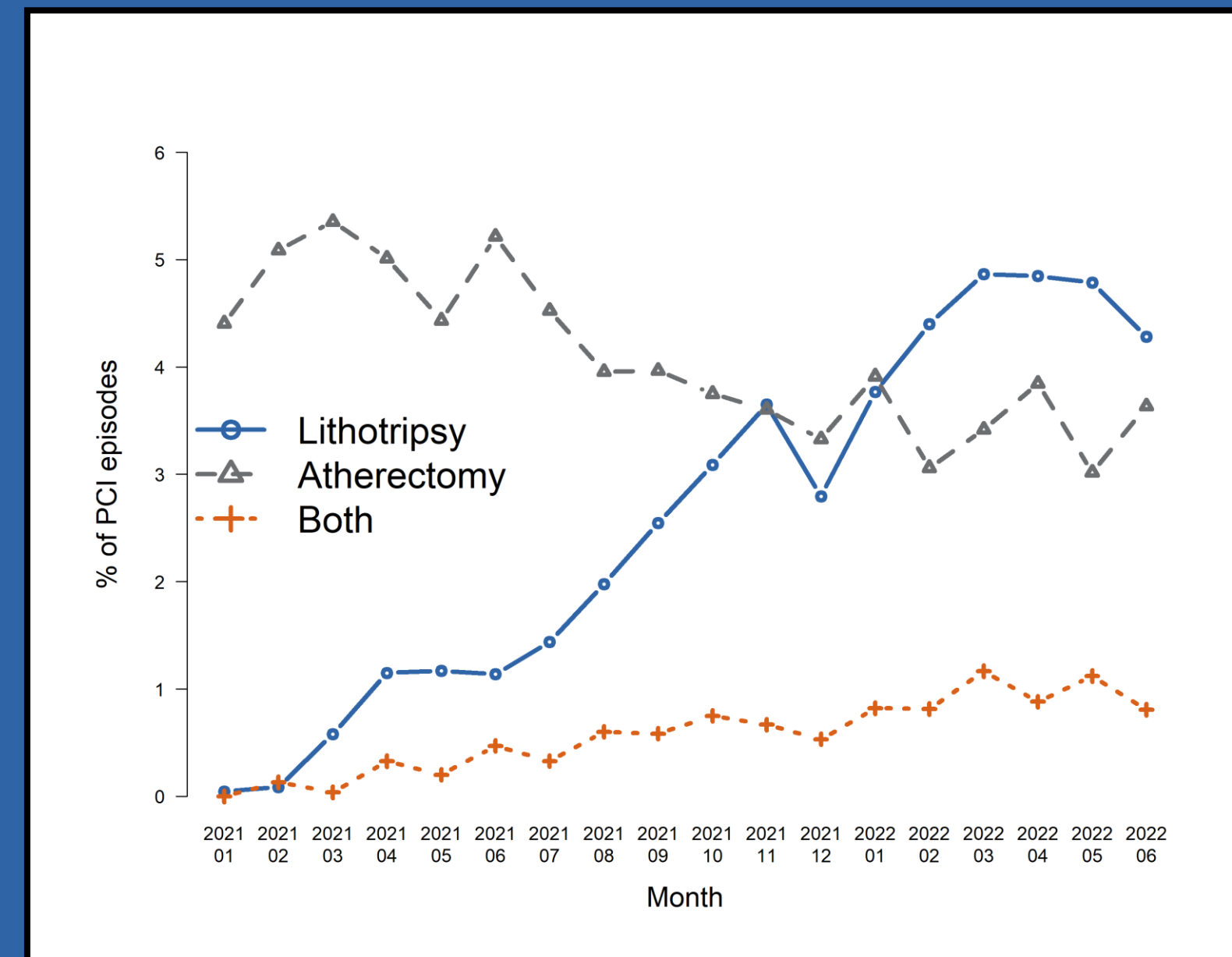
## METHODS

- We included all PCIs between 1/1/2021-6/30/2022 performed at 48 Michigan hospitals. We describe trends in the proportion of cases where IVL, atherectomy, or both were used.
- Major adverse cardiac events (MACE) was defined as a composite of in-hospital mortality, stroke, periprocedural MI, coronary perforation, or tamponade.
- Procedural success was defined at the PCI episode level as meeting the following requirements: 1) an absence of in-hospital MACE; 2) all lesions treated with a calcium modification device having residual stenosis <50% and TIMI-III flow; and 3) all *de novo* lesions treated with calcium modification devices had successful stent implantation.
- We also evaluated outcomes in the subgroup of patients who underwent elective PCI.

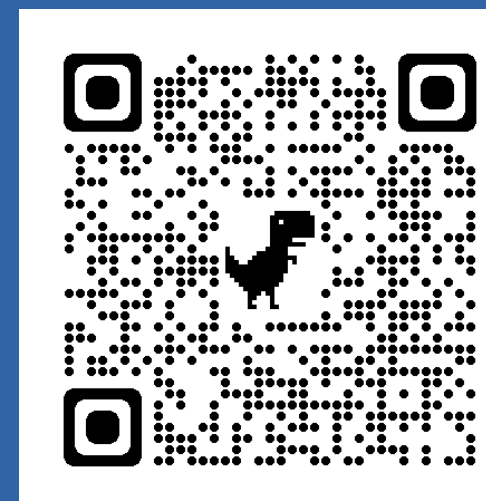
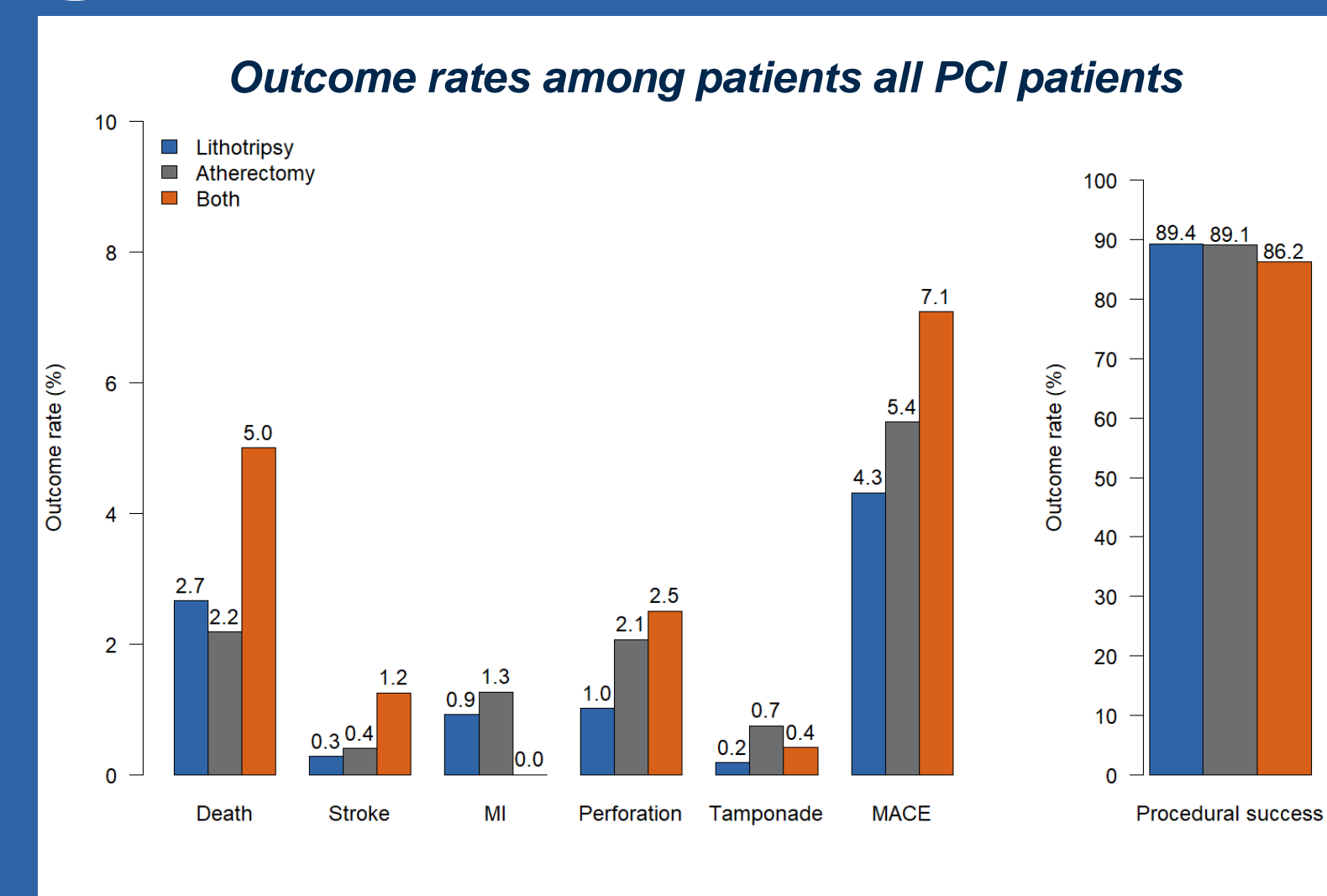
## RESULTS

- Between 1/1/2021 and 6/30/2022, a total of 42,440 patients underwent PCI across 48 sites in Michigan.
- IVL was used in 1,090 (2.6%) patients, atherectomy was used in 1,743 (4.1%) patients, and both were used in 240 (0.57%) of patients.
- Clinical demographic characteristics of patients treated with IVL or atherectomy were similar (Table 1).
- The overall rate of MACE was similar among patients treated with IVL compared with atherectomy.
- Procedural success was similar among patients treated with IVL compared with atherectomy (89.4% vs. 89.1%;  $p=0.88$ ).
- Patients undergoing elective PCI had lower rates of MACE and higher rates of procedural success compared with the overall cohort (Figure 1).
- There was substantial variation in the use of calcium management devices during the study period, ranging from 0% (11 hospitals) to 27.6% of PCIs.
- There was a significant positive correlation between operator-level and hospital-level IVL and atherectomy rates during the study period (Figures 2 and 3).

# Coronary intravascular lithotripsy use has increased dramatically and is the most common calcium modification device.



# Unadjusted outcomes demonstrate generally low rates of complications and high rates of procedural success



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Table 1

Select baseline characteristics.

	IVL (N=1,090)	Atherectomy (N=1,743)	Both (N=240)	P-value comparing IVL and atherectomy
<b>Demographics</b>				
Age, mean (SD)	71.85 (9.90)	72.54 (9.48)	72.62 (9.73)	0.062
Male sex	761 (69.8)	1211 (69.5)	174 (72.5)	0.882
White race	924 (84.8)	1508 (86.5)	209 (87.1)	0.214
Black race	128 (11.7)	160 (9.2)	22 (9.2)	0.033
<b>CAD presentation (%)</b>				
New Onset Angina	52 (4.8)	75 (4.3)	4 (1.7)	<0.001
No Angina	440 (40.4)	763 (43.8)	90 (37.5)	
Stable angina	211 (19.4)	451 (25.9)	70 (29.2)	
NSTE - ACS	346 (31.7)	424 (24.3)	68 (28.3)	
STEMI	41 (3.8)	30 (1.7)	8 (3.3)	
PCI for in-stent restenosis	243 (21.6)	96 (5.2)	39 (14)	<0.001

FIGURE 1

Outcome rates among patients undergoing elective PCI.

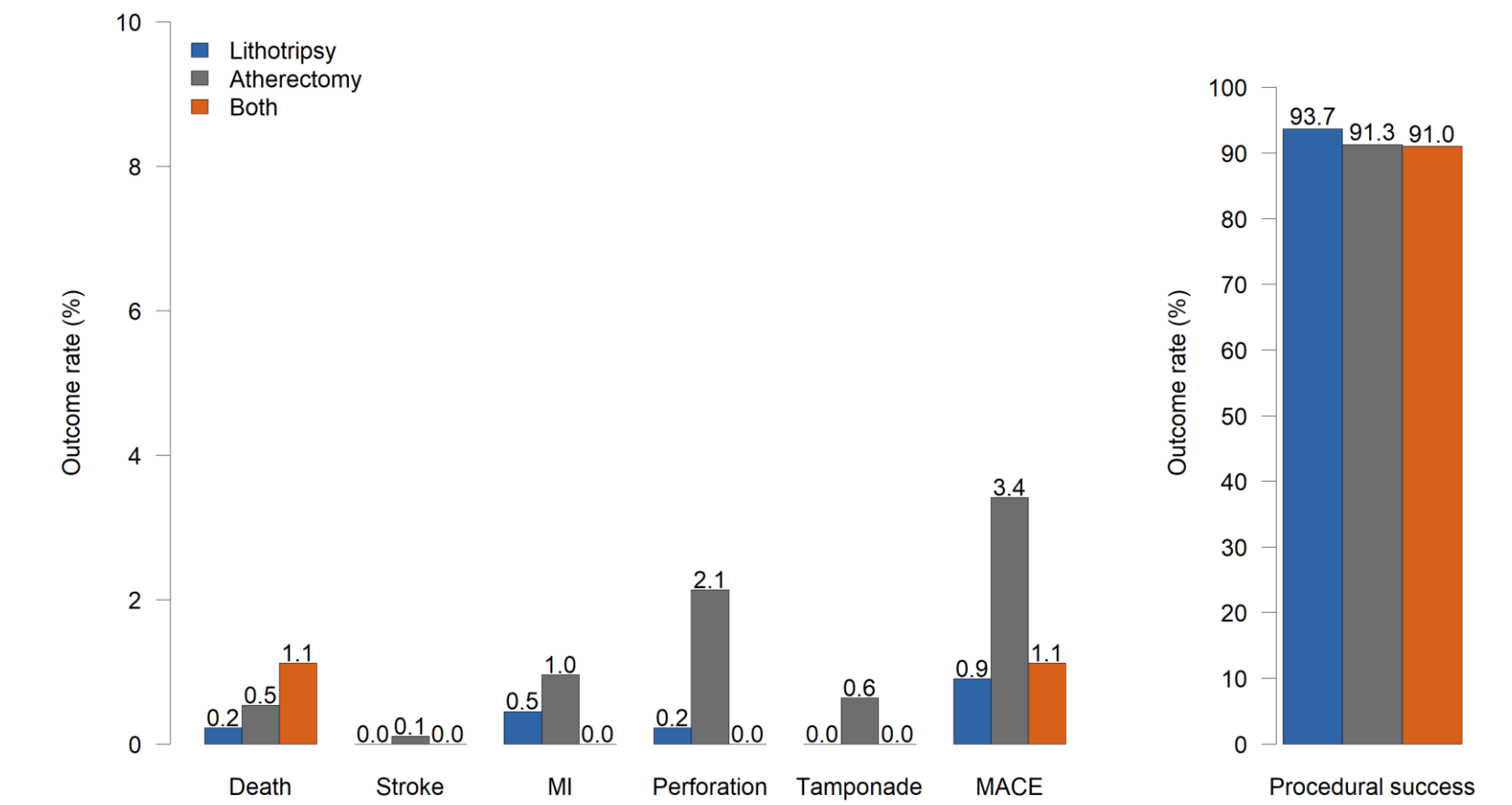
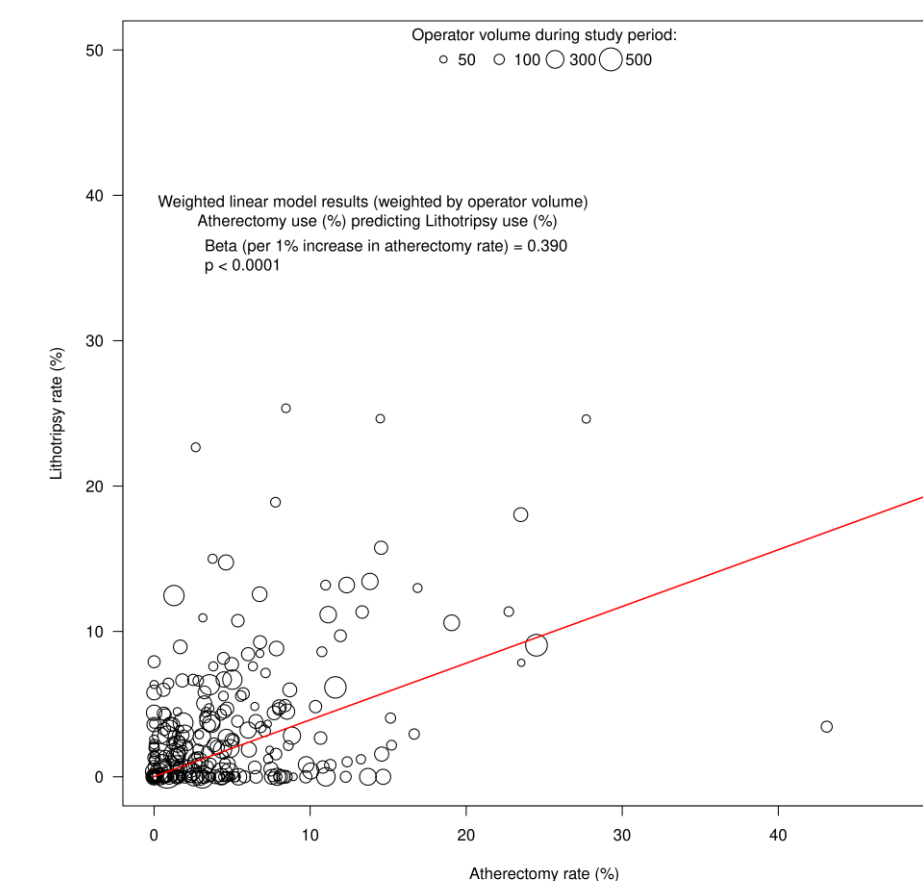


FIGURE 2

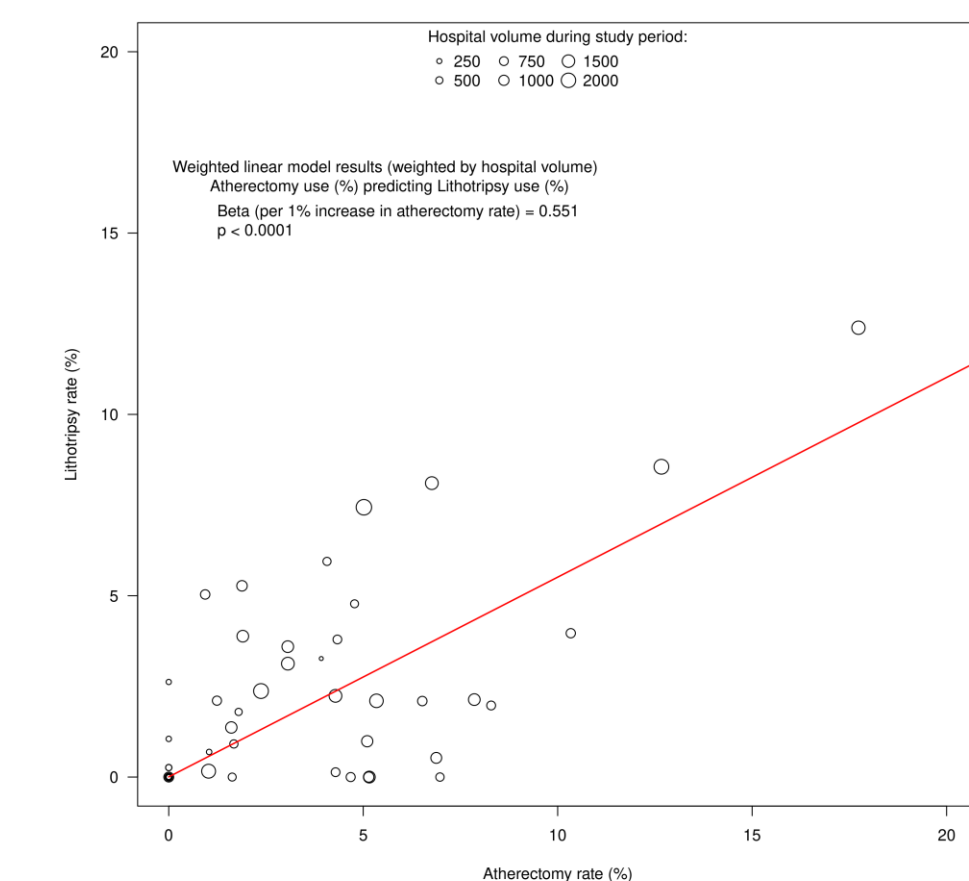
Correlation between atherectomy and IVL use by operator.



\*For the weighted regression, the operator with >40% atherectomy use was excluded.

FIGURE 3

Correlation between atherectomy and IVL use by hospital.



## CONCLUSION

- Since its FDA approval in February 2021, the use of coronary IVL has increased substantially while the use of atherectomy has decreased.
- Unadjusted outcomes demonstrate high rates of procedural success and generally low rates of complications, particularly among patients undergoing elective PCI.

## DISCLOSURE INFORMATION

Ryan Madder; Abbott Laboratories, Corindus, a Siemens Healthineers Company, Infraredx, Spectrawave. Mir Babar Basir; Abbott Vascular, Abiomed, Boston Scientific, Cardiovascular Systems, Cheisi, Saranas, Zoll. Lorenzo Azzalini; Abbott Laboratories, Abiomed, asahi intec, Cardiovascular Systems, Inc., GE Healthcare, Philips, Teleflex. Amir Kaki; Abbott, Abbott Vascular, Abiomed, AstraZeneca, CSI, Inari, Shockwave Medical, Terumo, Novartis Corporation. Hitinder S. Gurm; Osprey Medical, Contego Medical, Amplitude Vascular, Jiaxing Bossh Medical Technology Partnership. Devraj Sukul, Daniel Lee, Daniel Menees, and Milan Seth have nothing to disclose.