In-Stent Restenosis in Contemporary Clinical Practice

Incidence, Risk Factors, and Treatment Approaches -- Insights from BMC2

Elias J. Dayoub, MD, MPP
University of Michigan

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SCAI/MEDTRONIC EARLY CAREER RESEARCH GRANT RECIPIENT

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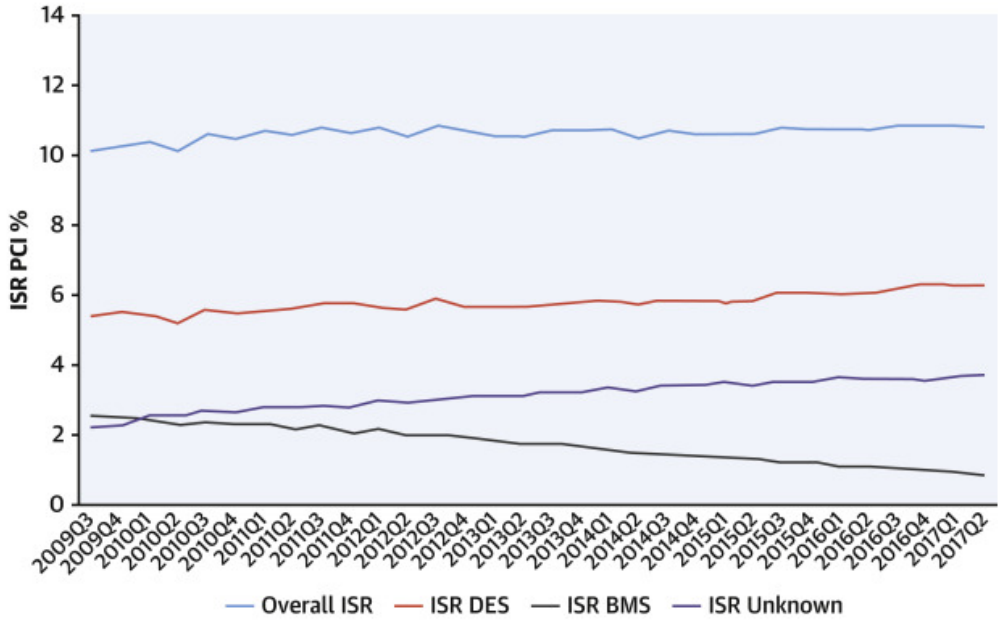
Disclosures

- None

Background

- **ISR has remained a major long-term complication of PCI.**
- **ISR PCI represents a significant share of all PCIs performed.**
  - An NCDR analysis of PCIs performed during years 2009-2017 found ISR PCI accounted for >10% of all PCIs performed



Moussa et al. *JACC* (2020).

- Substantial development in recent years in the assessment and treatment of both de novo and ISR lesions such as increased ICI use, IVL, and DCB; these adjunctive therapies may be associated with changes in prevalence and treatment outcomes.

- Understanding the predictors and incidence of ISR, the time to late stent related complications, and treatment patterns can help inform contemporary management of ISR.

Study Design

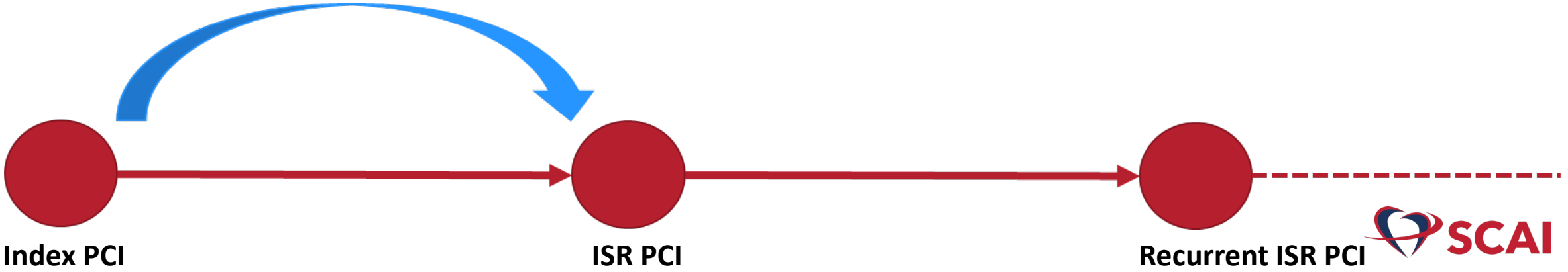
- **Data**
  - Blue Cross Blue Shield of Michigan Cardiovascular Consortium (BMC2) registry, a statewide registry that includes detailed patient, clinical, and procedural information for all PCIs performed in non-federal hospitals.
  - The BMC2 registry linked with Medicare claims data to identify longitudinal patient outcomes

- **Study population and period**
  - All Medicare FFS beneficiaries who had PCIs performed in Michigan from 1/1/2014 through 9/30/2023 (with follow-up through 9/30/2024).

Study Design

- **Primary Outcome**
  - ISR incidence at one year, defined as TLR treated with PCI.
  - Other outcomes include incidence of CABG and death.
  - Incidence of ISR, CABG, and death also measured at 5 years.

- **Secondary analysis**
  - Factors associated with ISR PCI using LASSO modeling.
    - Patient characteristics (e.g., diabetes, CKD)
    - Lesion characteristics (e.g., ACC/AHA lesion classification, bifurcation, presence of severe calcium, lesion location)
    - Procedural characteristics (e.g., ICI use, stent diameter, IVL/atherectomy)

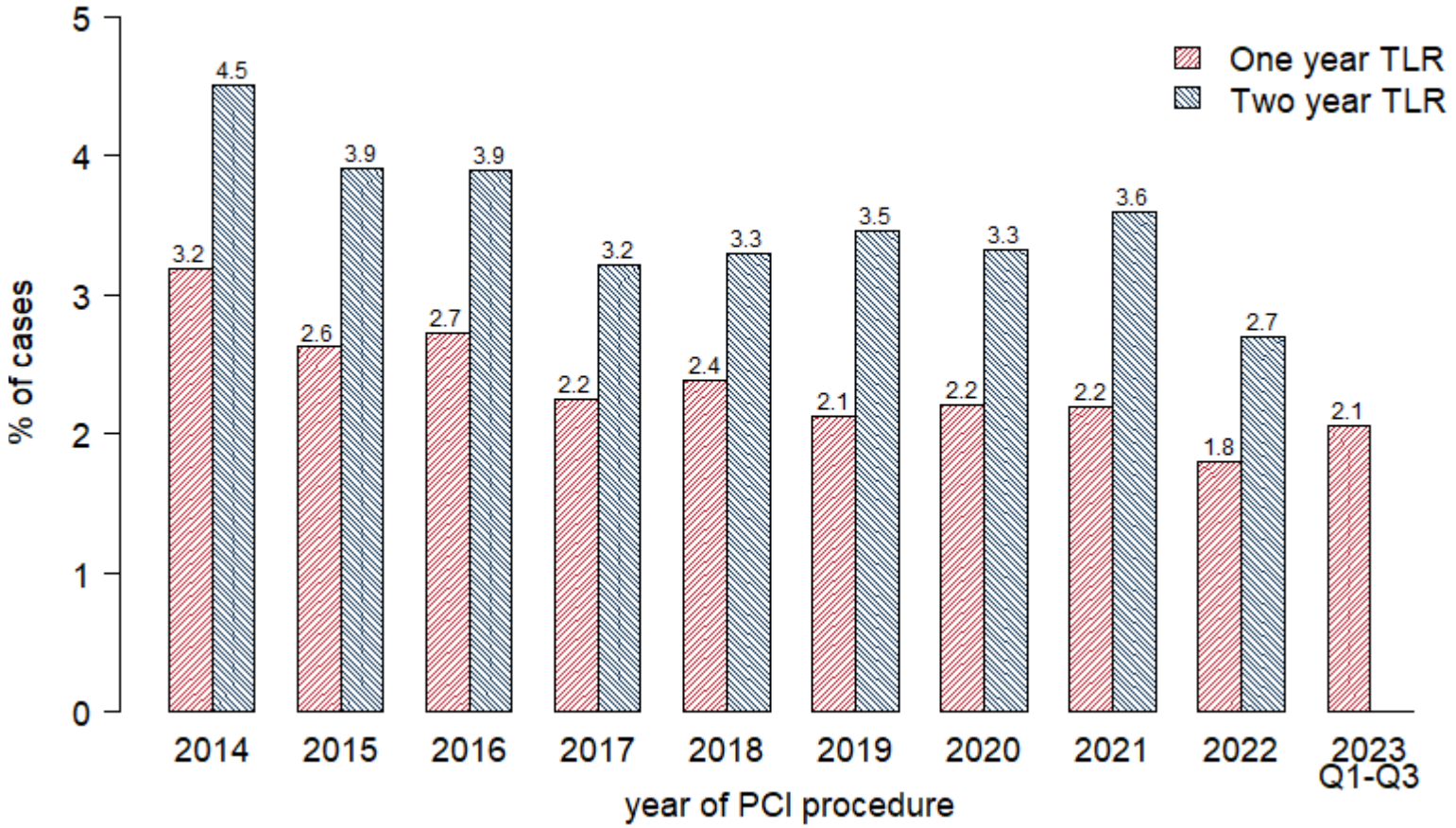


Results

- **A total of 45,981 patients underwent PCI for 62,993 *de novo* lesions from 1/2014-9/2023.**
  - 5.3% subsequently underwent ISR PCI during the follow-up period
  - Median time to ISR PCI was 429 days (IQR, 183 – 1013)
  - CTO and bypass graft PCIs were excluded from primary analysis.

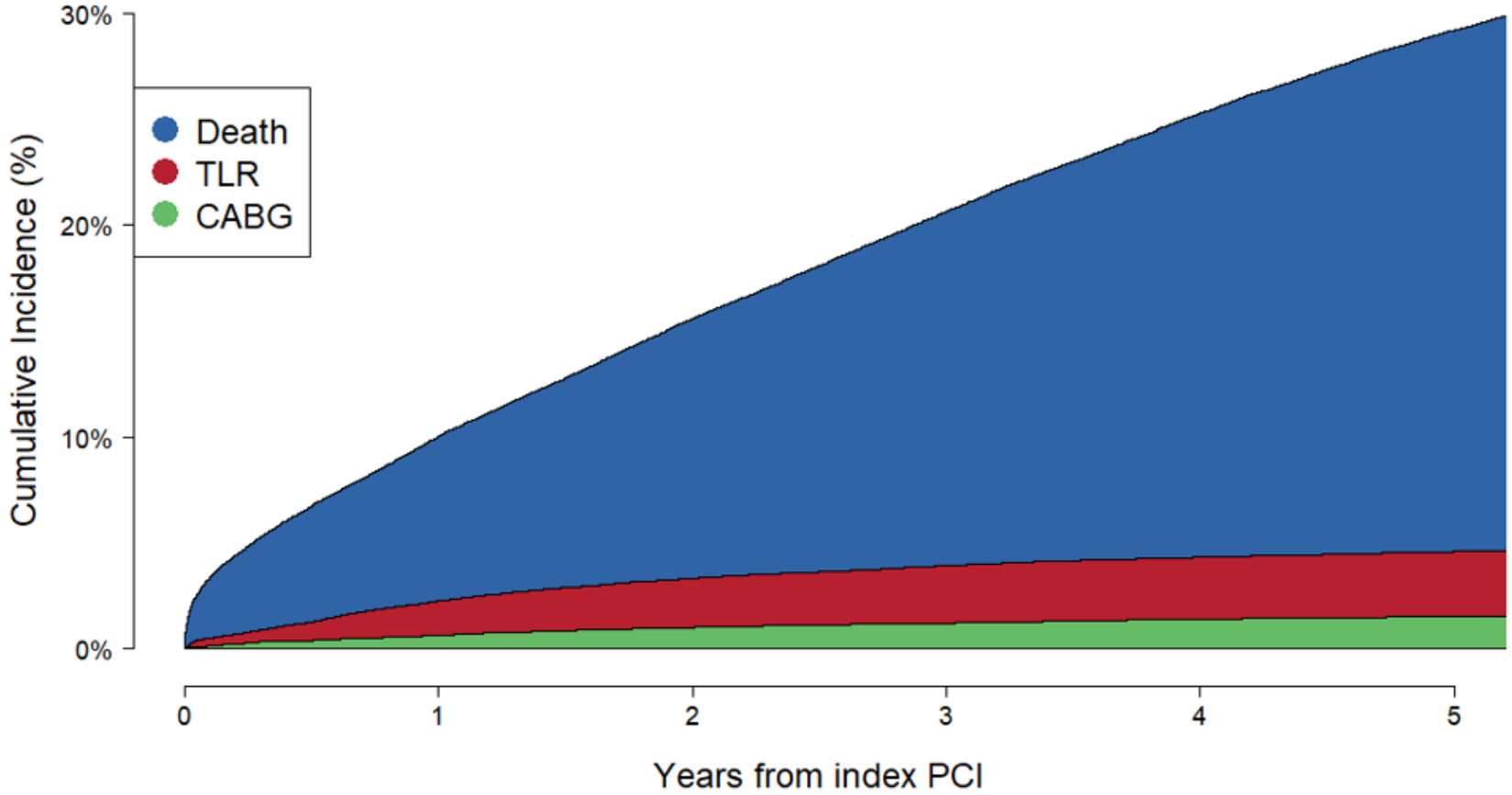
- **Sensitivity analysis of CTO and bypass graft PCI**
  - CTO PCI: 7.7% underwent ISR PCI in follow-up; median time to ISR PCI was 383 days (IQR, 112 – 1022)
  - Bypass graft PCI: 11.5% underwent ISR PCI in follow-up; median time to ISR PCI was 502 days (IQR, 231 – 974)

Temporal Trend in TLR



Cumulative Incidence

At risk:	62,993	54,879	46,724	39,245	32,146	25,748
Death	0.4%	10.0%	15.6%	20.7%	25.3%	29.2%
TLR	0.0%	2.3%	3.3%	3.9%	4.3%	4.6%
CABG	0.1%	0.6%	0.9%	1.2%	1.4%	1.5%



	No TLR at 1 year (n = 61,500)	TLR at 1 year (n = 1,493)	P-value
Age (mean (SD)), years	72.8 (9.3)	71.7 (9.6)	<0.001
Male sex	61.0%	63.8%	0.031
Race			<0.001
White	88.1%	84.5%	
Black	8.9%	13.2%	
Other	2.0%	2.3%	
Diabetes	42.1%	53.4%	<0.001
ESRD	3.1%	6.8%	<0.001
Heart failure	27.2%	30.7%	0.003
PCI Indication			<0.001
Non-ACS	37.1%	29.8%	
NSTE-ACS	52.3%	61.3%	
STEMI	10.6%	8.9%	
Vessel			0.001
LMCA	1.6%	2.1%	
LAD	40.7%	44.3%	
LCx	24.4%	24.1%	
RCA	31.3%	27.2%	
Severe calcification	4.7%	6.7%	0.001
Bifurcation	8.1%	12.2%	<0.001
IVUS/OCT optimization	9.4%	9.2%	0.855
IVL	1.2%	2.1%	0.003
Atherectomy	4.4%	7.8%	<0.001

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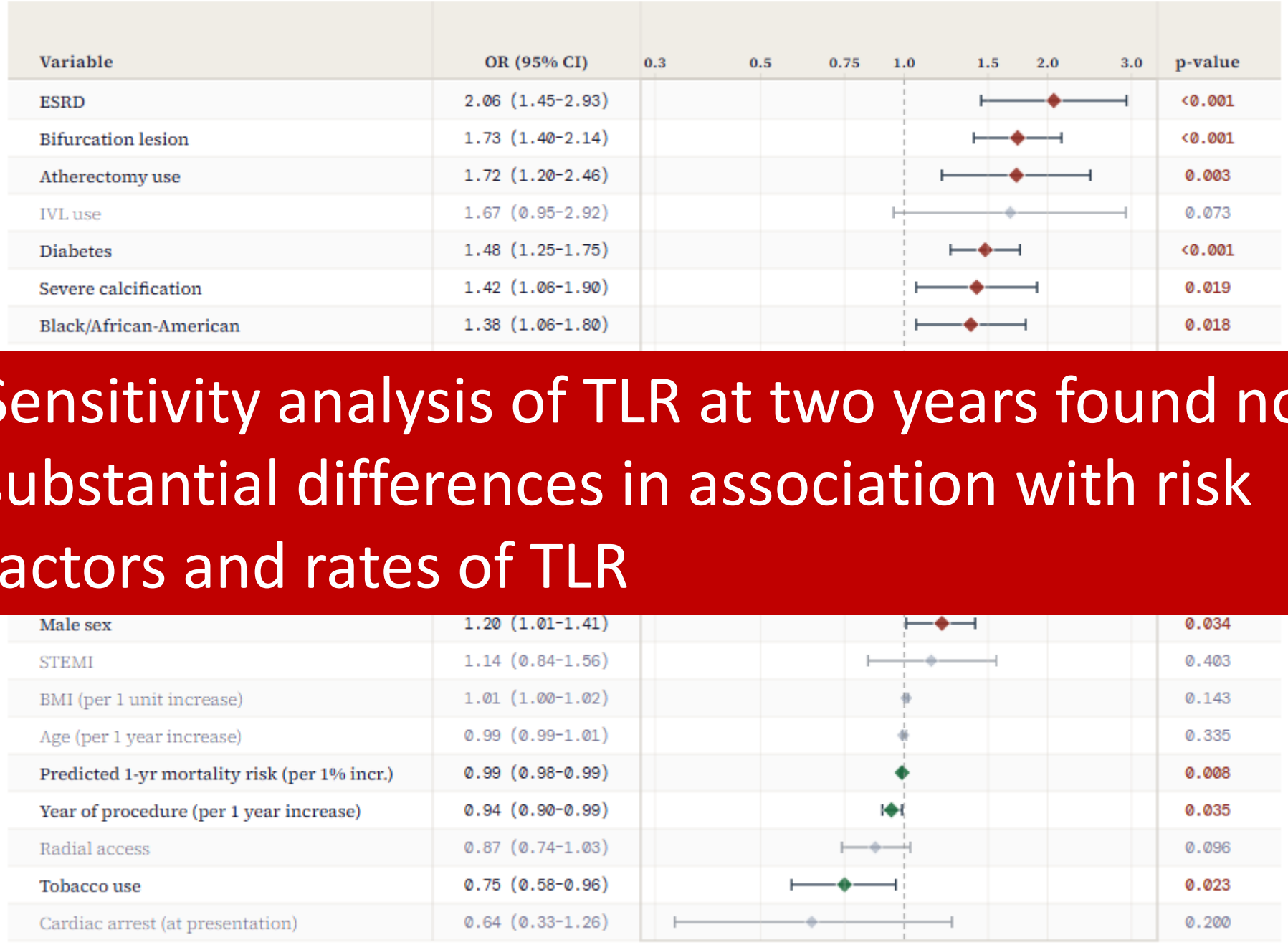

Sensitivity analysis of TLR at two years found no substantial differences in association with risk factors and rates of TLR

Takeaways

- **In comparison to older studies, the incidence of ISR has declined in contemporary practice.**
  - In up to 10 years of follow-up, incidence of ISR PCI for a *de novo* lesion was 5.3% with a median time to ISR of 429 days.
  - CTO PCI and bypass graft PCI had higher incidence of ISR in follow-up – 7.7% and 11.5%, respectively.
- **The incidence of one-year TLR rates is incrementally decreasing over time.**
  - A temporal decrease in TLR at one year was seen in both unadjusted analysis as well as when controlling for patient factors, procedural factors, and lesion characteristics.
  - This trend was present despite procedural characteristics associated with contemporary PCI, such as intracoronary imaging and intravascular lithotripsy, not being independently significant.
- **Patient and anatomic risk factors had the greatest association with one-year TLR rates**
  - ESRD, diabetes, severely calcified lesions, bifurcation lesions, and LAD or LM PCI were strongly associated with TLR at one year.
  - Other procedural factors traditionally associated with ISR, such as lesion length and small vessel diameter, did not have a significant association with TLR at one year.

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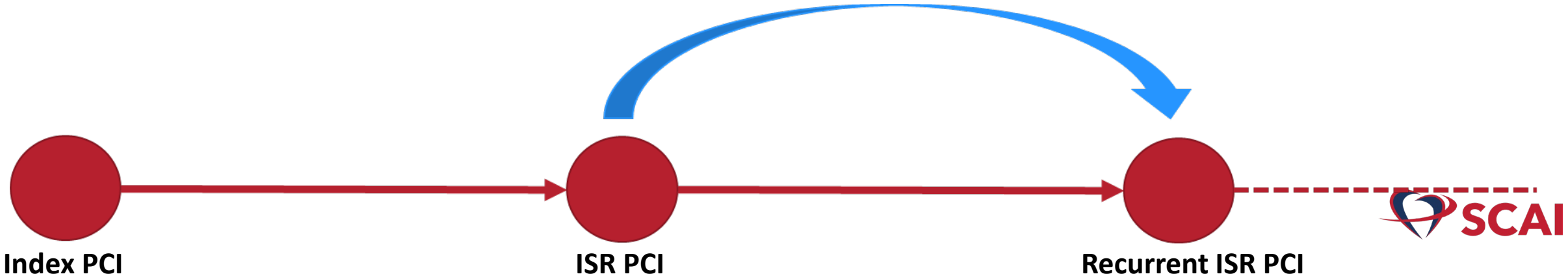
Points to consider

- **The study cohort was comprised of an elderly Medicare population from a single state.**
  - Our findings may not be generalizable to younger, healthier populations.

- **Our model assessed factors associated with ISR at one year.**
  - While no association was found for IVUS/OCT use or IVL use and ISR at one year (or at two years), it is possible that a significant association may exist in longer follow-up.

- **The primary analysis was for *de novo* lesions**



Questions?

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Supplementary Slides

	Odds Ratio	95% Confidence Interval	P-value
ESRD	**2.06**	**(1.45, 2.93)**	**<0.001**
Bifurcation lesion	**1.73**	**(1.40, 2.14)**	**<0.001**
Atherectomy use	**1.72**	**(1.20, 2.46)**	**0.003**
IVL use	1.67	(0.95, 2.92)	0.073
Diabetes	**1.48**	**(1.25, 1.75)**	**<0.001**
Severe calcification	**1.42**	**(1.06, 1.90)**	**0.019**
Black/African-American	**1.38**	**(1.06, 1.80)**	**0.018**
Family history of premature CAD	**1.37**	**(1.11, 1.70)**	**0.004**
Cerebrovascular disease	**1.35**	**(1.12, 1.62)**	**0.001**
NSTE-ACS	**1.34**	**(1.13, 1.58)**	**<0.001**
Peripheral arterial disease	**1.32**	**(1.08, 1.63)**	**0.007**
Dyslipidemia	1.29	(0.98, 1.70)	0.07
Heart failure	**1.28**	**(1.07, 1.54)**	**0.007**
LAD or LMCA PCI	**1.23**	**(1.05, 1.43)**	**0.008**
Male sex	**1.20**	**(1.01, 1.41)**	**0.034**
STEMI	1.14	(0.84, 1.56)	0.403
BMI (per 1 unit increase)	1.01	(1.0, 1.02)	0.143
Age (per 1 year increase)	0.995	(0.99, 1.01)	0.335
Predicted risk of 1 year mortality (per 1% increase in risk)	**0.99**	**(0.98, 0.99)**	**0.008**
Year of procedure (per 1 year increase)	**0.94**	**(0.90, 0.99)**	**0.035**
Radial access	0.87	(0.74, 1.03)	0.096
Tobacco use	**0.75**	**(0.58, 0.96)**	**0.023**
Cardiac arrest (at presentation)	0.64	(0.33, 1.26)	0.20

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