



Summarizing the Evidence Assessing Outcomes after Atherectomy for Peripheral Endovascular Interventions A Systematic Literature Review and Meta-Analysis of over 300 Original Investigations

Eric Secemsky,¹ Jeffrey Carr,² Ralf Langhoff³

1. Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, MA, USA;
2. CHRISTUS Health - Heart and Vascular Institute, Tyler, TX, USA;
3. Sankt Gertrauden-Krankenhaus GmbH, Acad. Teaching Hospital Charité - Humboldt University Berlin, Berlin, Germany

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What is the Evidence-based Clinical Utility of Atherectomy?

- PAD is progressive and chronic.
- Preserving future treatment options is critical.
- Atherectomy can modify or remove plaque, reducing the need for permanent scaffolds.¹⁻²
- However, there is an impression of limited published data supporting atherectomy use.³

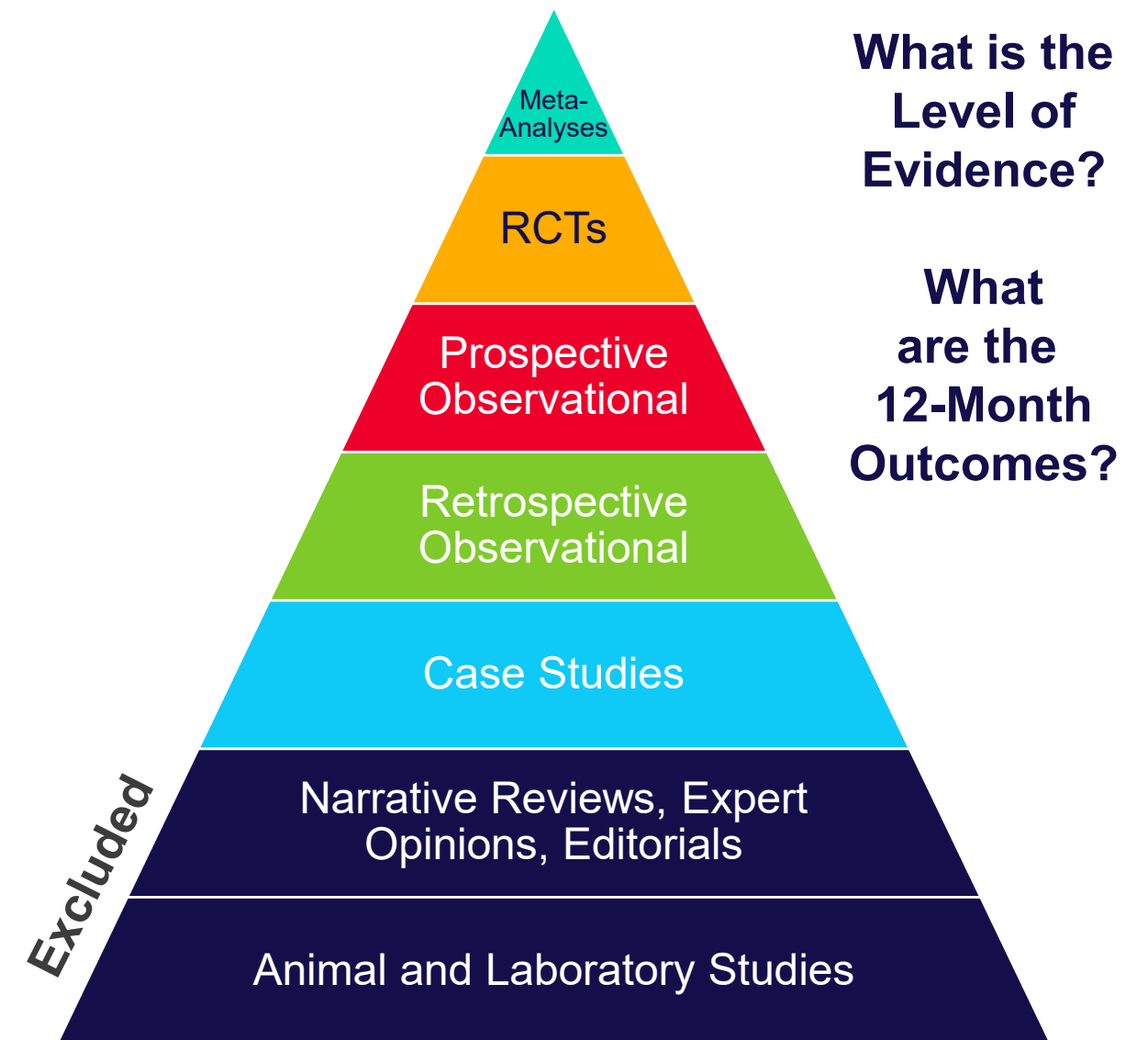
1. Pan et al. J Endovasc Ther. 2023;15266028231215354.

2. Wu et al. J Endovasc Ther. 2023;15266028231209236.

3. Pinto et al. Ann Vasc Surg. 2024;107:127-35.

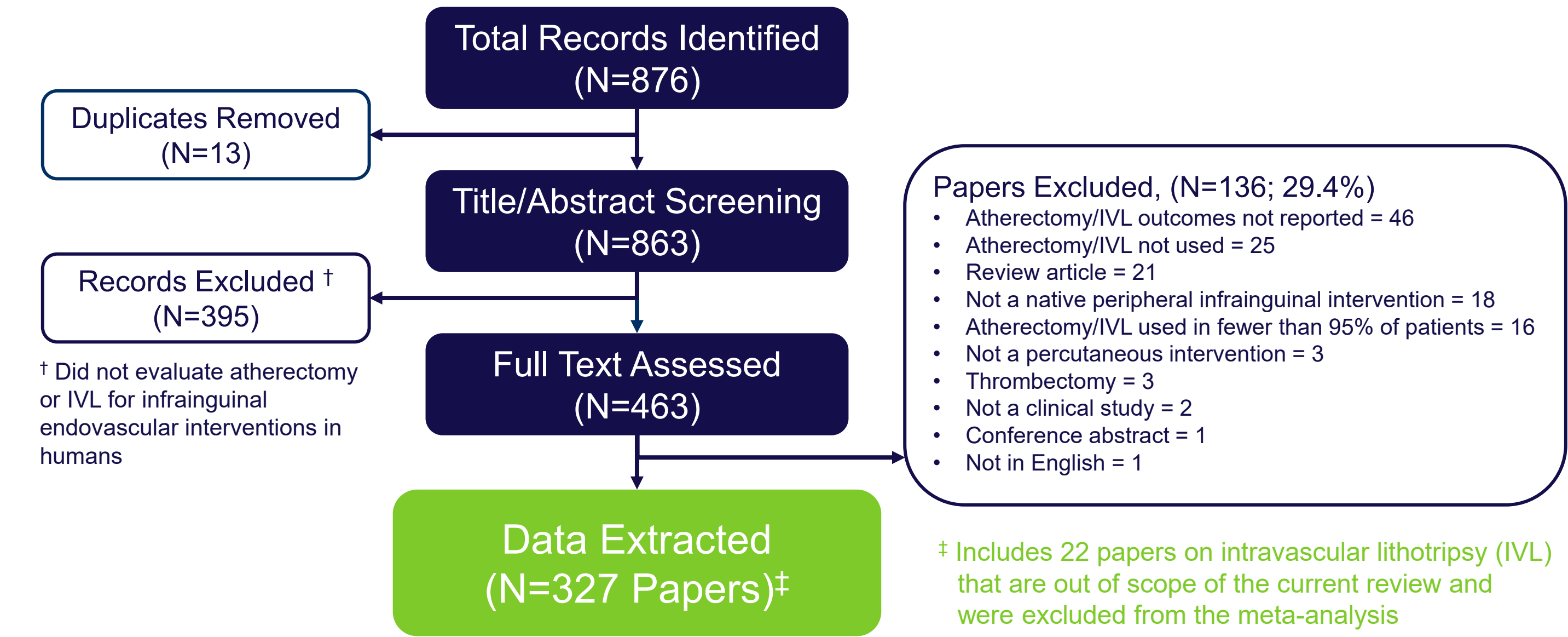
Objective and Design

- Medline, Embase, PubMed through May 2024
- Atherectomy for endovascular treatment of occlusive or stenotic disease in native, infrainguinal, peripheral arteries
- Papers on intravascular lithotripsy (IVL) were captured but are out of scope of this analysis



Search Results

Published Atherectomy Literature through May 2024



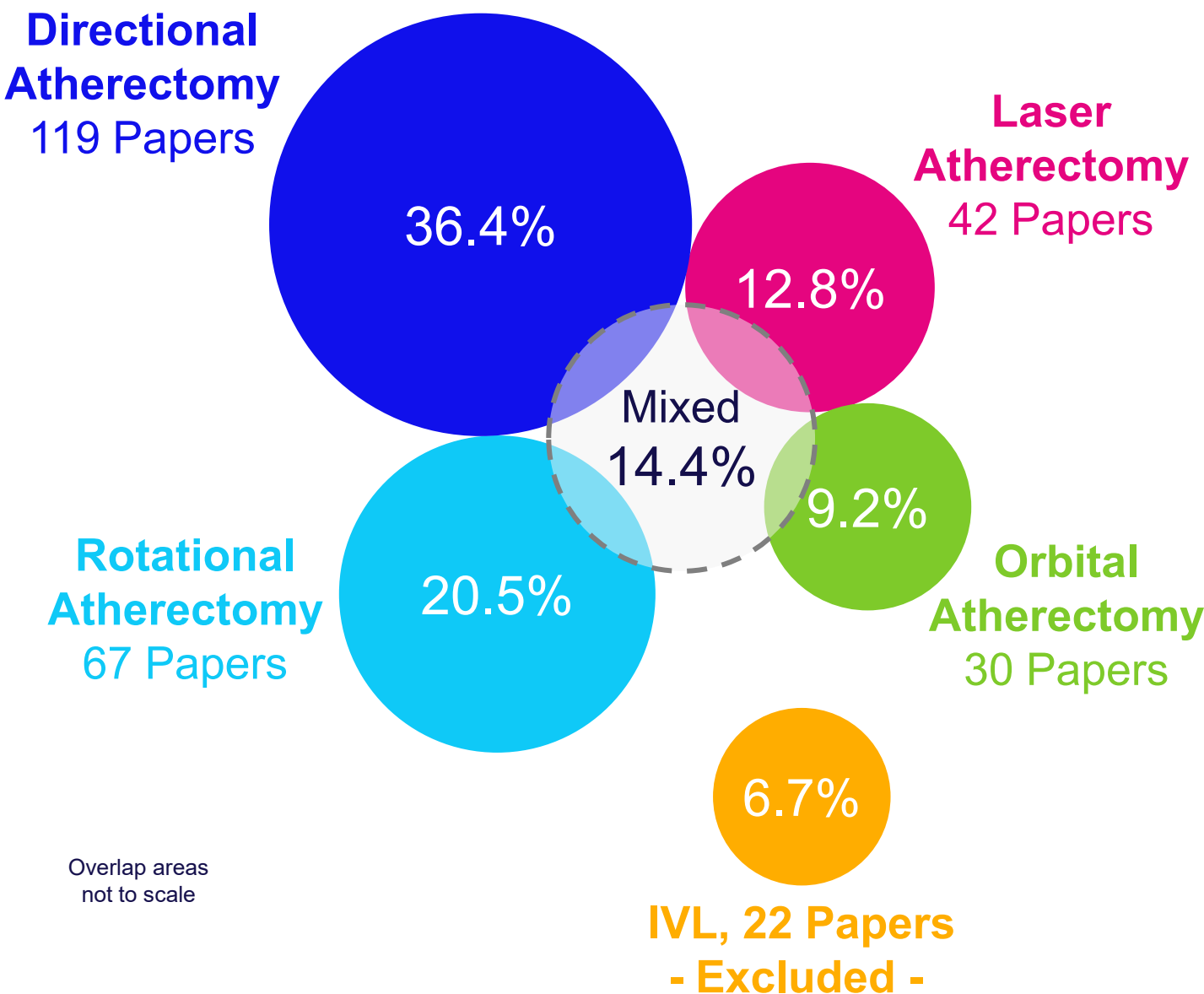
Device Types

Published Atherectomy Literature through May 2024

305 Published Papers

on **atherectomy** for endovascular treatment of occlusive or stenotic disease in native, infrainguinal, peripheral arteries

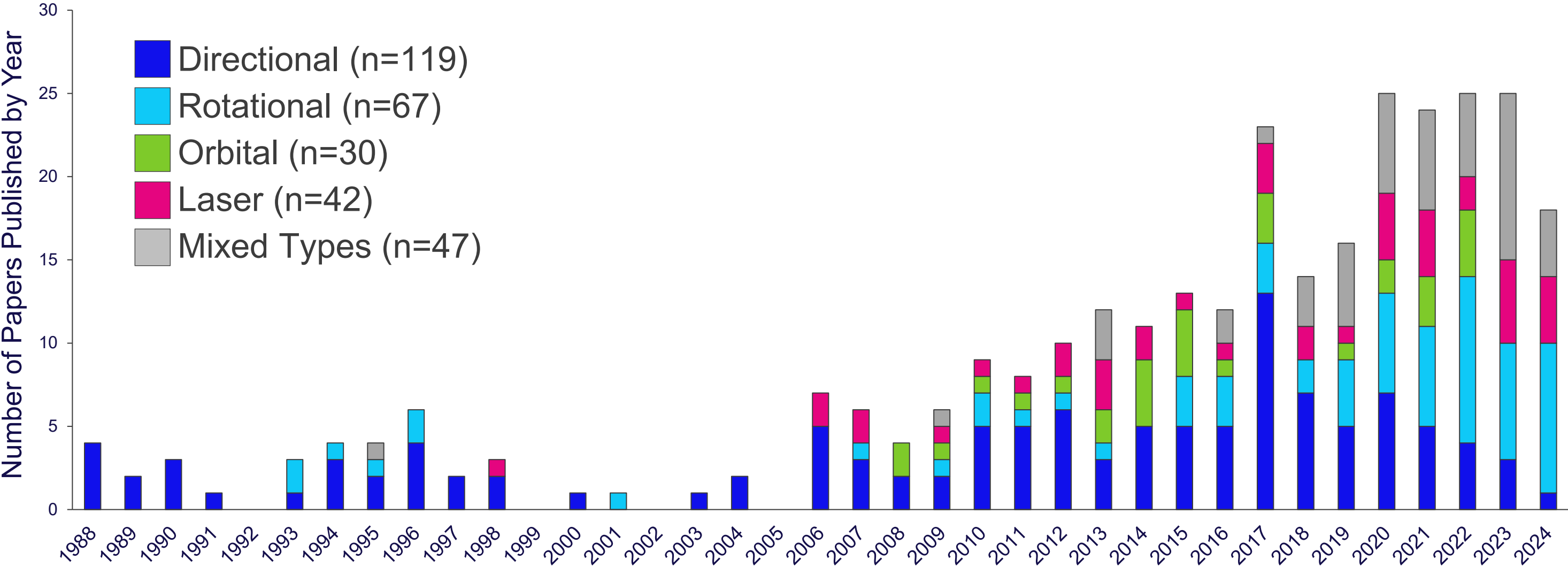
First Author's Reported Affiliation was a Hospital in **97% of Papers¹**



Poster presented by Secemsky et al. November 4-5, VIVA 2024
1. Data on file with Medtronic

Atherectomy Publications by Year

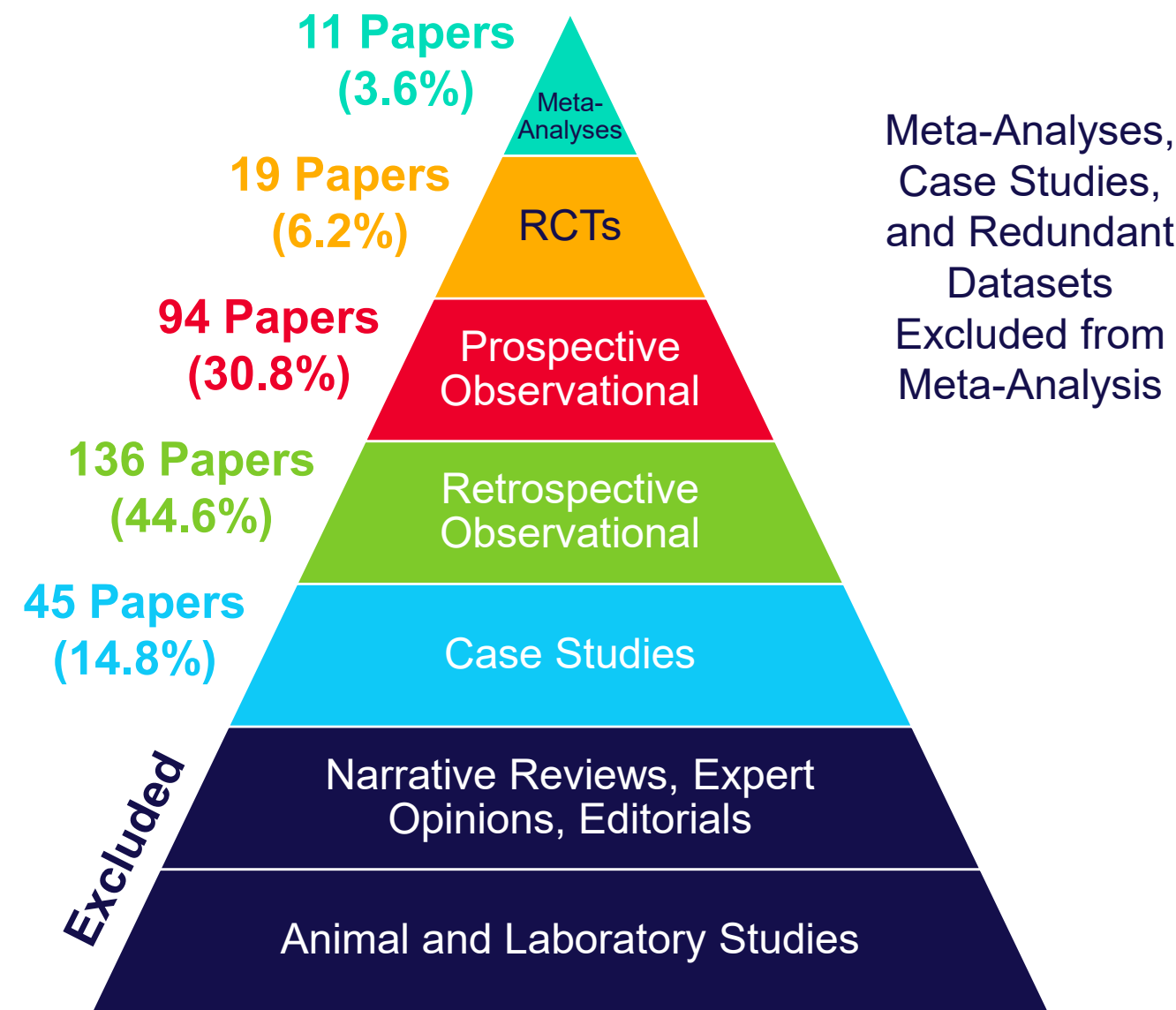
Published Atherectomy Literature through May 2024



Poster presented by Secemsky et al. November 4-5, VIVA 2024. Published Atherectomy Literature through May 2024.
DA: directional atherectomy; RA: rotational atherectomy; OA: orbital atherectomy; LA: laser atherectomy; IVL: intravascular lithotripsy.

Level of Evidence in the Atherectomy Literature

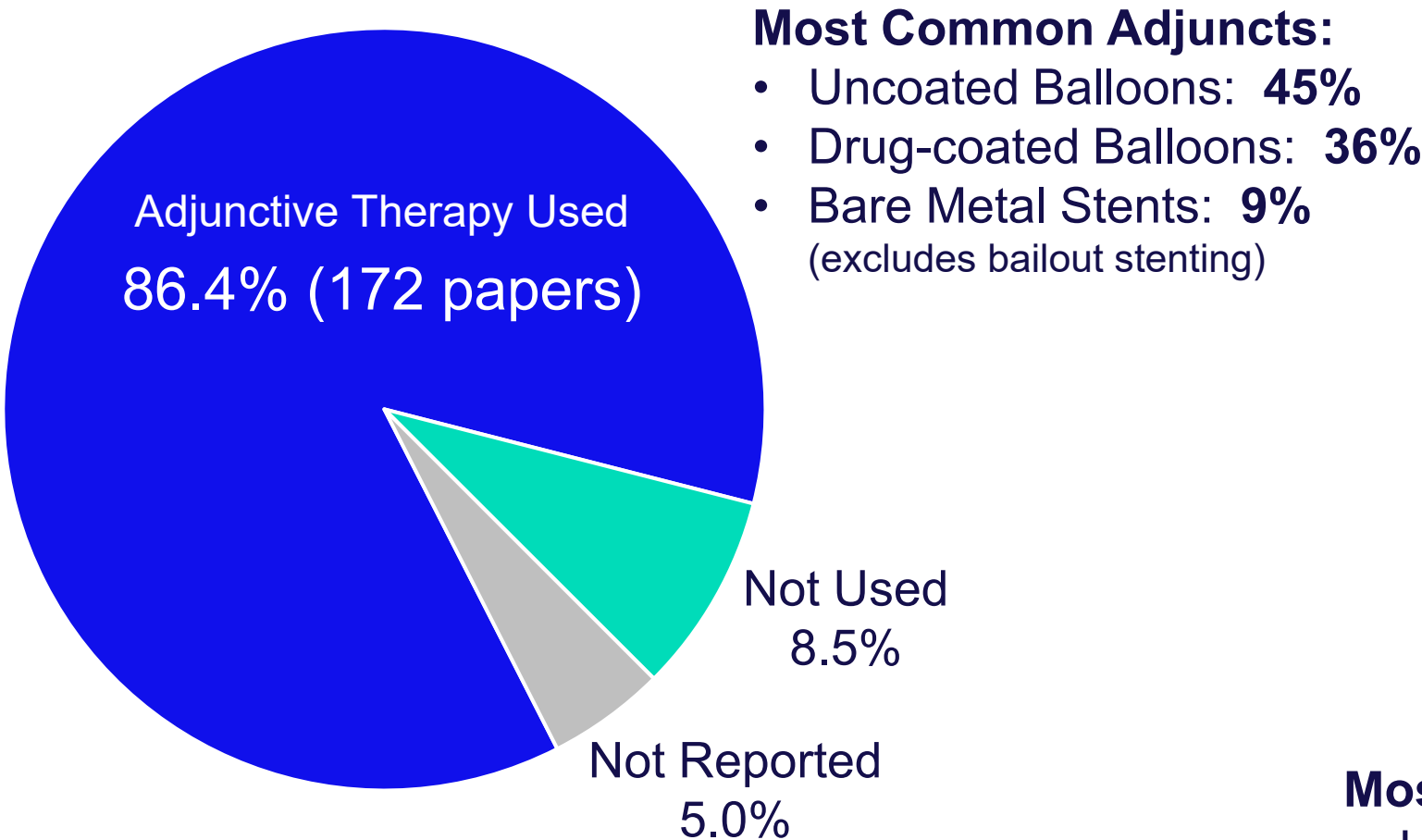
Published Atherectomy Literature through May 2024



Case studies defined as either single-patient case studies or case series with <10 patients and presenting no aggregate data.

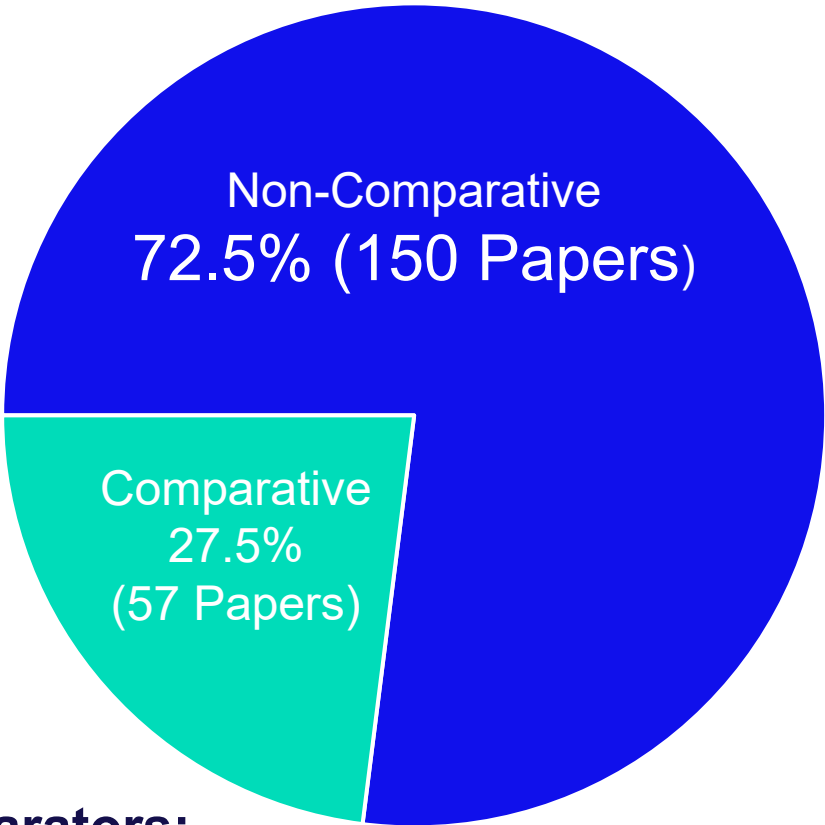
Adjunctive Therapies

199 Non-Redundant RCTs and Observational Studies
(Excludes Claims/Database Analyses)



Comparators

207 Non-Redundant RCTs and Observational Studies
(Includes Claims/Database Analyses)



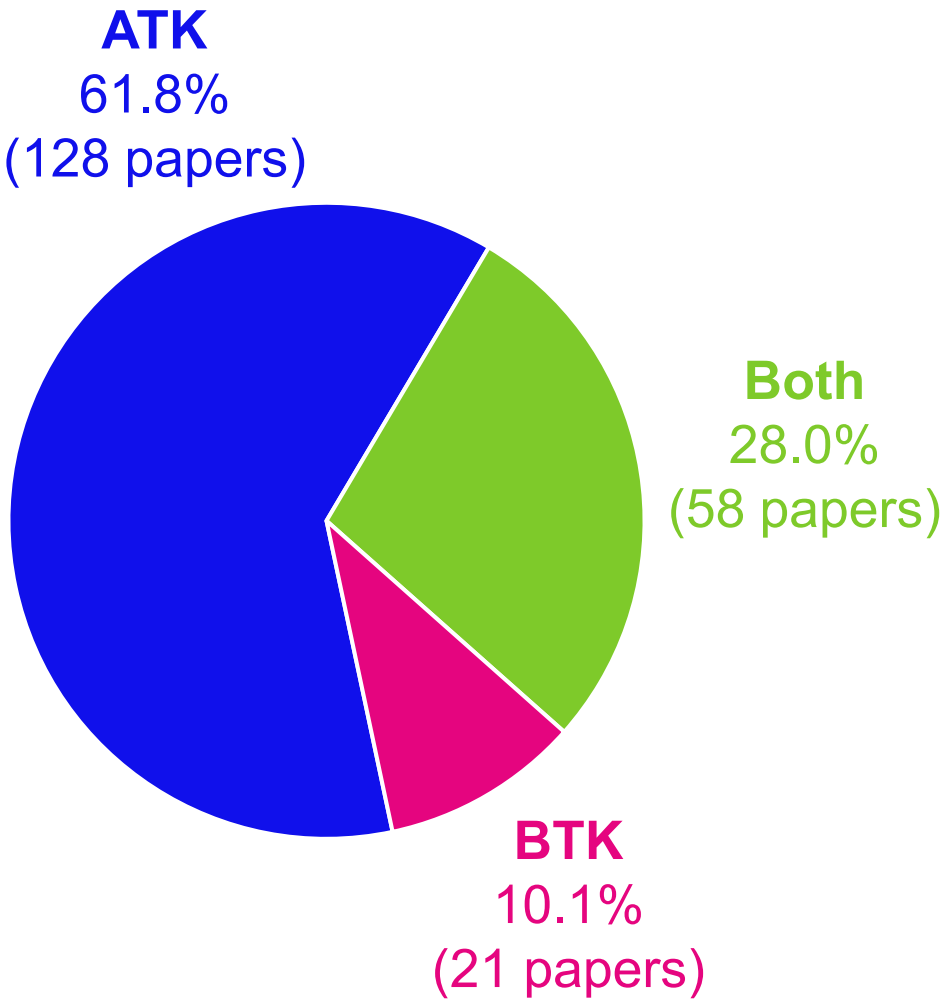
Patient and Lesion Characteristics

Published Atherectomy Literature through May 2024

Baseline Characteristic	Number of Papers [†]	Mean	Range
Lesion Length (mm)	127	115 mm	11 – 256 mm
Critical Limb Ischemia	169	44%	0 - 100%
Severe Calcification	67	39%	0 - 100%
Any Calcification	85	71%	0 - 100%
Total Occlusions	135	46%	0 - 100%
TASC C/D Lesions	69	56%	0 - 100%

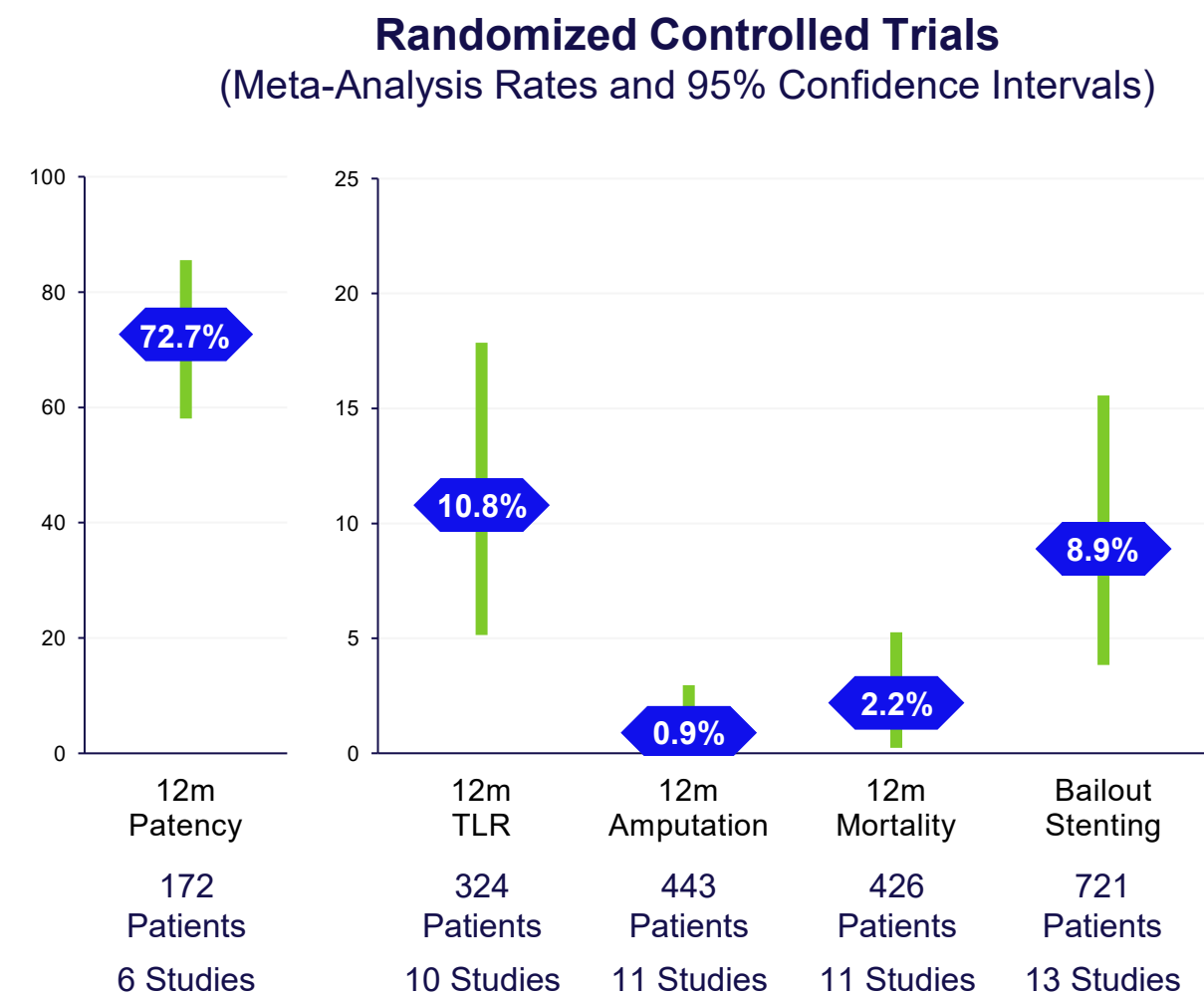
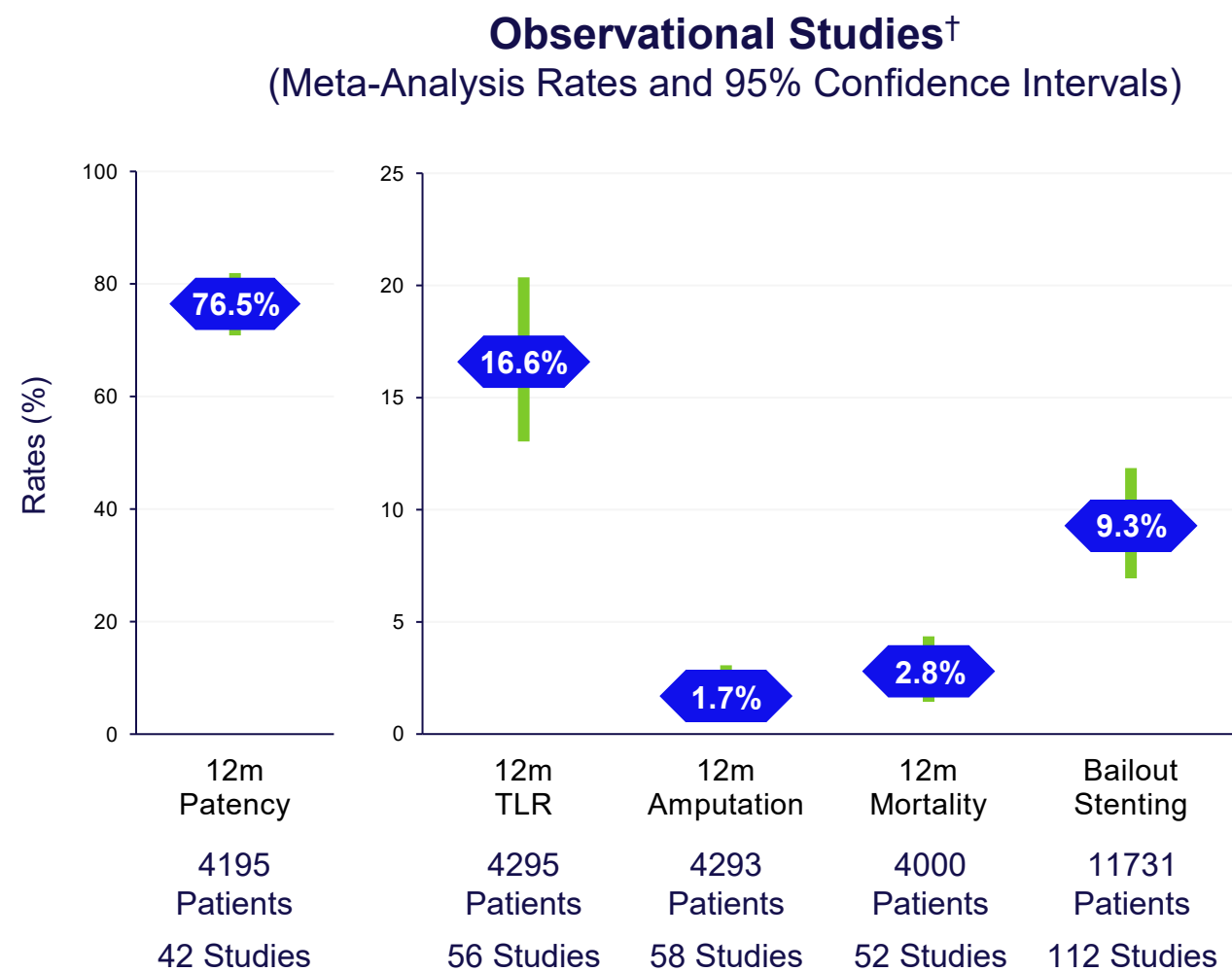
Published Literature as of May 31, 2024.
Includes 207 non-redundant RCTs and observational studies (including non-overlapping claims/database analyses).

[†] Papers reporting results from multiple subgroups may be counted more than once in the means



Poster presented by Secemsky et al. November 4-5, VIVA 2024.

Observational Studies vs RCTs in the Atherectomy Literature

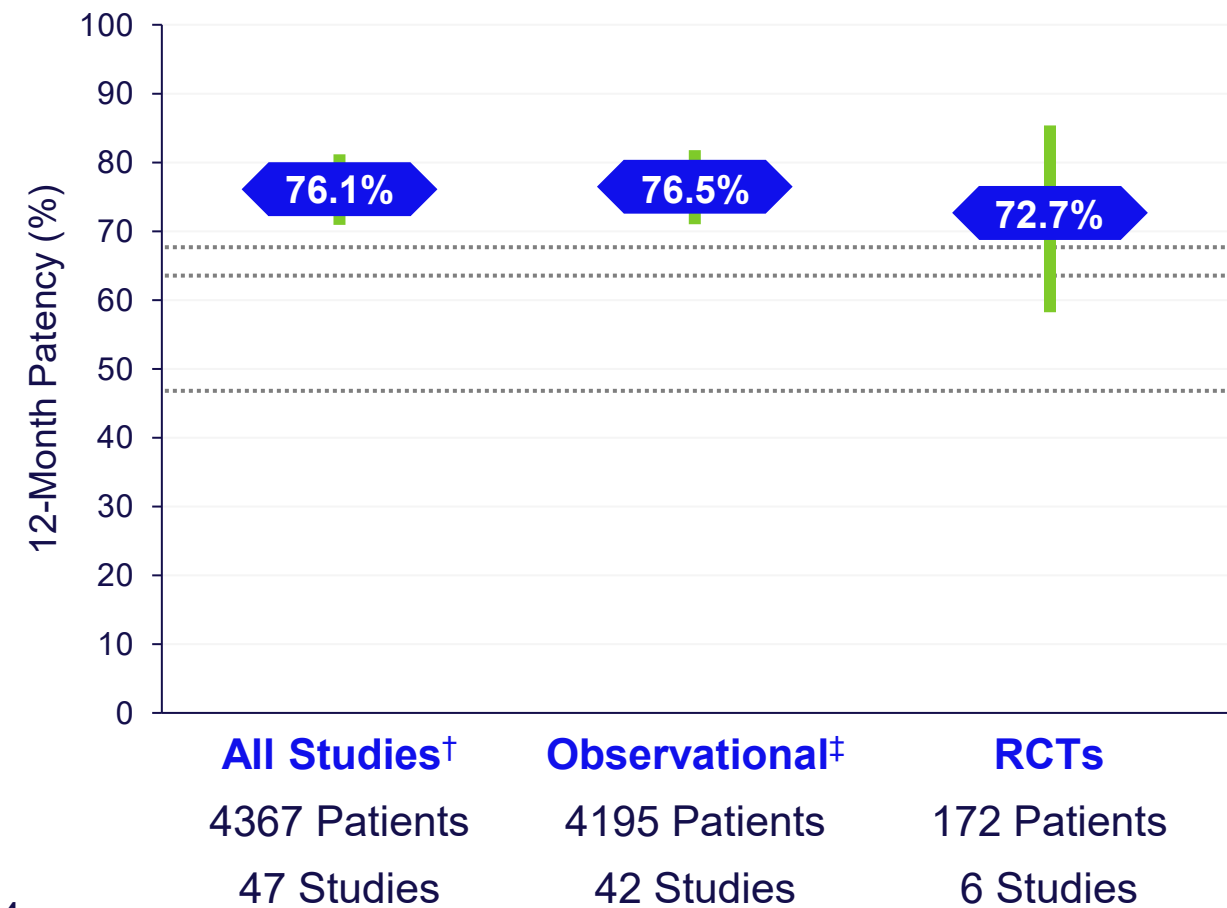


† Non-redundant prospective and retrospective observational studies. Excludes claims/database analyses (e.g., Medicare, VQI), case studies <10 patients, and meta-analyses.

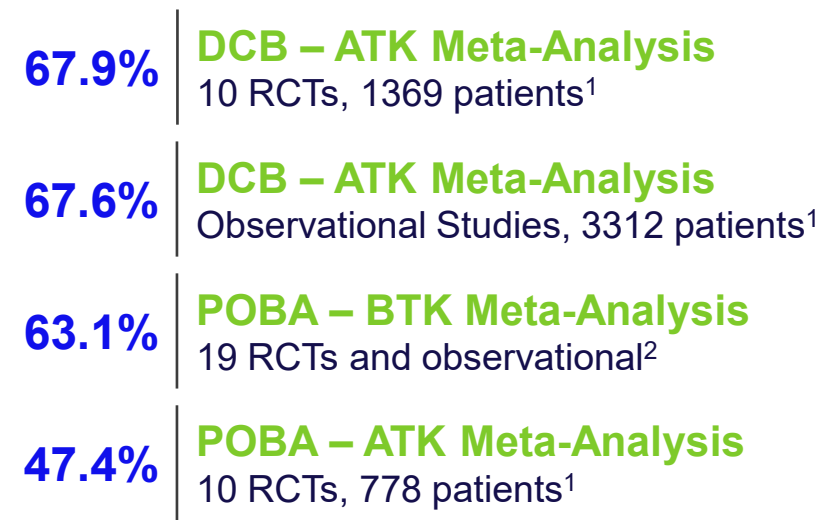
Poster presented by Secemsky et al. November 4-5, VIVA 2024.

12-Month Patency in the Atherectomy Literature

Meta-Analysis Rates
and 95% Confidence Intervals



Post-Hoc Literature Comparators



Definition

- 1. PSVR ≤2.4, or
- 2. Angiographic stenosis <50%, or
- 3. Freedom from TLR

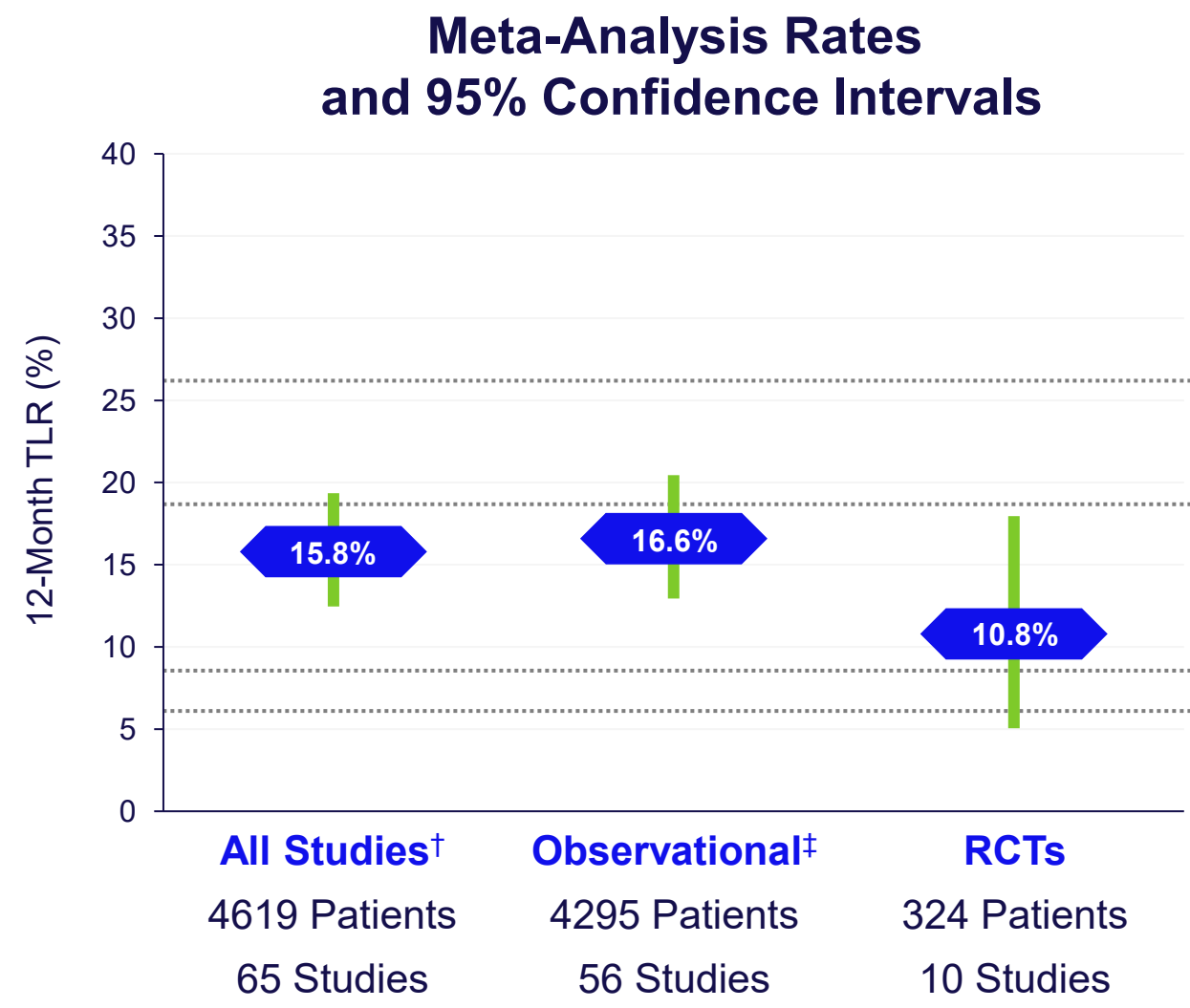
Studies using alternative patency definitions were excluded from the patency analysis

† Non-redundant RCTs, prospective and retrospective observational studies, and claims/database analyses (e.g., Medicare, VQI). Excludes case studies <10 patients and meta-analyses.
‡ Non-redundant prospective and retrospective observational studies. Excludes claims/database analyses (e.g., Medicare, VQI), case studies <10 patients, and meta-analyses

1. Caradu et al. J Vasc Surg. 2019;70:981-95 e10.
2. Mustapha et al. Circ Cardiovasc Interv. 2016;9:e003468.

Poster presented by Secemsky et al. November 4-5, VIVA 2024. "All Studies" rate: Data on file at Medtronic.

12-Month TLR in the Atherectomy Literature



Post-Hoc Literature Comparators

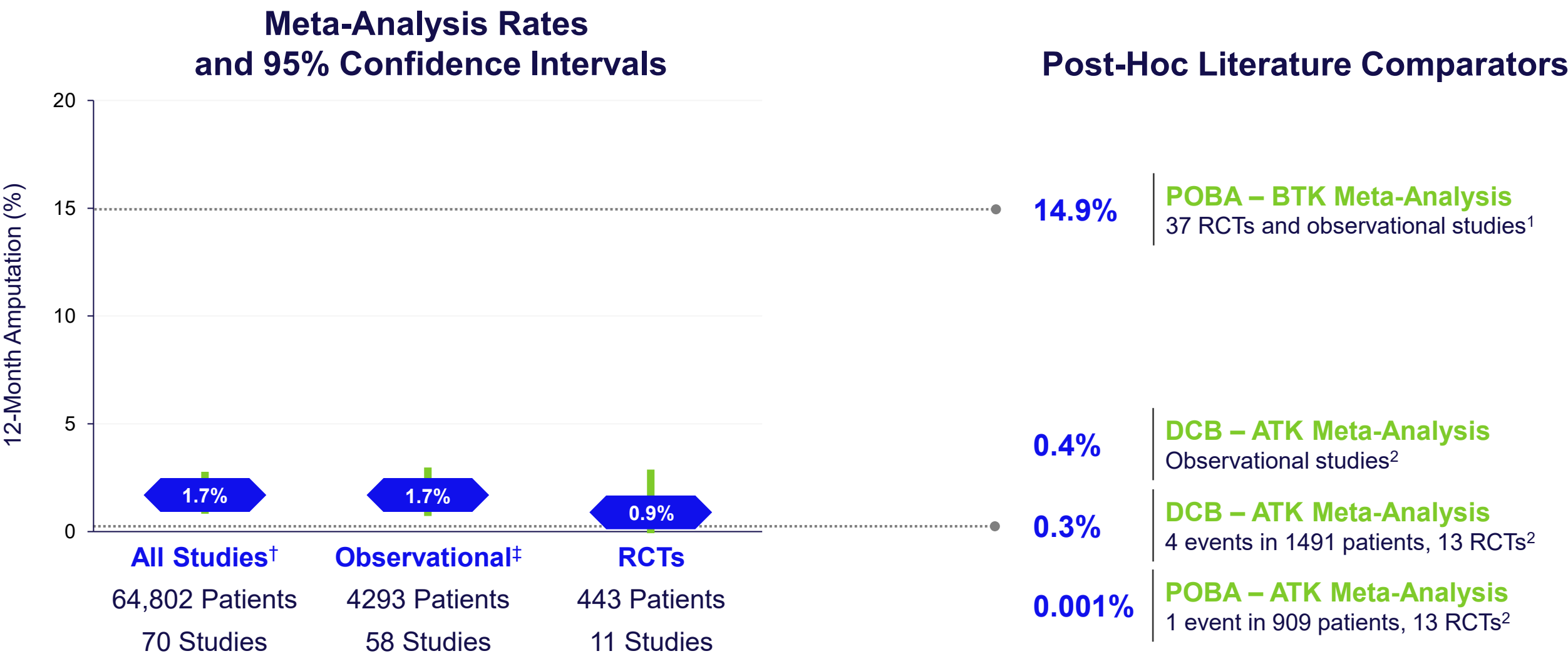
26.0%	POBA – ATK Meta-Analysis CD-TLR, 13 RCTs, 909 patients ¹
18.5%	POBA – BTK Meta-Analysis TLR, 3 RCTs, 200 patients ²
8.4%	DCB – ATK Meta-Analysis CD-TLR, 13 RCTs, 1491 patients ¹
6.3%	DCB – ATK Meta-Analysis CD-TLR, Observational studies ¹

† Non-redundant RCTs, prospective and retrospective observational studies, and claims/database analyses (e.g., Medicare, VQI). Excludes case studies <10 patients and meta-analyses.
‡ Non-redundant prospective and retrospective observational studies. Excludes claims/database analyses (e.g., Medicare, VQI), case studies <10 patients, and meta-analyses.

1. Caradu et al. J Vasc Surg. 2019;70:981-95 e10.
2. Cai et al. J Surg Res. 2022;278:303-16.

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12-Month Amputation in the Atherectomy Literature



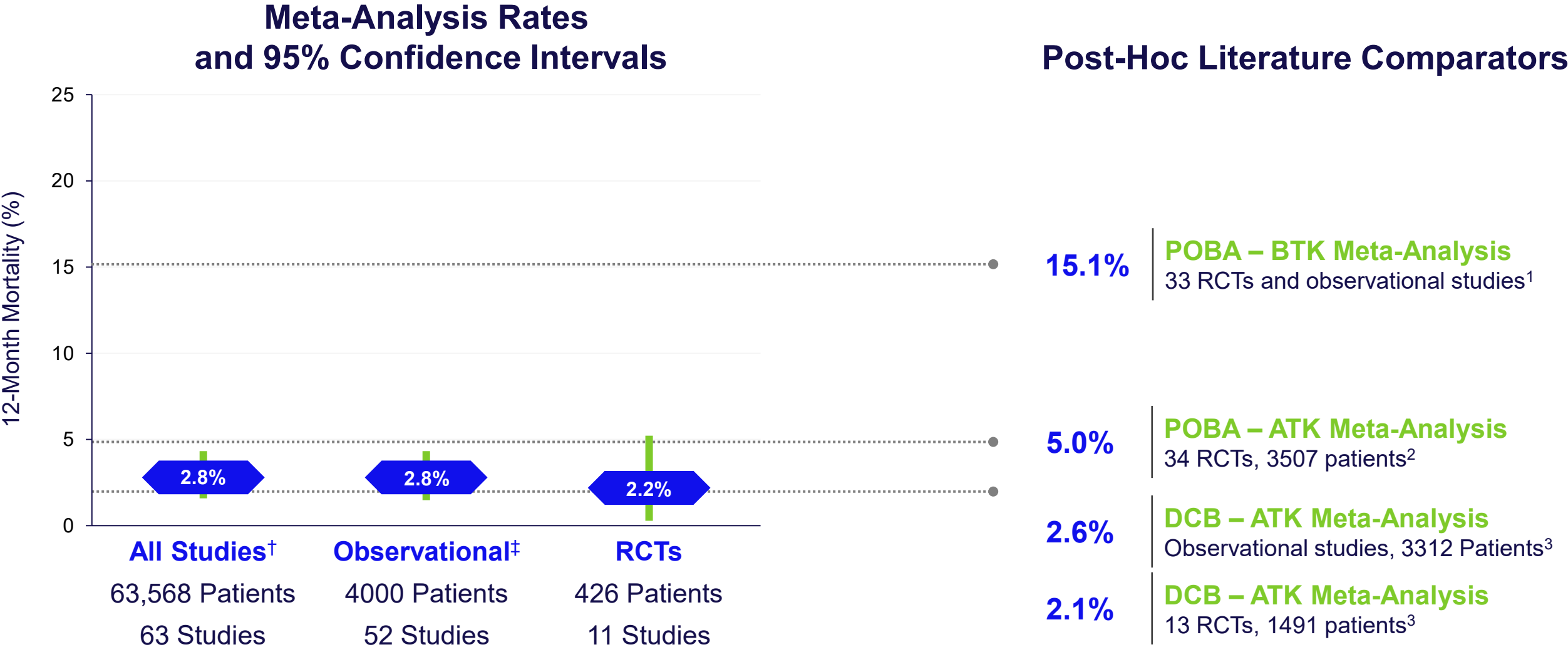
[†] Non-redundant RCTs, prospective and retrospective observational studies, and claims/database analyses (e.g., Medicare, VQI). Excludes case studies <10 patients and meta-analyses.

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12-Month Mortality in the Atherectomy Literature

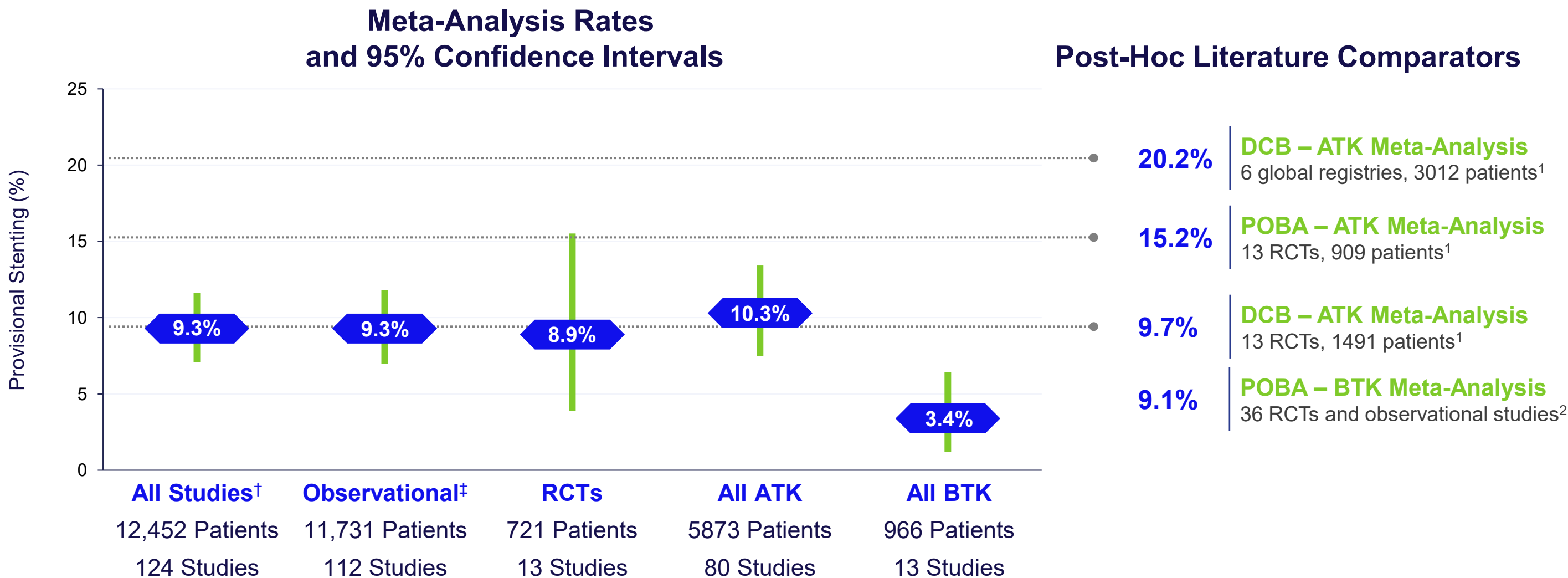


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1. Mustapha et al. Circ Cardiovasc Interv. 2016;9:e003468.
2. Dinh et al. J Endovasc Ther. 2021;28:755-77.
3. Caradu et al. J Vasc Surg. 2019;70:981-95 e10.

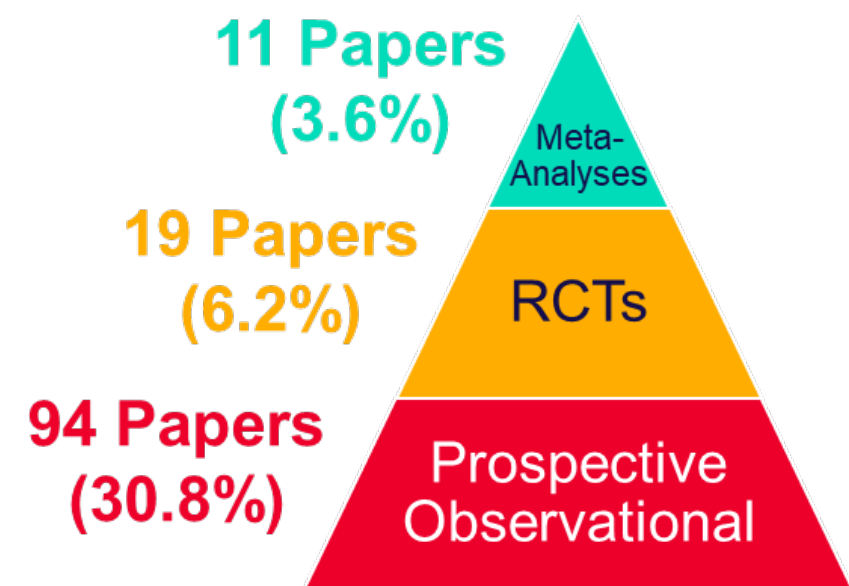
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Provisional Stenting in the Atherectomy Literature



Summary of Atherectomy Systematic Literature Review

Published evidence for atherectomy is extensive, with 305 original research articles published through May 2024, including high levels of evidence:



One-year rates of primary patency, TLR, major amputation, and mortality are similar or better than meta-analysis rates for POBA or DCB.¹⁻⁴

Compared to POBA or DCB (range 9.1% to 20.2%),^{1,2} **bailout stenting rates are low** in both observational (9.3%) and randomized atherectomy studies (8.9%).

- 1. Caradu et al. J Vasc Surg. 2019;70:981-95 e10.
- 2. Mustapha et al. Circ Cardiovasc Interv. 2016;9:e003468.
- 3. Cai et al. J Surg Res. 2022;278:303-16.
- 4. Dinh et al. J Endovasc Ther. 2021;28:755-77.



Medtronic

710 Medtronic Parkway
Minneapolis, MN 55432-5604
USA

Toll-free in USA: 800.633.8766
Worldwide: +1 763.514.4000

[medtronic.com](https://www.medtronic.com)

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