Carotid Stent: Systematic Review with ☸SAIMSARA.

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Abstract: This paper aims to synthesize current evidence on carotid stenting, focusing on procedural characteristics, clinical outcomes, and associated challenges, to identify key themes and future research directions. The review utilises 265 studies with 120140 total participants (naïve ΣN). The median in-stent restenosis rate after carotid artery stenting was 17.5%, with a wide range from 2.0% to 46.0% depending on definition, stent type, and patient population. Carotid stenting is a versatile procedure for various carotid pathologies, but its generalizability is limited by the heterogeneity of study designs and outcome reporting. The most significant limitation affecting certainty is the Variability in Reporting of restenosis definitions and follow-up durations. Clinicians should be aware of the varying restenosis rates associated with different stent designs and patient risk factors, and consider individualized antiplatelet strategies.

Keywords: Carotid Artery Stenting; Carotid Stenosis; In-Stent Restenosis; Stent Design

Review Stats

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- Scope: All fields
- Keyword Gate: Fuzzy (≥60% of required terms, minimum 2 terms matched in title/abstract)
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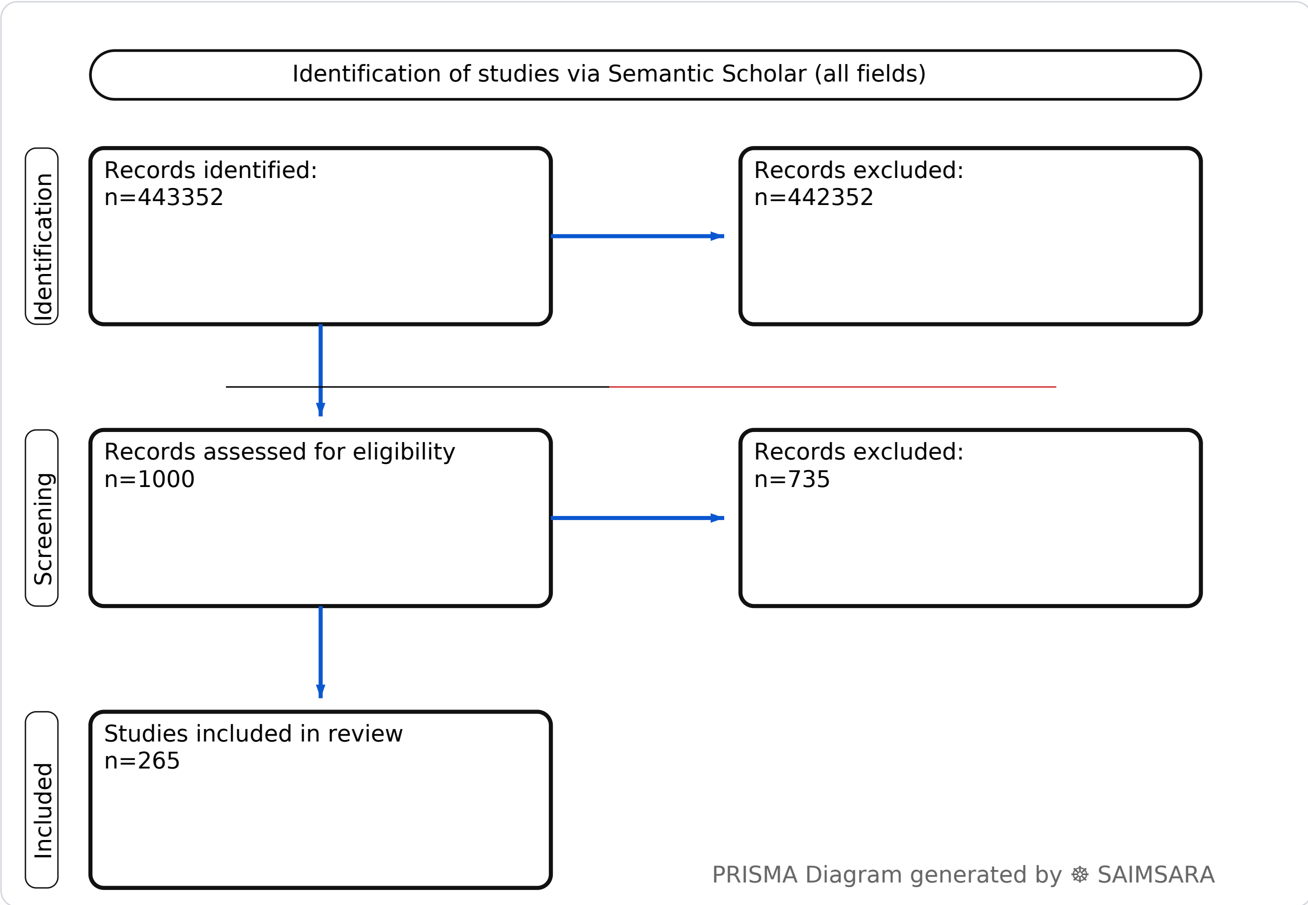
- Downloaded Abstracts/Papers: 1000
- Included original Abstracts/Papers: 265
- Total study participants (naïve ΣN): 120140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Identification
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Records excluded:
n=442352
Screening
Records assessed for eligibility
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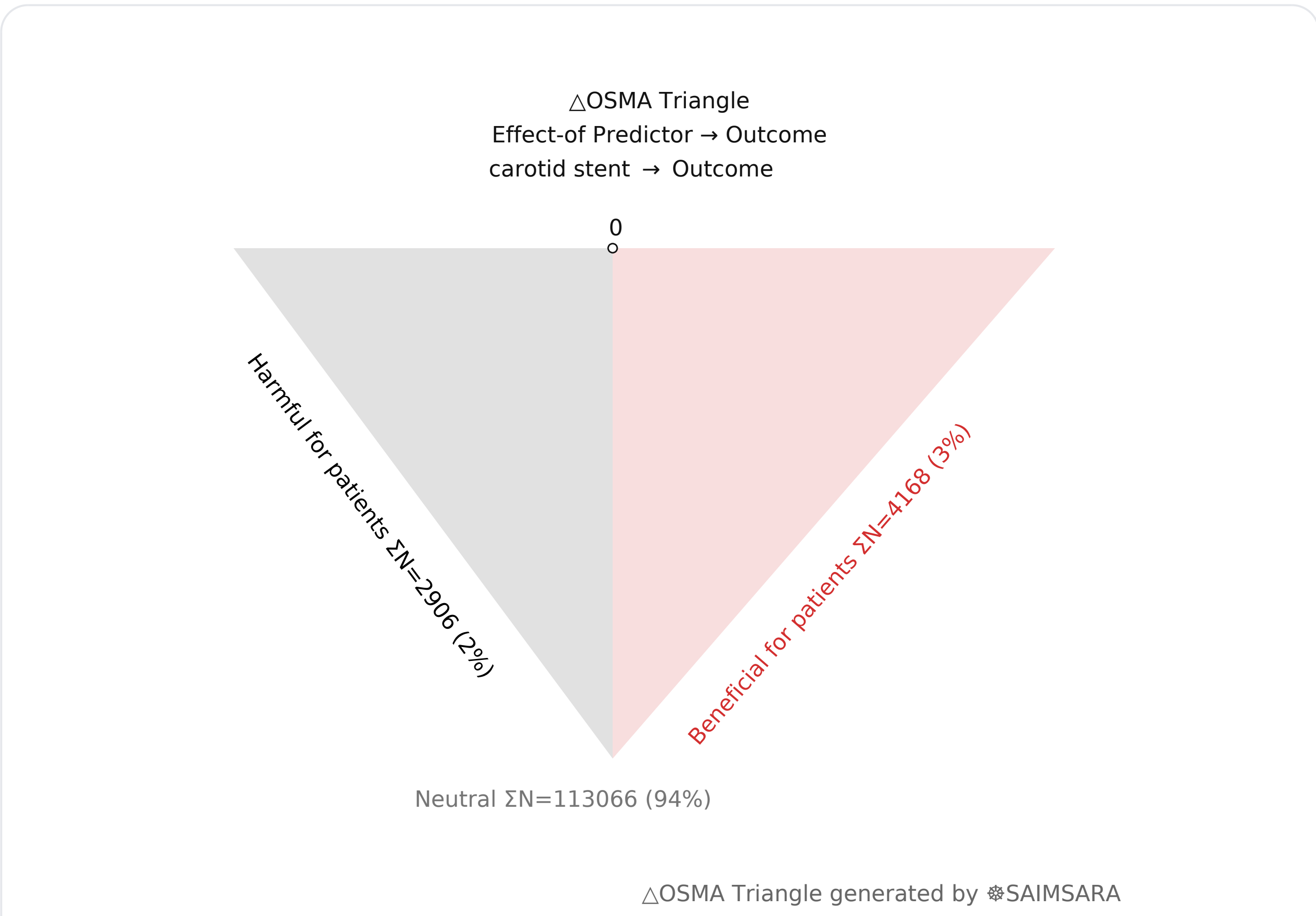
Records excluded:
n=735
Included
Studies included in review
n=265
PRISMA Diagram generated by ☸ SAIMSARA


△OSMA Triangle
Effect-of Predictor → Outcome
carotid stent → Outcome
0
Harmful for patients ΣN=2906 (2%)
Beneficial for patients ΣN=4168 (3%)
Neutral ΣN=113066 (94%)
△OSMA Triangle generated by ☸SAIMSARA

Outcome-Sentiment Meta-Analysis (OSMA): *(LLM-only)*

Frame: Effect-of Predictor → Outcome • *Source*: Semantic Scholar

Outcome: Outcome Typical timepoints: 30-day, 5-y. Reported metrics: %, CI, p.

Common endpoints: Common endpoints: complications, restenosis, mortality.

Predictor: carotid stent — exposure/predictor. Routes seen: intravenous. Typical comparator: open-cell stents, closed-cell stents. both stent, historic controls, transfemoral carotid artery….

- **1) Beneficial for patients** — Outcome with carotid stent — [3], [6], [16], [17], [25], [263] — ΣN=4168
- **2) Harmful for patients** — Outcome with carotid stent — [4], [5], [21] — ΣN=2906
- **3) No clear effect** — Outcome with carotid stent — [1], [2], [7], [8], [9], [10], [11], [12], [13], [14], [15], [18], [19], [20], [22], [23], [24], [26], [27], [28], [29], [30], [31], [32], [33], [34], [35], [36], [37], [38], [39], [40], [41], [42], [43], [44], [45], [46], [47], [48], [49], [50], [51], [52], [53], [54], [55], [56], [57], [58], [59], [60], [61], [62], [63], [64], [65], [66], [67], [68], [69], [70], [71], [72], [73], [74], [75], [76], [77], [78], [79], [80], [81], [82], [83], [84], [85], [86], [87], [88], [89], [90], [91], [92], [93], [94], [95], [96], [97], [98], [99], [100], [101], [102], [103], [104], [105], [106], [107], [108], [109], [110], [111], [112], [113], [114], [115], [116], [117], [118], [119], [120], [121], [122], [123], [124], [125], [126], [127], [128], [129], [130], [131], [132], [133], [134], [135], [136], [137], [138], [139], [140], [141], [142], [143], [144], [145], [146], [147], [148], [149], [150], [151], [152], [153], [154], [155], [156], [157], [158], [159], [160], [161], [162], [163], [164], [165], [166], [167], [168], [169], [170], [171], [172], [173], [174], [175], [176], [177], [178], [179], [180], [181], [182], [183], [184], [185], [186], [187], [188], [189], [190], [191], [192], [193], [194], [195], [196], [197], [198], [199], [200], [201], [202], [203], [204], [205], [206], [207], [208], [209], [210], [211], [212], [213], [214], [215], [216], [217], [218], [219], [220], [221], [222], [223], [224], [225], [226], [227], [228], [229], [230], [231], [232], [233], [234], [235], [236], [237], [238], [239], [240], [241], [242], [243], [244], [245], [246], [247], [248], [249], [250], [251], [252], [253], [254], [255], [256], [257], [258], [259], [260], [261], [262], [264], [265] — ΣN=113066

Introduction

Carotid artery stenting (CAS) is an established endovascular intervention aimed at preventing stroke by treating carotid artery stenosis and other vascular pathologies. Initially described in the mid-1990s as a neurovascular intervention [16, 38], CAS has evolved to address a range of complex conditions, including acute stroke, traumatic injuries, and aneurysms [5, 7, 36, 42, 44, 45, 56, 60, 84, 85, 87, 88, 89, 90, 91, 99, 106, 107, 118, 207]. The procedure involves the deployment of a stent to restore vessel patency and stabilize plaque, often complemented by cerebral protection devices to mitigate embolic risk [9, 46, 54, 93, 97, 98, 100, 102, 110, 121, 127, 131, 172, 191, 192, 199, 201, 209, 210, 216, 230, 234, 240, 241, 255]. Ongoing research continues to refine techniques, evaluate novel stent designs, and compare CAS outcomes against carotid endarterectomy (CEA) [23, 30, 35, 62, 78, 81, 103, 153, 154, 155, 157, 158, 160, 165, 177, 178, 181, 190, 195, 202, 204, 206, 228, 247, 251, 257, 264].

Aim

This paper aims to synthesize current evidence on carotid stenting, focusing on procedural characteristics, clinical outcomes, and associated challenges, to identify key themes and future research directions.

Methods

Systematic review with multilayer AI research agent: keyword normalization, retrieval & structuring, and paper synthesis (see SAIMSARA About section for details).

- **Bias:** Qualitatively inferred from study design fields, with a notable presence of mixed-design, cohort, and retrospective studies alongside randomized controlled trials (RCTs). Sample sizes vary widely, from single case reports to large registries, introducing potential for selection bias and varying levels of evidence.

Results

4.1 Study characteristics

The included studies encompass a range of designs, predominantly mixed-design and cohort studies, with several prospective randomized controlled trials (RCTs) also represented. Populations frequently include patients with symptomatic or asymptomatic carotid stenosis, high-surgical-risk individuals, and those undergoing emergency procedures for acute stroke or traumatic injuries. Follow-up periods vary significantly, ranging from immediate post-procedural assessment (e.g., 30 days) to intermediate (e.g., 9 months, 23 months) and long-term evaluations (e.g., 4.0 years, 5 years, up to 13 years).

4.2 Main numerical result aligned to the query

In-stent restenosis (ISR) rates following carotid artery stenting show considerable variability depending on stent design, patient characteristics, and follow-up duration. The median reported rate for moderate or higher ISR was 17.5%, with a range from 2.0% (for ≥70% ISR) [4] to 46.0% (for closed-cell stents) [3]. Specific populations, such as those with radiation-induced carotid stenosis, demonstrated higher ISR rates (25.7%) compared to atherosclerotic stenosis (4.2%) [161], and younger patients showed higher post-Wingspan ISR rates (45.2%) compared to older patients (24.2%) [183].

4.3 Topic synthesis

- **Stent Design and Hemodynamics:** Closed-cell stents are associated with larger areas of low Wall Shear Stress (WSS), elevated Oscillatory Shear Index (OSI), and high Relative Residence Time (RRT) compared to open-cell stents, which may influence restenosis [2, 18]. Open-cell stents demonstrated less moderate or higher restenosis (35.5%) compared to closed-cell stents (46.0%) over 4.0 years [3]. Computational fluid dynamics (CFD) and in-vitro studies analyze stent cell design and vessel scaffolding [8, 28, 65, 262].
- **In-Stent Restenosis (ISR) and its Predictors:** ISR is a significant complication, with reported rates ranging from 2.0% (≥70% ISR) to 46.0% [3, 4, 21]. Predictors include initial Carotid Wallstent implantation [4], contralateral carotid occlusion, carotid endarterectomy (CEA) restenosis, and postprocedural carotid duplex ultrasound with a peak systolic velocity (PSV) ≥120 cm/s [21]. Radiation-induced stenosis is also a strong predictor of ISR (25.7%) [161]. Inflammation and specific serum markers are implicated in ISR development [20, 47, 50, 249].
- **Cerebral Protection and Embolic Events:** Distal embolic protection devices reduce periprocedural diffusion-weighted imaging (DWI) lesion burden [6, 9]. Studies have evaluated various protection systems, including filter devices and balloon occlusion-aspiration, demonstrating their efficacy in preventing cerebral embolic events and collecting embolized debris [46, 54, 97, 98, 102, 110, 121, 127, 131, 172, 191, 192, 199, 201, 209, 210, 216, 230, 234, 240, 241, 255]. However, intraplaque hemorrhage was not a significant risk factor for cerebral embolism during CAS [86].
- **Comparison with Carotid Endarterectomy (CEA):** Transcarotid artery revascularization (TCAR) was associated with a lower risk of in-hospital stroke or death (1.6% vs 3.1%) compared to transfemoral carotid artery stenting (TF-CAS) [17]. Randomized trials comparing CAS and CEA show varied outcomes; for instance, CAS had a higher risk of stroke, death, or procedural myocardial infarction within 120 days (8.5% vs 5.2%) but similar long-term fatal or disabling stroke rates compared to CEA [157]. Overall, CAS is often associated with higher periprocedural stroke rates, while CEA may have a survival advantage [155, 158, 160, 165].
- **Procedural Complications and Management:** Complications include in-stent thrombosis (20.8%) and stent occlusion (7.5%) in emergent extracranial internal carotid artery (ICA) stenting for tandem occlusions [83]. Stent occlusions (5 cases) were noted in novel double-

layer mesh stents used for acute stroke [5]. Periprocedural hypotension and bradycardia are common, with carotid sinus reactions influencing clinical outcomes [12, 31, 48, 79, 141, 193, 197, 259]. Symptomatic intracranial hemorrhage (sICH) rates ranged from 9% to 16.6% in emergency stenting with mechanical thrombectomy [87, 89], with higher intraprocedural heparin dosage increasing risk in specific subgroups [39].

- **Specialized Applications and Novel Techniques:** Intravascular lithotripsy has been used as an adjunct for stent expansion in heavily calcified lesions [1]. Robotic-assisted CAS demonstrates technical feasibility and safety, with 100% technical success and no neurological complications in small series [25, 150, 151]. Covered stents (e.g., Willis stent) are used for complex traumatic direct carotid-cavernous fistulas, pseudoaneurysms, and coil herniation during aneurysm embolization [7, 42, 45, 106, 107, 207]. Flow-diverter stents (FDSs) are used for aneurysms, though covering the ophthalmic artery may lead to complications (40%) despite patency (86%) [88, 146].
- **Imaging and Monitoring:** Duplex ultrasound is crucial for diagnosing and following up ISR, with specific velocity criteria established [24, 52, 58, 59, 74, 75, 117, 126, 130, 145]. Advanced imaging techniques like contrast-enhanced magnetic resonance angiography (CE-MRA), 3D time-of-flight (TOF), computed tomography angiography (CTA), and optical coherence tomography (OCT) are used for pre- and post-stent evaluation, though artificial lumen narrowing can be a challenge [22, 29, 32, 33, 115]. Near-infrared spectroscopy (NIRS) can predict cerebral hyperperfusion syndrome [174].

Discussion

5.1 Principal finding

The median in-stent restenosis rate after carotid artery stenting was 17.5%, with a wide range from 2.0% to 46.0% depending on definition, stent type, and patient population [3, 4, 21, 26, 27, 154, 161, 183].

5.2 Clinical implications

- **Stent Selection:** Open-cell stents may be preferred over closed-cell designs to reduce the risk of moderate or higher restenosis [3].
- **Risk Stratification:** Patients with radiation-induced carotid stenosis, a history of CEA restenosis, or younger age may be at higher risk for ISR and require closer monitoring [21, 161, 183].
- **Cerebral Protection:** Embolic protection devices are critical for reducing periprocedural cerebral embolic events and should be routinely employed in carotid stenting procedures [6, 9, 172, 191].

- **Antiplatelet Therapy:** Dual antiplatelet therapy is associated with better functional outcomes in acute stroke patients with tandem occlusions [39], and resistance to antiplatelet agents, particularly clopidogrel (51.9%), is a concern [147].
- **Emergency Settings:** While emergency stenting for acute stroke and tandem occlusions appears safe and effective for recanalization, careful management of antiplatelet agents and heparin is crucial to mitigate hemorrhage risk [39, 87, 89, 152].

5.3 Research implications / key gaps

- **Long-term Outcomes of Novel Techniques:** Further long-term follow-up studies are needed to fully establish the durability and safety of newer techniques like robotic-assisted stenting, intravascular lithotripsy, and specific covered/flow-diverter stents [1, 25, 88, 146, 151].
- **Optimal Antiplatelet Regimens:** Research is warranted to determine optimal antiplatelet strategies, particularly in patients with detected resistance or those undergoing emergency procedures, to balance thrombosis and hemorrhage risks [36, 39, 147, 194, 205, 231].
- **Stent Design and Hemodynamics:** More prospective studies are needed to correlate computational fluid dynamics (CFD) predictions of Wall Shear Stress (WSS) and Oscillatory Shear Index (OSI) with long-term clinical outcomes, especially ISR rates, across different stent designs [2, 18, 30].
- **Cognitive Function Impact:** The long-term impact of carotid stenting on various cognitive domains requires more comprehensive and standardized assessment beyond short-term improvements in specific scores [116, 129, 175].
- **Imaging Modality Standardization:** Development of standardized, stent-specific imaging protocols (e.g., CTA, CE-MRA, duplex ultrasound) is needed to accurately assess in-stent lumen and restenosis, accounting for artificial lumen narrowing [29, 32, 52, 58, 59, 74, 75].

5.4 Limitations

- **Heterogeneity of Study Designs** — The diverse range of study designs (mixed, cohort, RCTs, case reports) limits direct comparability and meta-analysis of outcomes.
- **Variability in Reporting** — Inconsistent reporting of restenosis definitions (e.g., >50% vs ≥70%), follow-up durations, and specific patient populations complicates the synthesis of robust numerical results.
- **Limited Long-term Data** — While some studies offer long-term follow-up, many newer techniques or specific stent designs lack extensive long-term outcome data.

- **Small Sample Sizes** — Many studies, particularly those on novel techniques or specific complications, involve small sample sizes, which restricts the generalizability of their findings.
- **Lack of Standardized Metrics** — Different studies use varying metrics for success, complications, and imaging criteria, making it challenging to draw definitive comparative conclusions.

5.5 Future directions

- **Standardized Outcome Reporting** — Implement uniform definitions and reporting standards for restenosis, stroke, and other complications across studies.
- **Comparative Effectiveness Trials** — Conduct large-scale, long-term randomized controlled trials comparing newer CAS techniques (e.g., TCAR, robotic-assisted) against established methods like transfemoral CAS and CEA.
- **Advanced Imaging Biomarkers** — Develop and validate advanced imaging techniques (e.g., AI-enhanced CTA/MRA, NIRS) for early detection of ISR, hyperperfusion syndrome, and plaque vulnerability.
- **Robotic System Integration** — Explore the integration of robotic systems for carotid stenting in diverse clinical settings, including remote locations, to improve precision and access.
- **Personalized Antiplatelet Regimens** — Investigate genotype-guided or platelet function-guided antiplatelet therapy to optimize outcomes and minimize complications in CAS patients.

Conclusion

The median in-stent restenosis rate after carotid artery stenting was 17.5%, with a wide range from 2.0% to 46.0% depending on definition, stent type, and patient population [3, 4, 21, 26, 27, 154, 161, 183]. Carotid stenting is a versatile procedure for various carotid pathologies, but its generalizability is limited by the heterogeneity of study designs and outcome reporting. The most significant limitation affecting certainty is the **Variability in Reporting** of restenosis definitions and follow-up durations. Clinicians should be aware of the varying restenosis rates associated with different stent designs and patient risk factors, and consider individualized antiplatelet strategies.

References

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Figure 1. Publication-year distribution of included originals

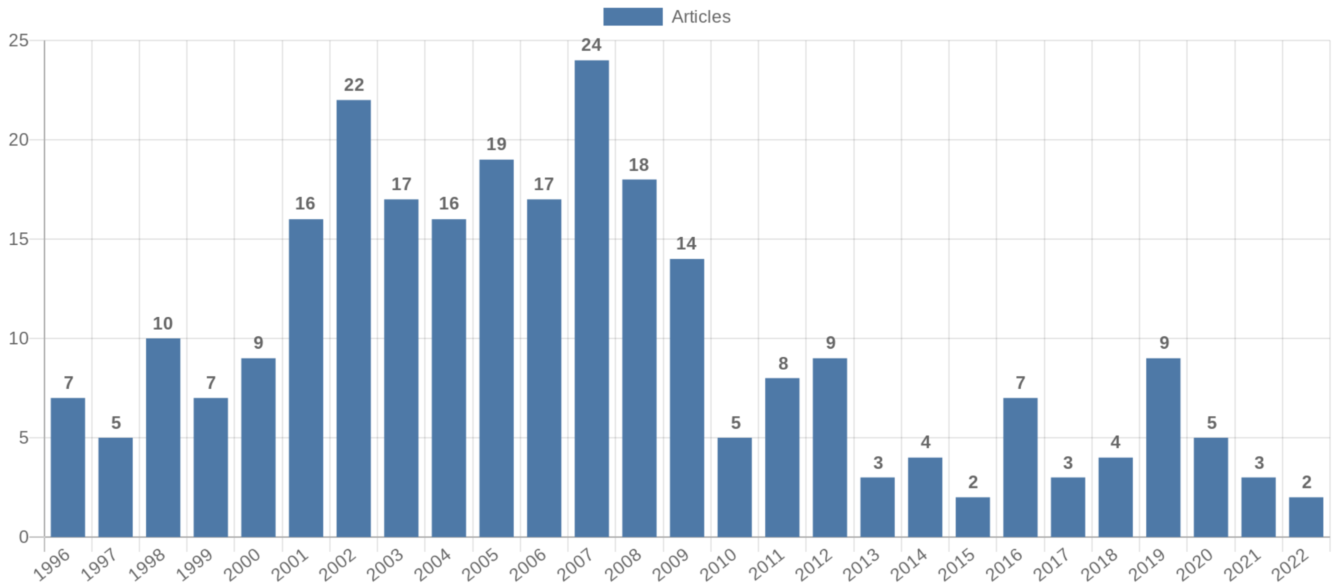

Figure 2. Study-design distribution of included originals

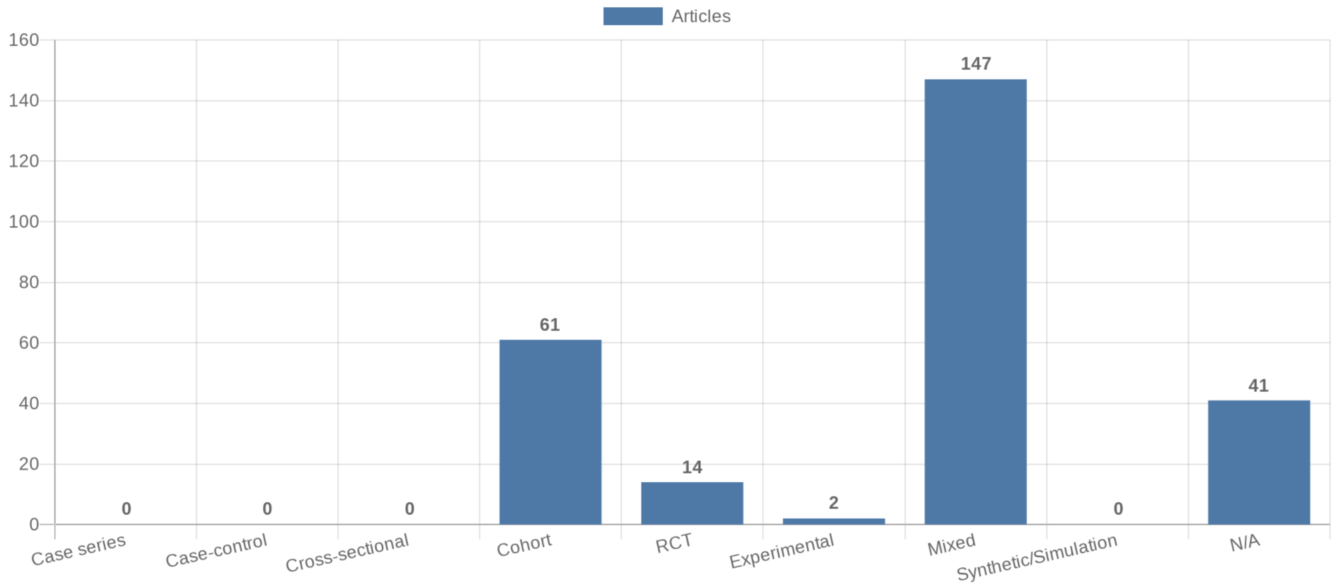

Figure 3. Study-type (directionality) distribution of included originals

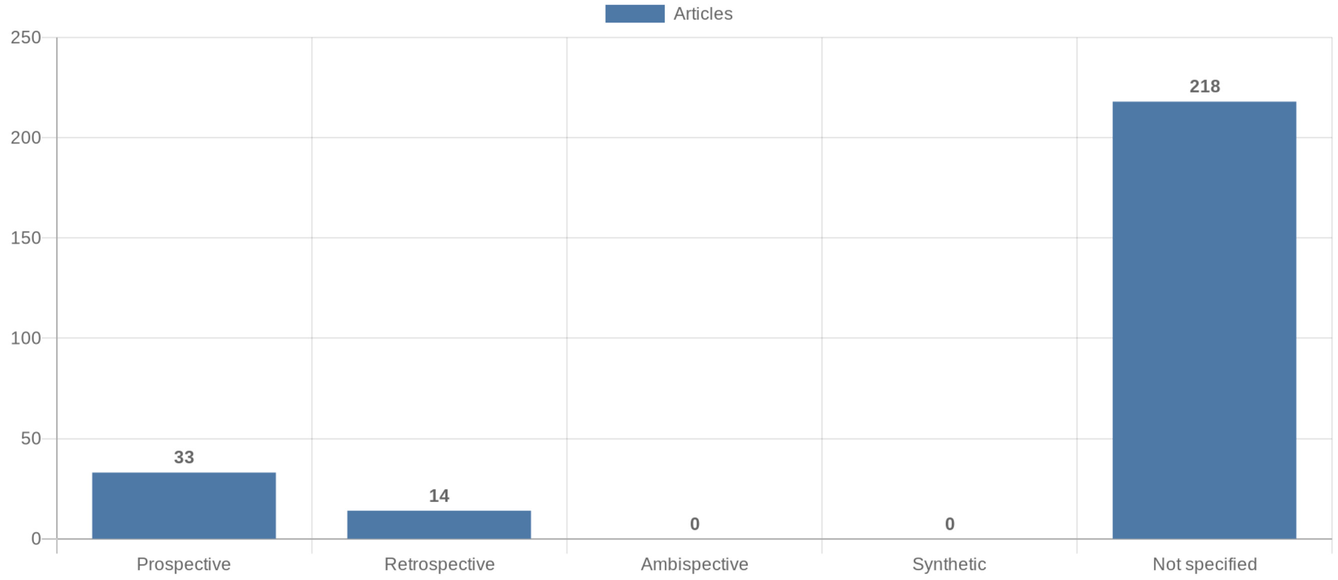

Figure 4. Main extracted research topics

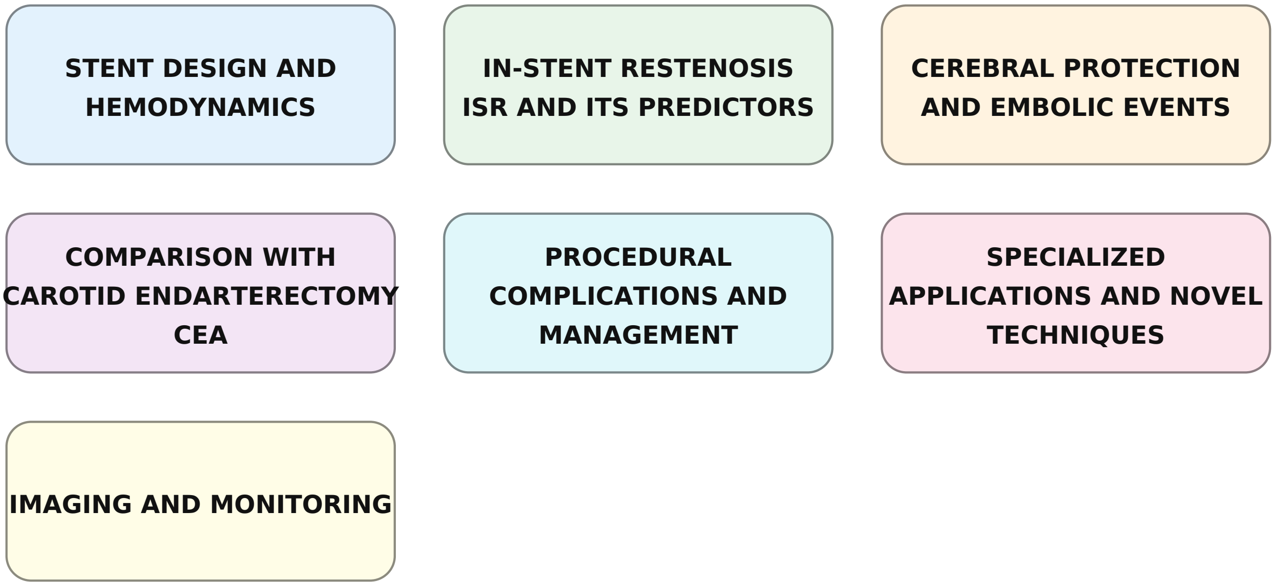

Figure 5. Limitations of current studies (topics)

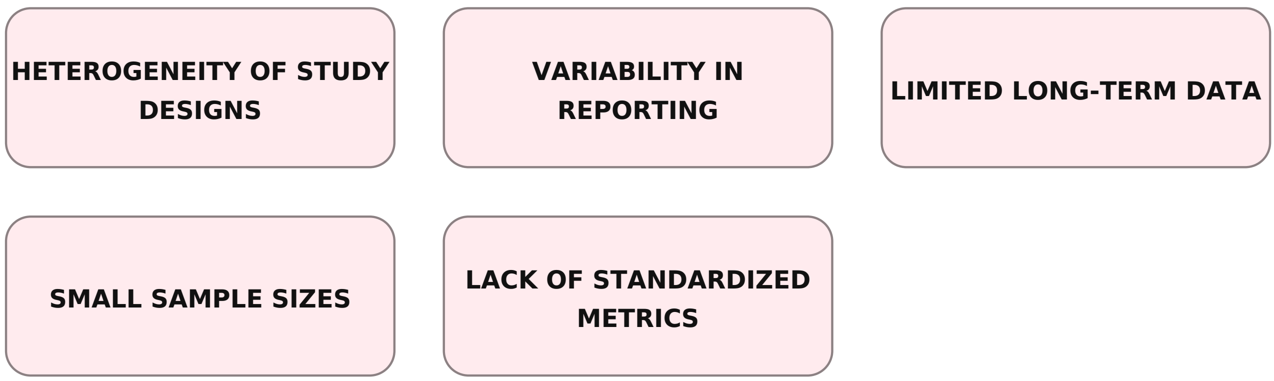

Figure 6. Future research directions (topics)

LONG-TERM OUTCOMES OF NOVEL TECHNIQUES

OPTIMAL ANTIPLATELET REGIMENS

STENT DESIGN AND HEMODYNAMICS

COGNITIVE FUNCTION IMPACT

IMAGING MODALITY STANDARDIZATION

STANDARDIZED OUTCOME REPORTING

COMPARATIVE EFFECTIVENESS TRIALS