Stent Peripheral Artery Disease: Systematic Review with ☸SAIMSARA.

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Abstract: This paper aims to systematically review the current evidence regarding the use of stents in peripheral artery disease, focusing on their efficacy, safety, and the factors influencing outcomes, to identify clinical implications and future research directions. The review utilises 168 studies with 256041 total participants (naïve ΣN). The median 12-month primary patency rate for various stent types in peripheral artery disease was 85.6%, ranging from 73.1% to 100%, indicating that stent-based interventions are generally effective for revascularization in symptomatic peripheral artery disease, particularly in femoropopliteal and aortoiliac segments. However, the heterogeneity of stent types, lesion characteristics, and follow-up durations across studies represents the most significant limitation to drawing definitive conclusions. Clinicians should consider drug-eluting stents for superior patency in appropriate lesions, while future research must prioritize large-scale, long-term randomized controlled trials to definitively assess the safety of paclitaxel-coated devices and optimize antiplatelet regimens.

Keywords: Peripheral Artery Disease; Stents; Drug-Eluting Stents; Femoropopliteal Artery; Restenosis; Primary Patency; Endovascular Procedures; Target Lesion Revascularization; Bare Metal Stents; In-Stent Restenosis

Review Stats

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- Scope: All fields
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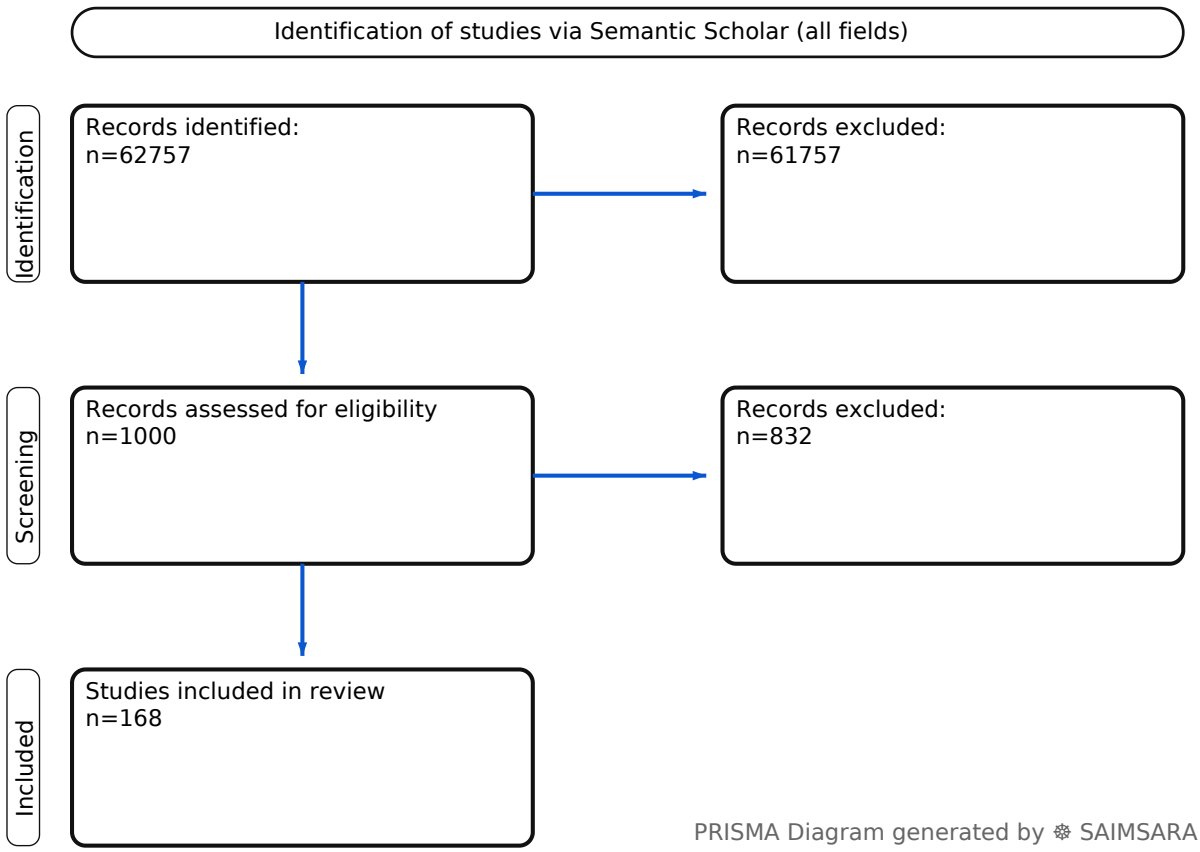
- Included original Abstracts/Papers: 168
- Total study participants (naïve ΣN): 256041


Identification of studies via Semantic Scholar (all fields)
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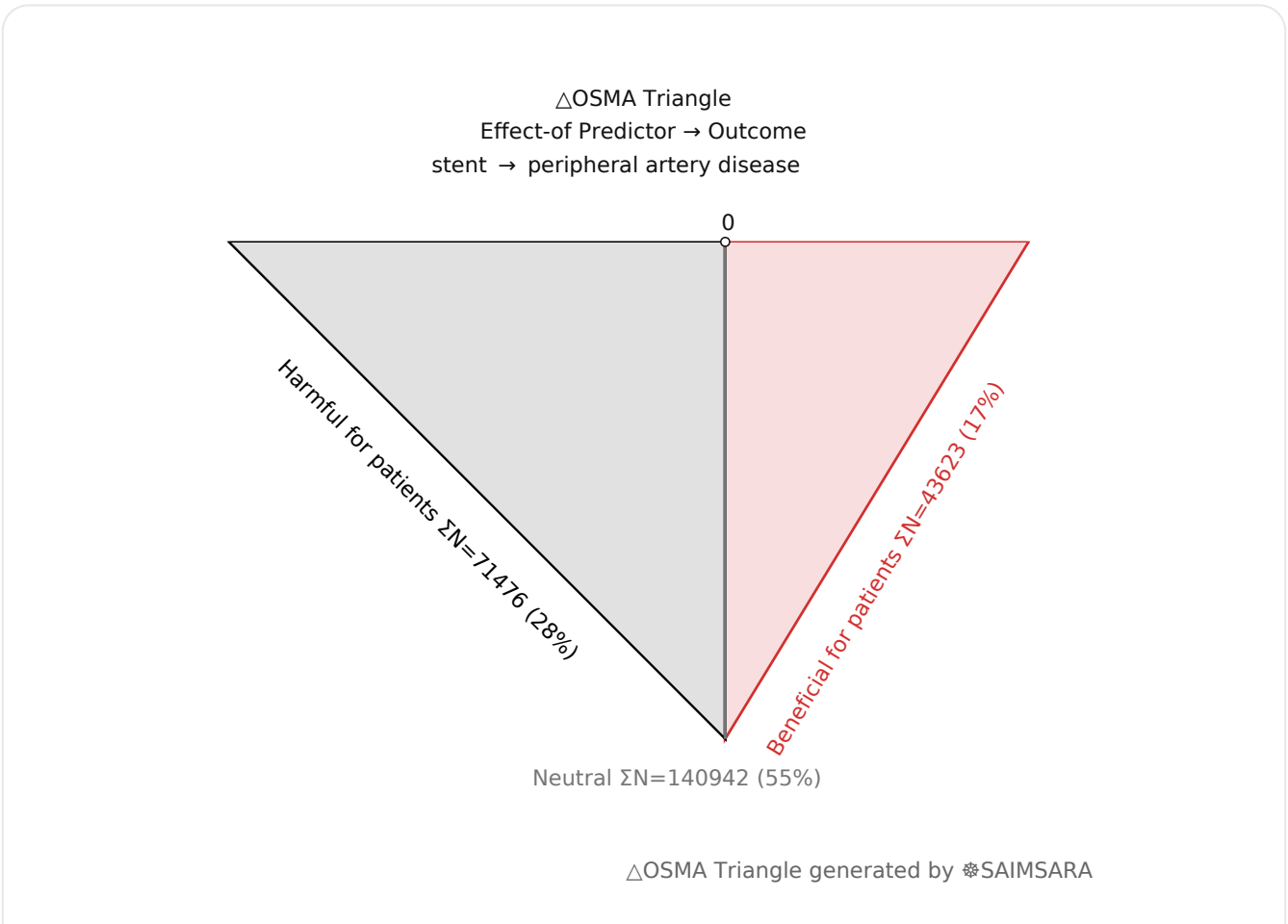
Records excluded:
n=61757
Screening
Records assessed for eligibility
n=1000
Records excluded:
n=832
Included
Studies included in review
n=168
PRISMA Diagram generated by ☸ SAIMSARA


△OSMA Triangle
Effect-of Predictor → Outcome
stent → peripheral artery disease
0
Harmful for patients ΣN=71476 (28%)
Beneficial for patients ΣN=43623 (17%)
Neutral ΣN=140942 (55%)
△OSMA Triangle generated by ☸SAIMSARA

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

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

Outcome: peripheral artery disease Typical timepoints: 12-mo, 24-mo. Reported metrics: %, CI, p.

Common endpoints: Common endpoints: patency, restenosis, mortality.

Predictor: stent — procedure/intervention. Typical comparator: bare metal stents, non-stent interventions but, stent grafts in peripheral, those who did not receive ivus....

- **1) Beneficial for patients** — peripheral artery disease with stent — [1], [3], [10], [22], [23], [27], [28], [30], [31], [34], [38], [40], [41], [43], [44], [46], [47], [48], [49], [54], [55], [58], [61], [62], [64], [69], [70], [75], [76], [80], [83], [84], [87], [88], [90], [91], [92], [93], [97], [98], [99], [104], [106], [110], [111], [115], [116], [118], [121], [122], [123], [124], [159], [160] — ΣN=43623
- **2) Harmful for patients** — peripheral artery disease with stent — [12], [19], [26], [29], [33], [35], [39], [42], [45], [50], [51], [52], [73], [74], [77], [78], [94], [100], [101], [105], [107], [125], [155], [156], [164], [165], [167] — ΣN=71476
- **3) No clear effect** — peripheral artery disease with stent — [2], [4], [5], [6], [7], [8], [9], [11], [13], [14], [15], [16], [17], [18], [20], [21], [24], [25], [32], [36], [37], [53], [56], [57], [59], [60], [63], [65], [66], [67], [68], [71], [72], [79], [81], [82], [85], [86], [89], [95], [96], [102], [103], [108], [109], [112], [113], [114], [117], [119], [120], [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], [157], [158], [161], [162], [163], [166], [168] — ΣN=140942

1) Introduction

Peripheral artery disease (PAD) represents a significant global health burden, characterized by atherosclerotic narrowing of non-coronary arteries, most commonly affecting the lower extremities. Symptomatic PAD often manifests as claudication or critical limb ischemia (CLI), necessitating revascularization to improve blood flow, alleviate symptoms, and prevent limb loss. Endovascular interventions, particularly stent implantation, have become a cornerstone of PAD management, offering a less invasive alternative to open surgical bypass. Stents mechanically support the vessel lumen, aiming to restore patency and reduce the incidence of restenosis. However, the landscape of stent technology is continuously evolving, with various stent types (e.g., bare metal stents (BMS), drug-eluting stents (DES), covered stents, bioresorbable scaffolds) and adjunctive therapies being developed and evaluated. This paper synthesizes current evidence on the efficacy, safety, and

associated factors of stent-based interventions for PAD, drawing upon a comprehensive structured extraction of recent literature.

2) Aim

This paper aims to systematically review the current evidence regarding the use of stents in peripheral artery disease, focusing on their efficacy, safety, and the factors influencing outcomes, to identify clinical implications and future research directions.

3) 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. Randomized controlled trials (RCTs) offer the highest level of evidence, while retrospective cohort studies and single-center experiences are prone to selection and reporting biases. Animal models provide mechanistic insights but have limited direct clinical applicability.

4) Results

4.1 Study characteristics

The included literature comprises a diverse range of study designs, predominantly retrospective and prospective cohort studies, with several randomized controlled trials (RCTs) and experimental animal models. Populations primarily consisted of patients with symptomatic peripheral artery disease, often involving femoropopliteal, aortoiliac, and infrapopliteal arterial segments, with some studies focusing on specific subgroups such as diabetics or those with calcified lesions. Follow-up periods varied widely, ranging from short-term (e.g., 30 days) to extended durations (up to 7 years), with 12-month and 24-month outcomes commonly reported for patency and reintervention rates.

4.2 Main numerical result aligned to the query

The median 12-month primary patency rate for various stent types in peripheral artery disease was 85.6%, ranging from 73.1% to 100% [1, 34, 70, 93, 99, 103, 110, 111, 126]. For instance, one RCT reported 12-month primary patency for DES at 83.2% compared to 74.3% for BMS ($P<0.01$) [1]. Another study found 12-month primary patency rates of 84.9% for Zilver PTX and 88.1% for Eluvia stents [103].

4.3 Topic synthesis

- **Stent Efficacy and Patency Rates:** Drug-eluting stents (DES) consistently demonstrate superior primary patency compared to bare metal stents (BMS), with 1-year primary patency

rates of 83.2% for DES versus 74.3% for BMS in femoropopliteal disease [1]. DES also showed significantly longer patency (373 days longer on average) than drug-coated balloons (DCB) in patients requiring target lesion reintervention [3]. For infrapopliteal arteries, DES improved primary patency (Odds Ratio (OR) 3.49) and reduced major amputation rates (OR 0.56) [123]. Specific stent designs like the Supera interwoven nitinol stent exhibited 69.5% primary patency at 36 months [28], while kissing-stenting for aortoiliac lesions achieved 87.3% 1-year primary patency [34].

- **Mechanisms and Predictors of Restenosis/Thrombosis:** In-stent restenosis (ISR) is primarily driven by smooth muscle cell (SMC) hyperplasia [17]. Biomarkers such as down-regulated MiR-140-3p [5], elevated tissue factor (TF) and fibrinogen [24], and higher platelet-to-lymphocyte ratio (PLR) and neutrophil-to-lymphocyte ratio (NLR) [42] are associated with restenosis. Increased platelet reactivity (18.5% incidence) was predictive of subacute graft/stent thrombosis [39], and a C-reactive protein/albumin ratio (CAR) > 0.29 predicted ISR with 97.5% sensitivity [94].
- **Procedural Guidance and Adjunctive Techniques:** Intravascular ultrasound (IVUS) use in aortoiliac stenting did not significantly impact 12-month restenosis rates [14, 67], but it was associated with more nominally deployed stents and lower reintervention rates [22], and improved patency outcomes when combined with new endovascular technologies [25]. Intravascular lithotripsy (IVL) for calcified lesions showed significant stenosis reduction and low complication rates, with bailout stenting necessary in 12.5% of lesions [83, 116, 118]. Robotic-assisted peripheral vascular intervention is feasible, reducing operator radiation exposure by 96.9% [79].
- **Stent Technology and Design Evolution:** Novel biodegradable paclitaxel-eluting stents show promising patency results in porcine models [10]. Self-expanding bioresorbable stents demonstrated efficient delivery, accelerated resorption, and low luminal loss (<25% at 180 days) in animal models [27]. Supera interwoven nitinol stents were associated with a reduced risk of 1-year repeat target limb revascularization compared to bare nitinol stents [54]. Stent design parameters can be optimized to minimize cross-sectional pinching in femoropopliteal arteries during limb flexion [113].
- **Safety, Complications, and Patient-Specific Factors:** All-cause mortality rates varied, with DES showing 2.7% versus BMS 1.1% at 12 months (P=0.15) [1]. Stent-based interventions incurred higher procedural costs ($6215) compared to non-stent interventions ($4790) [4]. Malnutrition was an independent predictor of major adverse limb events [12]. While some studies found no increased mortality risk with paclitaxel-coated devices over 5 years [48, 60, 71, 104, 112], systematic reviews raised concerns about an increased risk of late death [136, 137]. Distal embolization occurred in 0.9% of endovascular revascularization interventions, more frequently with femoropopliteal stenting [142].

- **Long-Term Durability and Anatomical Considerations:** The Zilver PTX Drug-Eluting Stent demonstrated long-term effectiveness for femoropopliteal PAD [7]. Kissing-stenting achieved 7-year primary patency of 65.0% [34]. For common femoral artery (CFA) lesions, Supera stents showed 100% primary patency at 12 months [99]. In complex TASC II D femoropopliteal lesions, 3-year primary patency was 52% [151]. Institutional volume was associated with a significantly lower 12-month restenosis rate (6.5% vs 15.8%) after aortoiliac stenting [75].

5) Discussion

5.1 Principal finding

The median 12-month primary patency rate for various stent types in peripheral artery disease was 85.6%, ranging from 73.1% to 100% [1, 34, 70, 93, 99, 103, 110, 111, 126], indicating generally favorable short-to-mid-term outcomes for stent-based interventions.

5.2 Clinical implications

- **Stent Selection:** Drug-eluting stents (DES) are generally favored over bare metal stents (BMS) for superior patency in femoropopliteal lesions [1], and bailout stenting may offer better reintervention rates than drug-eluting balloons (DCB) in some cases [110].
- **Antiplatelet Management:** Patients undergoing stenting require careful consideration of antiplatelet therapy, as impaired responsiveness to clopidogrel and aspirin is linked to stent thrombosis [16], and increased platelet reactivity predicts subacute thrombosis [39].
- **Advanced Imaging Utilization:** Intravascular ultrasound (IVUS) can improve stent deployment and reduce reintervention rates [22], suggesting its utility in optimizing procedural success, especially when assessing reference vessel diameter [119].
- **Patient Risk Stratification:** Factors like malnutrition [12], specific inflammatory markers [94], and low mean corpuscular volume [107] can predict adverse limb events and restenosis, necessitating personalized risk assessment and follow-up.
- **Adjunctive Therapies:** Cilostazol treatment following DES implantation can reduce restenosis [8], and intensive exercise significantly improves bare nitinol stent patency [40], highlighting the importance of comprehensive post-procedural care.

5.3 Research implications / key gaps

- **Long-Term Paclitaxel Safety:** Definitive, large-scale randomized controlled trials with extended follow-up are needed to resolve conflicting evidence regarding the long-term all-

cause mortality risk associated with paclitaxel-coated devices [48, 136].

- **Optimal Antiplatelet Regimens:** Future studies should compare the efficacy and safety of different durations and types of dual antiplatelet therapy (DAPT) after peripheral stenting to establish optimal guidelines [109, 114].
- **Comparative Intervention Efficacy:** Research is needed to rigorously compare outcomes of combined atherectomy and stenting versus stenting alone, particularly in complex lesion morphologies [2, 121].
- **Biomarker-Guided Therapy:** Prospective studies are warranted to validate the clinical utility of emerging biomarkers (e.g., CAR, PLR, HBDH) for predicting restenosis and thrombosis, enabling personalized treatment strategies [94, 42, 129].
- **Novel Stent Technologies:** Further rigorous human trials are required to evaluate the safety and long-term efficacy of innovative stent designs, such as bioresorbable and biodegradable stents, in diverse patient populations and lesion types [27, 21].

5.4 Limitations

- **Heterogeneity of Stent Types** — The review encompasses a wide variety of stent designs, materials, and drug coatings, making direct comparisons and generalizations challenging.
- **Varied Lesion Characteristics** — Studies often included diverse lesion lengths, calcification levels, and anatomical locations (femoropopliteal, aortoiliac, infrapopliteal), which significantly influence outcomes.
- **Inconsistent Follow-up Durations** — Follow-up periods ranged from short-term (30 days) to long-term (7 years), limiting the ability to draw consistent conclusions on long-term durability and safety.
- **Methodological Diversity** — The included studies comprise RCTs, retrospective cohorts, and animal models, leading to varying levels of evidence quality and potential for bias.
- **Limited Direct Comparisons** — While some studies directly compare stent types, many evaluate single technologies, hindering comprehensive comparative effectiveness assessments.

5.5 Future directions

- **Standardized Reporting Outcomes** — Implement uniform reporting of patency, reintervention, and safety endpoints across studies to facilitate meta-analysis.

- **Long-Term Paclitaxel Safety** — Conduct large-scale, long-term randomized controlled trials to definitively assess the all-cause mortality risk associated with paclitaxel-coated devices.
- **Biomarker-Guided Therapy** — Develop and validate predictive biomarkers (e.g., CAR, PLR, HBDH) for restenosis and thrombosis to personalize antiplatelet and follow-up strategies.
- **Novel Stent Technology Trials** — Evaluate emerging biodegradable and bioresorbable stent designs in rigorous human clinical trials with extended follow-up periods.
- **Comparative Intervention Studies** — Design RCTs comparing atherectomy plus stenting versus stenting alone, or different stent types in specific complex lesion subsets.

6) Conclusion

The median 12-month primary patency rate for various stent types in peripheral artery disease was 85.6%, ranging from 73.1% to 100% [1, 34, 70, 93, 99, 103, 110, 111, 126], indicating that stent-based interventions are generally effective for revascularization in symptomatic peripheral artery disease, particularly in femoropopliteal and aortoiliac segments. However, the heterogeneity of stent types, lesion characteristics, and follow-up durations across studies represents the most significant limitation to drawing definitive conclusions. Clinicians should consider drug-eluting stents for superior patency in appropriate lesions, while future research must prioritize large-scale, long-term randomized controlled trials to definitively assess the safety of paclitaxel-coated devices and optimize antiplatelet regimens.

References

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Figure 1. Publication-year distribution of included originals

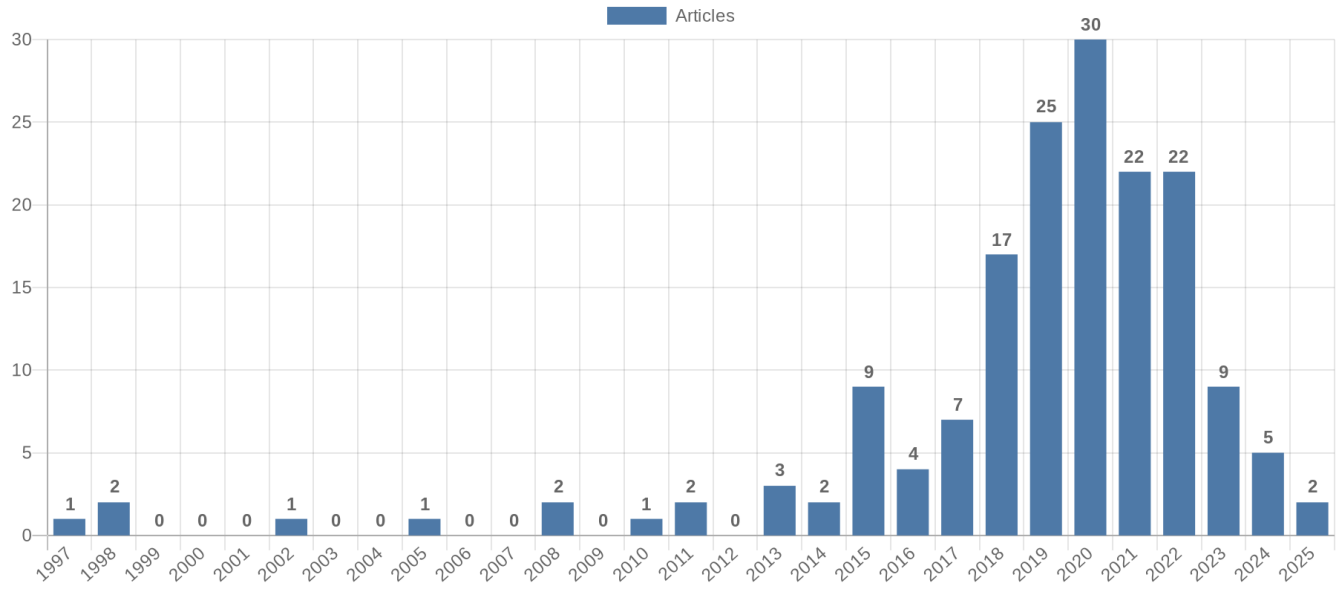

Figure 2. Study-design distribution of included originals

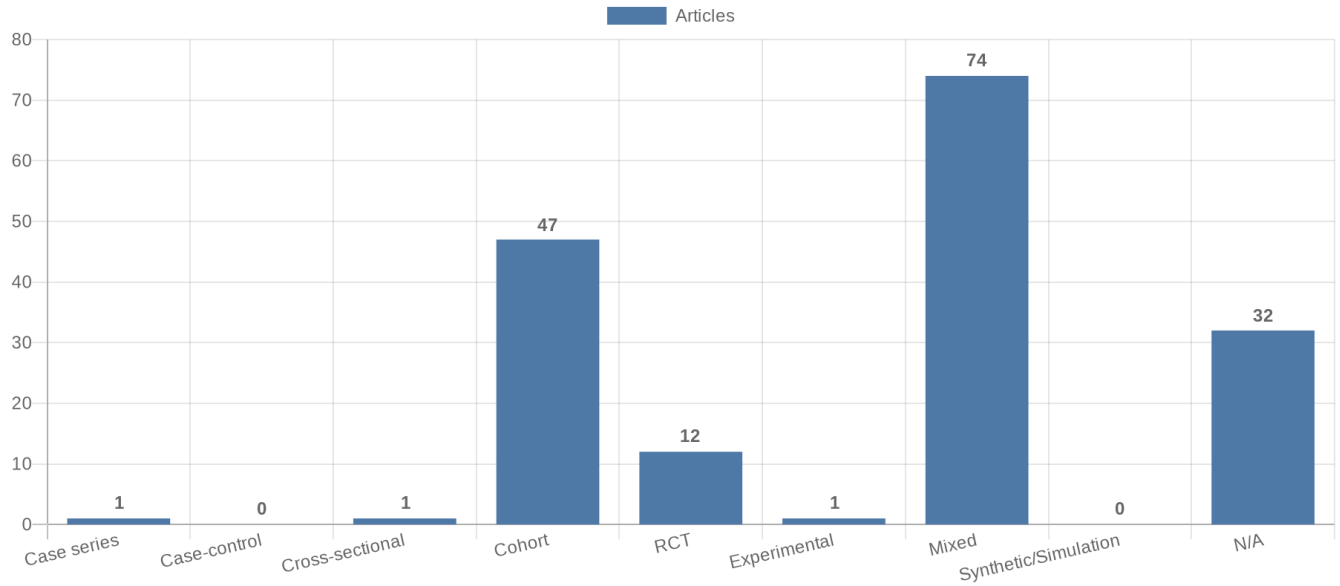

Figure 3. Study-type (directionality) distribution of included originals

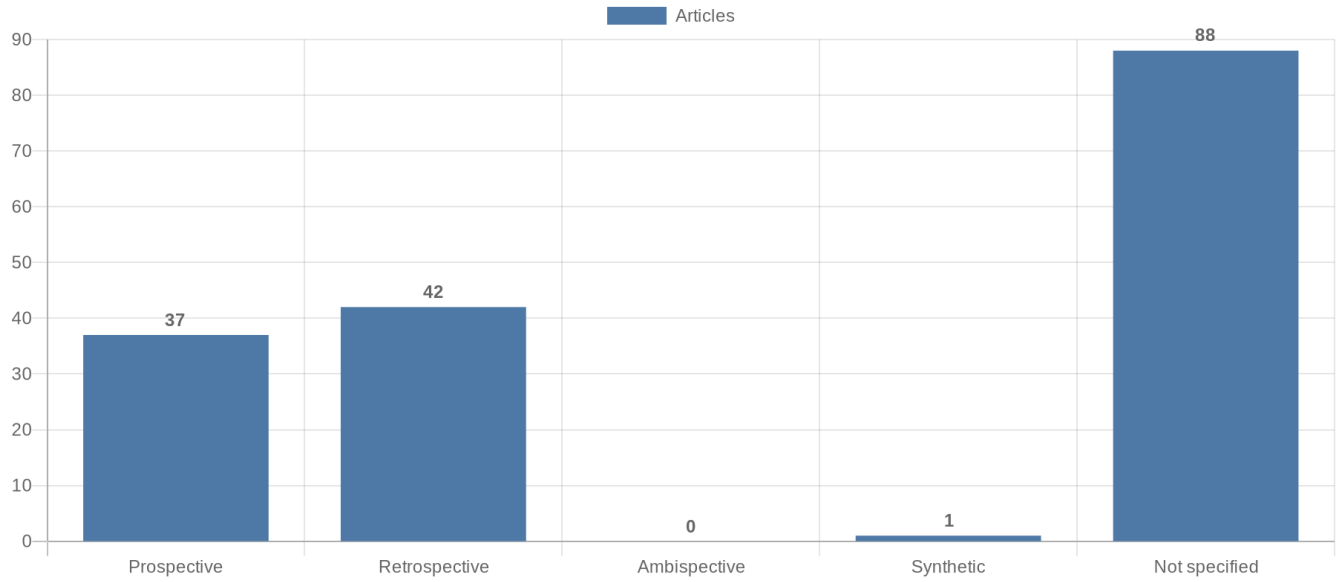

Figure 4. Main extracted research topics

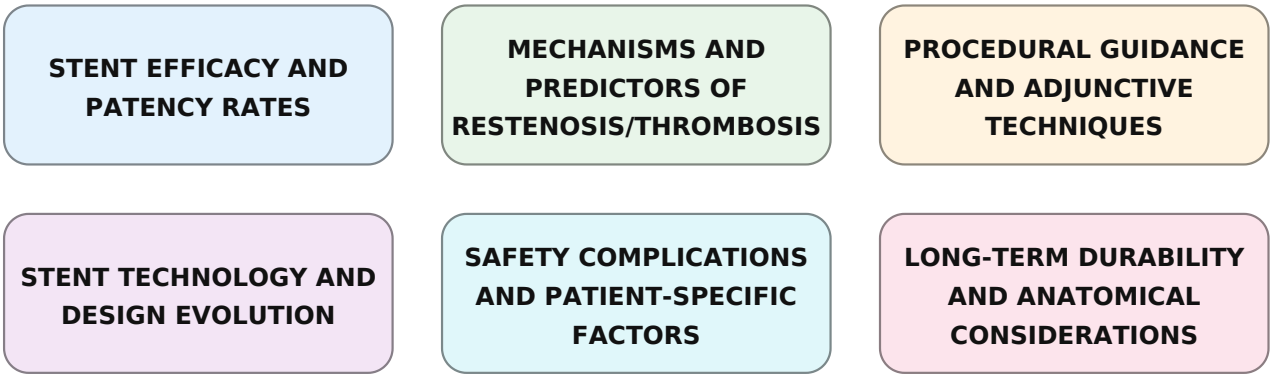

Figure 5. Limitations of current studies (topics)

Figure 6. Future research directions (topics)