Drug Coated Balloon: Systematic Review with ☸SAIMSARA.

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Abstract: The aim of this paper is to systematically review and synthesize the current evidence regarding the clinical performance, applications, and emerging trends of drug-coated balloons across diverse patient populations and anatomical sites. The review utilises 361 studies with 108502 total participants (naïve ΣN). The median target lesion failure (TLF) or target lesion revascularization (TLR) rate for drug-coated balloon (DCB) treatment was 6.2%, with a range from 1.1% to 16.4%. This indicates generally favorable outcomes for DCBs in a wide array of vascular and non-vascular applications, from coronary and peripheral artery disease to urethral strictures. However, the heterogeneity in study designs and outcome definitions across the literature is the single limitation that most affects certainty. Future research should prioritize head-to-head randomized controlled trials comparing different DCB drug types and optimizing adjunctive therapies to further refine clinical guidelines.

Keywords: Drug-coated balloon; Coronary artery disease; Urethral stricture disease; Femoropopliteal artery disease; In-stent restenosis; Percutaneous coronary intervention; Paclitaxel-coated balloon; Dual antiplatelet therapy; Chronic total occlusions; Intravascular ultrasound

Review Stats

- Generated: 2026-02-11 14:54:53 CET
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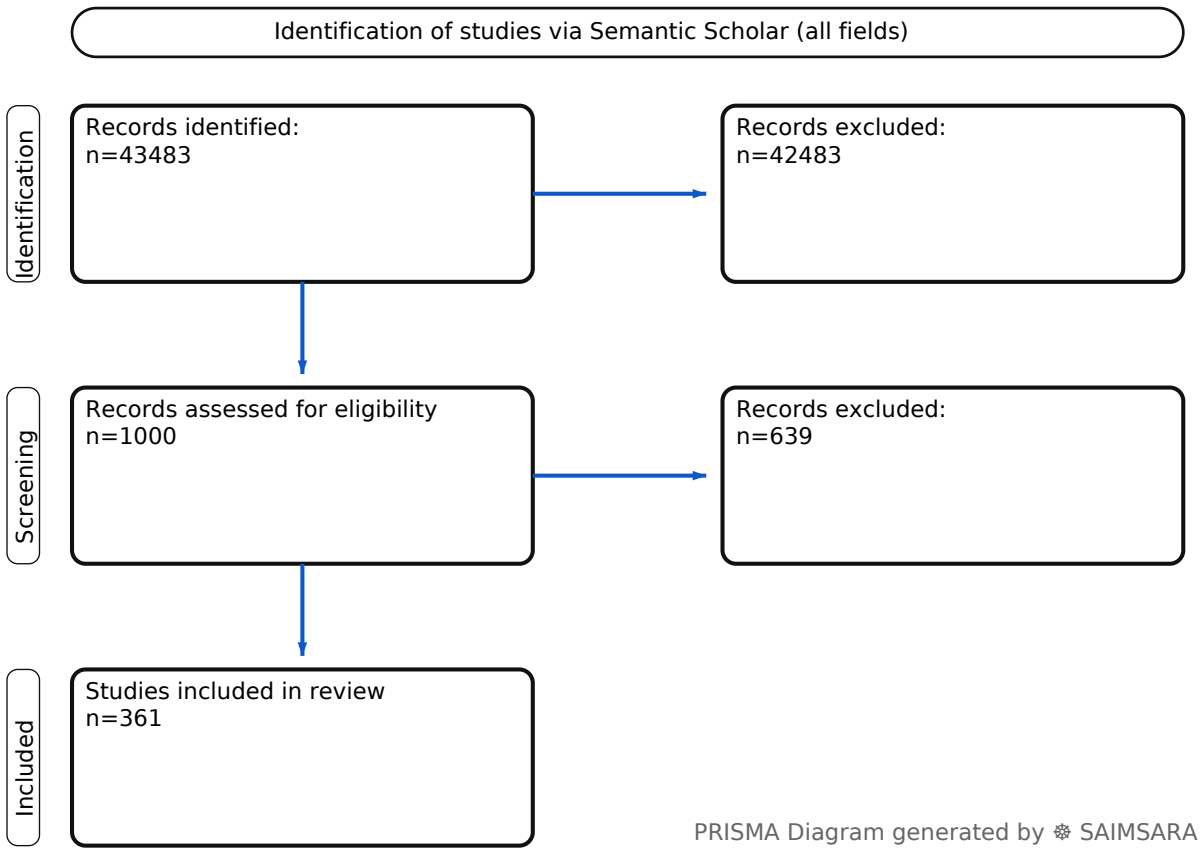
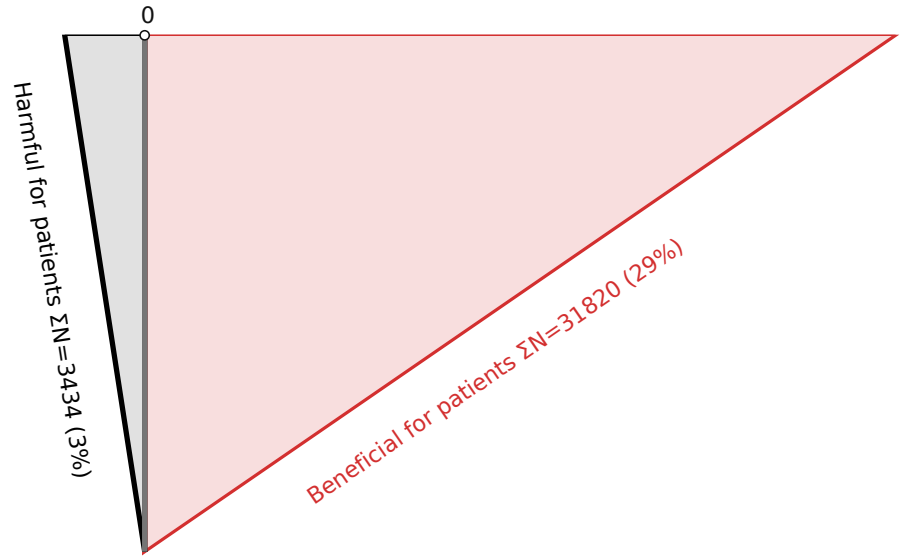
- Source: Semantic Scholar
- Scope: All fields
- Keyword Gate: Fuzzy (≥60% of required terms, minimum 2 terms matched in title/abstract)
- Total Abstracts/Papers: 43483
- Downloaded Abstracts/Papers: 1000
- Included original Abstracts/Papers: 361
- Total study participants (naïve ΣN): 108502



PRISMA Diagram generated by ☸ SAIMSARA

△OSMA Triangle
Effect-of Predictor → Outcome
drug coated balloon → Outcome



Neutral ΣN=73248 (68%)

△OSMA Triangle generated by ☸SAIMSARA

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

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

Outcome: Outcome Typical timepoints: 12-mo, 1-y. Reported metrics: %, CI, p.

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

Predictor: drug coated balloon — exposure/predictor. Typical comparator: those without a history of, angiography-guided angioplasty, plain balloon, des-only pci….

- **1) Beneficial for patients** — Outcome with drug coated balloon — [1], [3], [4], [5], [7], [8], [10], [11], [13], [15], [16], [17], [18], [19], [21], [22], [23], [25], [29], [31], [32], [34], [35], [36], [37], [38], [41], [42], [43], [44], [45], [46], [47], [52], [54], [56], [59], [60], [61], [67], [68], [69], [71], [72], [73], [74], [75], [76], [77], [80], [83], [84], [85], [86], [90], [93], [94], [97], [99], [100], [174], [181], [183], [184], [185], [187], [188], [189], [190], [196], [197], [199], [211], [212], [215], [216], [217], [221], [232], [233], [234], [236], [239], [241], [245], [282], [284], [288], [291], [296], [298], [299], [300], [303], [306], [309], [310], [312], [315], [316], [318], [319], [320], [321], [322], [326], [341], [345], [346], [348], [350] — ΣN=31820
- **2) Harmful for patients** — Outcome with drug coated balloon — [9], [48], [50], [51], [78], [81], [88], [154], [180], [182], [206], [248], [301] — ΣN=3434
- **3) No clear effect** — Outcome with drug coated balloon — [2], [6], [12], [14], [20], [24], [26], [27], [28], [30], [33], [39], [40], [49], [53], [55], [57], [58], [62], [63], [64], [65], [66], [70], [79], [82], [87], [89], [91], [92], [95], [96], [98], [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], [155], [156], [157], [158], [159], [160], [161], [162], [163], [164], [165], [166], [167], [168], [169], [170], [171], [172], [173], [175], [176], [177], [178], [179], [186], [191], [192], [193], [194], [195], [198], [200], [201], [202], [203], [204], [205], [207], [208], [209], [210], [213], [214], [218], [219], [220], [222], [223], [224], [225], [226], [227], [228], [229], [230], [231], [235], [237], [238], [240], [242], [243], [244], [246], [247], [249], [250], [251], [252], [253], [254], [255], [256], [257], [258], [259], [260], [261], [262], [263], [264], [265], [266], [267], [268], [269], [270], [271], [272], [273], [274], [275], [276], [277], [278], [279], [280], [281], [283], [285], [286], [287], [289], [290], [292], [293], [294], [295], [297], [302], [304], [305], [307], [308], [311], [313], [314], [317], [323], [324], [325], [327], [328], [329], [330], [331], [332], [333], [334], [335], [336], [337], [338], [339], [340], [342], [343], [344], [347], [349], [351], [352], [353], [354], [355], [356], [357], [358], [359], [360], [361] — ΣN=73248

1) Introduction

Drug-coated balloons (DCBs) represent a significant advancement in interventional medicine, offering a stent-free approach to deliver antiproliferative agents directly to the vessel wall, thereby mitigating restenosis. This technology has expanded its application across various vascular beds and anatomical locations, including coronary, peripheral, and even non-vascular strictures. The primary objective of DCB therapy is to improve long-term patency and reduce the need for repeat revascularization procedures by locally inhibiting neointimal hyperplasia, a common cause of treatment failure. This paper synthesizes recent findings on the efficacy, safety, and optimal application strategies of DCBs, drawing from a comprehensive body of clinical trials and real-world studies.

2) Aim

The aim of this paper is to systematically review and synthesize the current evidence regarding the clinical performance, applications, and emerging trends of drug-coated balloons across diverse patient populations and anatomical sites.

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) and prospective cohort studies generally offer higher certainty, while retrospective studies and mixed designs may introduce selection or reporting biases. Studies with larger sample sizes and longer follow-up periods provide more robust evidence. Preclinical studies, case series, and registry analyses offer early insights but have inherent limitations in generalizability and definitive conclusions.

4) Results

4.1 Study characteristics: The included studies predominantly comprise prospective randomized controlled trials (RCTs), prospective and retrospective cohort studies, and mixed-design analyses. Populations spanned adults (18-80 years) with acute coronary syndrome (ACS) [1], de novo coronary artery disease (CAD) [3, 6, 9], in-stent restenosis (ISR) in coronary [7, 23, 154] and peripheral arteries [61, 72], femoropopliteal (FP) artery disease [4, 17, 31], infrapopliteal lesions [53, 67], various bifurcation lesions [12, 14, 32], urethral strictures [2, 5, 10], and arteriovenous (AV) fistulas for hemodialysis [69, 99]. Follow-up periods ranged from a few months (e.g., 3.5 months for urethral

strictures [2]) to 10 years for coronary ISR [7], with many studies reporting 12-month, 2-year, or 5-year outcomes.

4.2 Main numerical result aligned to the query: The median target lesion failure (TLF) or target lesion revascularization (TLR) rate for drug-coated balloon (DCB) treatment was 6.2% across various vascular beds and indications. The rates ranged from 1.1% [76] to 16.4% [89]. This metric, while broadly reported, exhibits heterogeneity in specific definitions and follow-up durations across studies.

4.3 Topic synthesis:

- **Coronary Artery Disease (CAD) and De Novo Lesions:** DCB-only strategies are safe and effective for de novo lesions, including large vessels [26, 82, 118, 161] and small vessels [56, 170, 172, 183, 187, 307, 308, 314, 319], showing comparable efficacy to drug-eluting stents (DES) [172, 175, 304, 313, 315, 316]. Specific predictors for successful angiographic outcomes include maximal post-DCB minimal luminal diameter (MLD) and optimal balloon-to-artery ratio [3].
- **In-Stent Restenosis (ISR):** DCBs are highly effective for coronary ISR, significantly reducing TLR and improving patency compared to plain balloon (PB) angioplasty [7, 23, 154, 208, 237, 272, 355]. For femoropopliteal ISR, DCBs also demonstrate superior patency and reduced revascularization rates [61, 72, 119, 211, 218].
- **Peripheral Artery Disease (PAD) and Femoropopliteal (FP) Lesions:** DCBs consistently show superior primary patency and lower clinically driven target lesion revascularization (CD-TLR) rates compared to plain balloon angioplasty (PTA) [31, 60, 68, 74, 84, 94, 100, 212, 216, 221, 245]. Long-term durability up to 5 years has been demonstrated [47, 54, 345]. However, some studies suggest that high-dose DCBs may offer better outcomes than low-dose DCBs for restenosis lesions [22, 309].
- **Urethral Strictures:** Optilume paclitaxel-coated balloons show sustained improvement in voiding parameters and high early success rates for male anterior urethral strictures, including those with prior urethroplasty [2, 5, 10, 29, 41, 46, 73, 75]. Functional success rates range from 58% at 5 years [5] to 90.7% not requiring repeat intervention at 9 months [10].
- **Arteriovenous (AV) Fistulas and Dialysis Access:** DCBs improve primary patency and reduce reintervention rates for dysfunctional AV fistulas and grafts compared to conventional angioplasty [99, 105, 107, 188, 189, 233, 300]. However, some studies report conflicting results or worse outcomes compared to standard balloon angioplasty [69, 180, 210, 361].
- **Intracranial Atherosclerotic Stenosis (ICAS):** DCB angioplasty effectively reduces restenosis incidence compared to conventional balloon angioplasty for symptomatic ICAS

[15, 71, 358], with low complication rates and good clinical outcomes for non-acute occlusions [42, 43, 111, 326].

- **Complex Lesions and Adjunctive Therapies:**
- **Calcified Lesions:** DCB treatment is safe and effective for severe coronary artery calcification (CAC) often combined with rotational atherectomy (RA) [20, 89, 91, 109, 116, 294]. Intravascular lithotripsy (IVL) combined with DCB also shows promising outcomes for calcified femoropopliteal [19, 25, 350] and infrapopliteal lesions [27].
- **Bifurcation Lesions:** DCB-only or hybrid strategies (DES in main branch, DCB in side branch) are being explored for coronary bifurcation lesions, including left main (LM) bifurcations [12, 14, 30, 32, 34, 39, 57, 64, 153, 174, 296, 257].
- **Guidance and Preparation:** Intravascular ultrasound (IVUS)-guided DCB angioplasty significantly improves primary patency and clinical outcomes for femoropopliteal artery disease [4]. Optimal vessel preparation, including aggressive lesion predilation [3, 66, 277], scoring balloons [76, 132, 277], directional atherectomy (DA) [59, 62, 95, 207], or super slow inflation (SSI) [199], is crucial.
- **Drug Types and Delivery:** Paclitaxel-coated balloons (PCBs) are widely studied [1, 7, 154, 208]. Sirolimus-coated balloons (SCBs) are emerging as effective alternatives, showing non-inferiority to paclitaxel [171, 176, 177, 198, 204, 209, 269, 279, 285, 321, 342, 346, 348]. Novel coatings incorporating gefitinib [322], everolimus [185], resveratrol [181, 224], microRNA-22 [280], plasmid DNA [293], or nanomotors [203, 231] are under preclinical investigation to improve drug retention and delivery.
- **Specific Patient Populations:** DCBs are evaluated in high-risk patients [55, 168], those with diabetes mellitus (DM) [13, 35, 50, 176, 305], chronic kidney disease (CKD) [187], and acute coronary syndrome (ACS) [1, 175, 196, 275, 308, 310, 315, 316]. While DM patients may have higher TLF/TLR rates [50], DCB-based revascularization can reduce major adverse cardiovascular events (MACE) compared to DES-only PCI in DM patients with multivessel CAD [13, 35].
- **Safety and Mortality:** Large real-world analyses indicate no increased long-term mortality associated with paclitaxel-based drug-coated devices [70, 202, 281, 291, 324, 344]. Major bleeding events may be lower with DCB compared to DES in small coronary arteries [18, 187].

5) Discussion

5.1 Principal finding: The median target lesion failure (TLF) or target lesion revascularization (TLR) rate for drug-coated balloon (DCB) treatment was 6.2%, with a range from 1.1% [76] to 16.4% [89], indicating generally favorable outcomes across various applications.

5.2 Clinical implications:

- **Reduced Stent Burden:** DCBs offer a "stent-less" strategy, reducing the need for permanent implants and potentially lowering associated thrombotic risks in coronary arteries [16, 32, 191, 303, 306].
- **Effective for Restenosis:** DCBs are a highly effective treatment for in-stent restenosis (ISR) in both coronary and peripheral arteries, often outperforming plain balloon angioplasty [7, 61, 119, 154, 272, 355].
- **Improved Patency in PAD:** In peripheral artery disease (PAD), especially femoropopliteal lesions, DCBs consistently demonstrate superior primary patency and lower reintervention rates compared to conventional balloon angioplasty [31, 68, 74, 100, 221, 245].
- **Urological and Neurovascular Applications:** The Optilume DCB provides sustained symptomatic improvement for recurrent urethral strictures [5, 10, 29, 41, 46], while DCBs reduce restenosis in intracranial atherosclerotic stenosis [15, 71, 358].
- **Procedural Optimization:** Achieving maximal post-DCB minimal luminal diameter (MLD) through aggressive predilation and optimal balloon-to-artery ratio is crucial for successful angiographic outcomes [3, 277]. Imaging guidance (e.g., IVUS) can further improve results [4].

5.3 Research implications / key gaps:

- **Long-term Efficacy in Specific Anatomies:** The long-term efficacy of DCB angioplasty for large bifurcation lesions, especially those involving the left main trunk (LMT), remains unclear [12].
- **Sirolimus vs. Paclitaxel DCBs:** Further randomized controlled trials are needed to definitively compare the long-term efficacy and safety of sirolimus-coated balloons (SCBs) versus paclitaxel-coated balloons (PCBs) across various vascular beds [198, 257, 269, 279, 343].
- **Optimal Vessel Preparation:** More research is needed to define the optimal vessel preparation strategies (e.g., atherectomy, lithotripsy, scoring balloons) for different lesion types (e.g., calcified, chronic total occlusions) to maximize DCB efficacy [66, 89, 207].
- **Drug Delivery and Kinetics:** Studies investigating novel coating technologies and drug delivery systems are essential to enhance drug anchoring, retention, and penetration into diseased vessel walls, particularly in calcified lesions [178, 197, 203, 231, 240, 250, 251, 255, 259, 263, 268, 271, 278, 280, 287, 289, 290, 293, 312, 341, 347, 349].
- **DCB in Challenging Populations:** The utility of DCBs in dialysis vascular access remains unsettled due to conflicting results from randomized clinical trials [361]. Further studies are needed to clarify their role in these vulnerable patient groups.

5.4 Limitations:

- **Heterogeneous Study Designs** — The included studies vary widely in design (RCTs, cohorts, mixed), directionality (prospective, retrospective), and sample sizes, limiting direct comparability and meta-analytic pooling.
- **Varied Follow-up Durations** — Follow-up periods range from a few months to 10 years, making it challenging to draw consistent conclusions about long-term durability across all applications.
- **Inconsistent Outcome Definitions** — While "TLR" and "TLF" are common, their precise definitions and composite endpoints can vary, introducing heterogeneity in reported success rates.
- **Lack of Direct Comparisons** — Many studies compare DCBs to uncoated balloons or DES, but head-to-head comparisons between different DCB types (e.g., paclitaxel vs. sirolimus) or different adjunctive therapies are less frequent.
- **Preclinical and Case Report Data** — A portion of the evidence comes from preclinical animal models or single-case reports, which have limited generalizability to human clinical practice.

5.5 Future directions:

- **Sirolimus DCB vs DES** — Conduct large-scale RCTs comparing sirolimus-coated balloons to drug-eluting stents for de novo lesions in large coronary vessels [171].
- **Sirolimus vs Paclitaxel DCB** — Perform multicenter RCTs to assess the non-inferiority of sirolimus-coated balloons to paclitaxel-coated balloons for femoropopliteal artery disease [198].
- **AV Fistula Patency** — Design randomized controlled trials to compare different drug-coated balloon types (paclitaxel, sirolimus) against uncoated balloons for preserving arteriovenous fistula patency [343].
- **Novel Coating Technologies** — Further preclinical and early-phase clinical studies on rapamycin-loaded nanoparticle coatings and other advanced drug delivery systems to improve drug anchoring and retention [341].
- **Vulnerable Plaque Treatment** — Investigate the role of drug-coated balloons in treating vulnerable plaques in ongoing research to understand their impact on plaque stabilization [360].

6) Conclusion

The median target lesion failure (TLF) or target lesion revascularization (TLR) rate for drug-coated

balloon (DCB) treatment was 6.2%, with a range from 1.1% [76] to 16.4% [89]. This indicates generally favorable outcomes for DCBs in a wide array of vascular and non-vascular applications, from coronary and peripheral artery disease to urethral strictures. However, the heterogeneity in study designs and outcome definitions across the literature is the single limitation that most affects certainty. Future research should prioritize head-to-head randomized controlled trials comparing different DCB drug types and optimizing adjunctive therapies to further refine clinical guidelines.

References

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Figure 1. Publication-year distribution of included originals

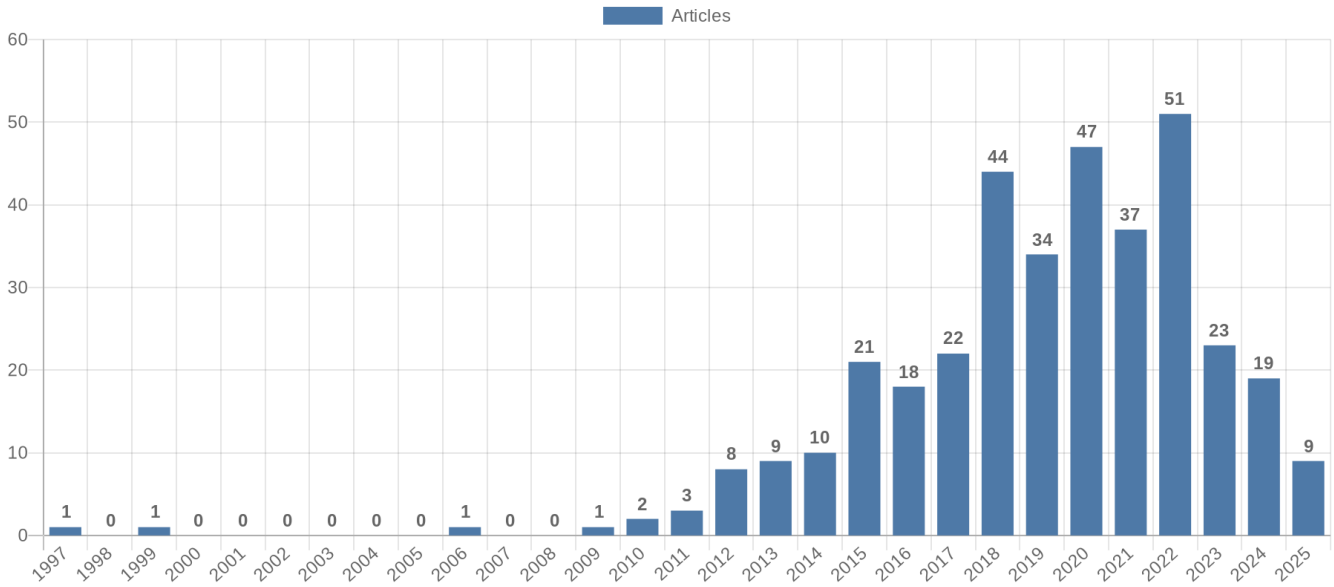

Figure 2. Study-design distribution of included originals

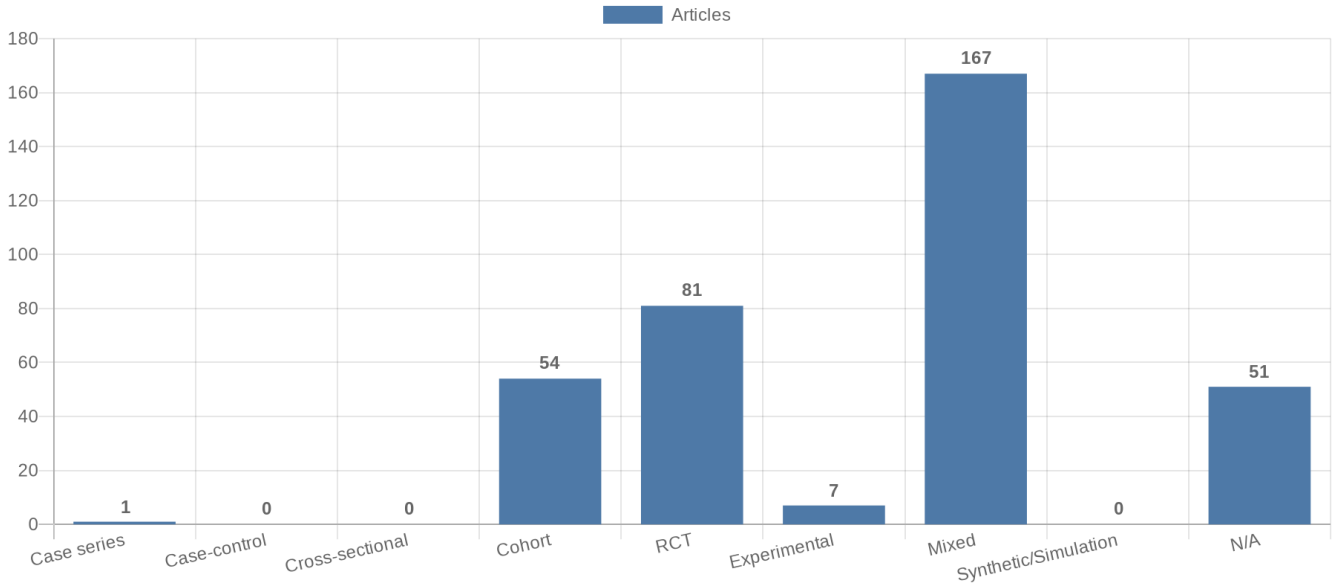

Figure 3. Study-type (directionality) distribution of included originals

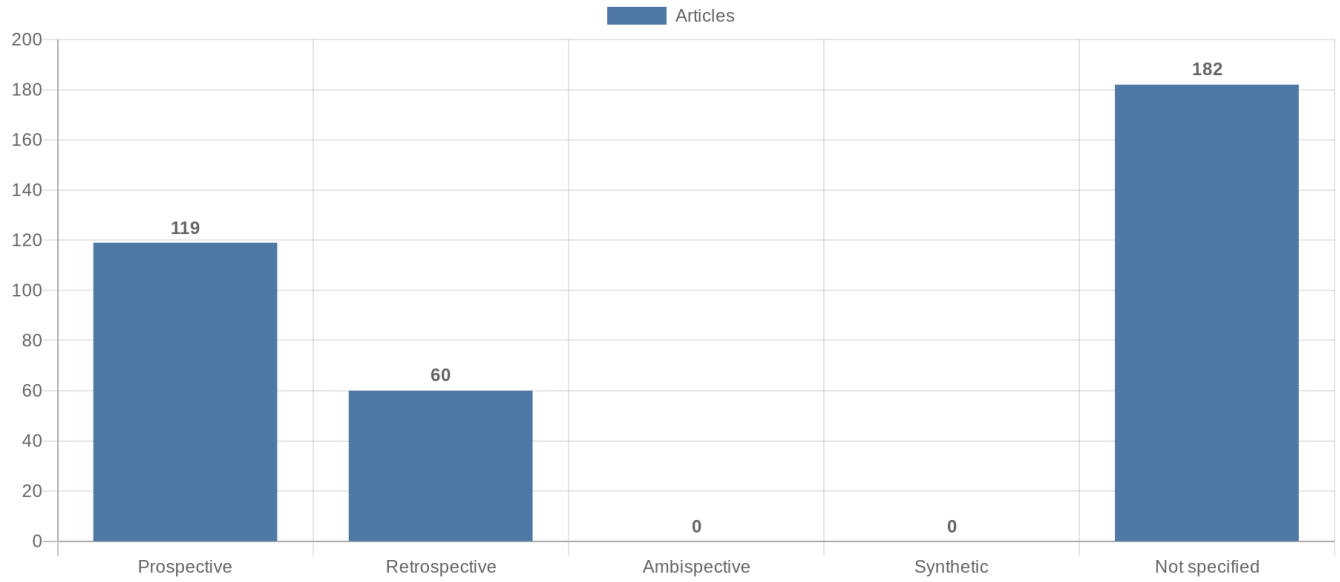

Figure 4. Main extracted research topics

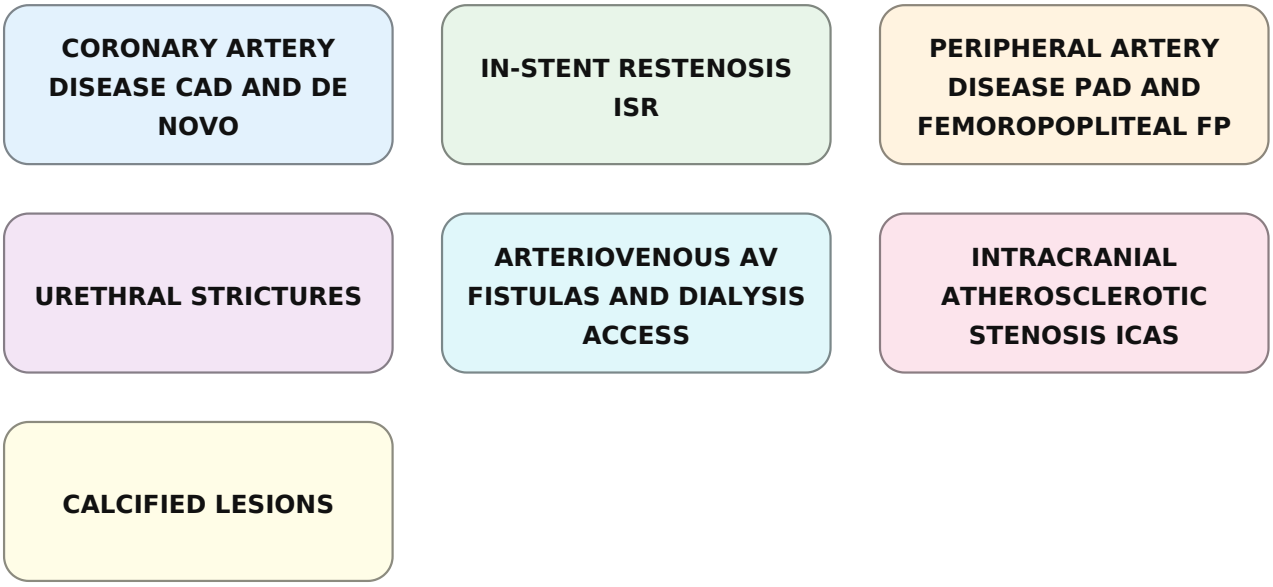

Figure 5. Limitations of current studies (topics)

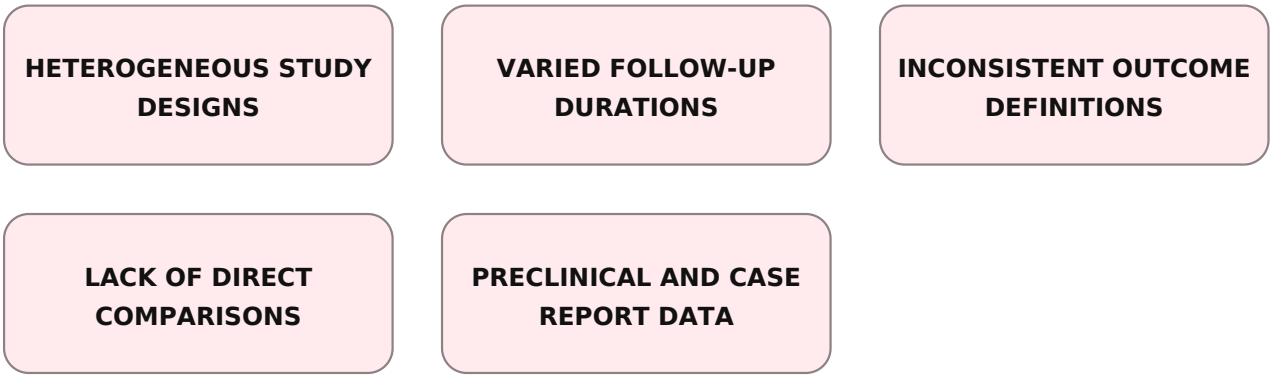

Figure 6. Future research directions (topics)

SIROLIMUS DCB VS DES

SIROLIMUS VS PACLITAXEL DCB

AV FISTULA PATENCY

NOVEL COATING TECHNOLOGIES

VULNERABLE PLAQUE TREATMENT

LONG-TERM EFFICACY IN SPECIFIC ANATOMIES

OPTIMAL VESSEL PREPARATION