Atherectomy" PAD: Systematic Review with ☸SAIMSARA.

Abstract: The aim of this paper is to systematically review and synthesize the available evidence regarding the performance, safety, and clinical outcomes associated with atherectomy procedures in the treatment of peripheral artery disease. The review utilises 76 studies with 23255 total participants (naïve ΣN). Atherectomy procedures in Peripheral Artery Disease consistently achieve high procedural and technical success rates, with a median of 97.3% (range 84-100%). These interventions are widely applicable across various anatomical sites and lesion complexities in PAD patients, including those with calcified lesions and critical limb ischemia. The primary limitation affecting certainty is the heterogeneity in study designs and outcome reporting, which complicates direct comparisons and comprehensive meta-analysis. A crucial next step is to conduct large-scale, randomized controlled trials with standardized outcome measures to definitively establish the long-term comparative effectiveness of different atherectomy modalities and their role in contemporary PAD management.

Keywords: Atherectomy; Peripheral Artery Disease; Endovascular Procedures

Review Stats

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- Source: Semantic Scholar
- Scope: All fields
- Keyword Gate: Fuzzy (≥60% of required terms, minimum 2 terms matched in title/abstract)
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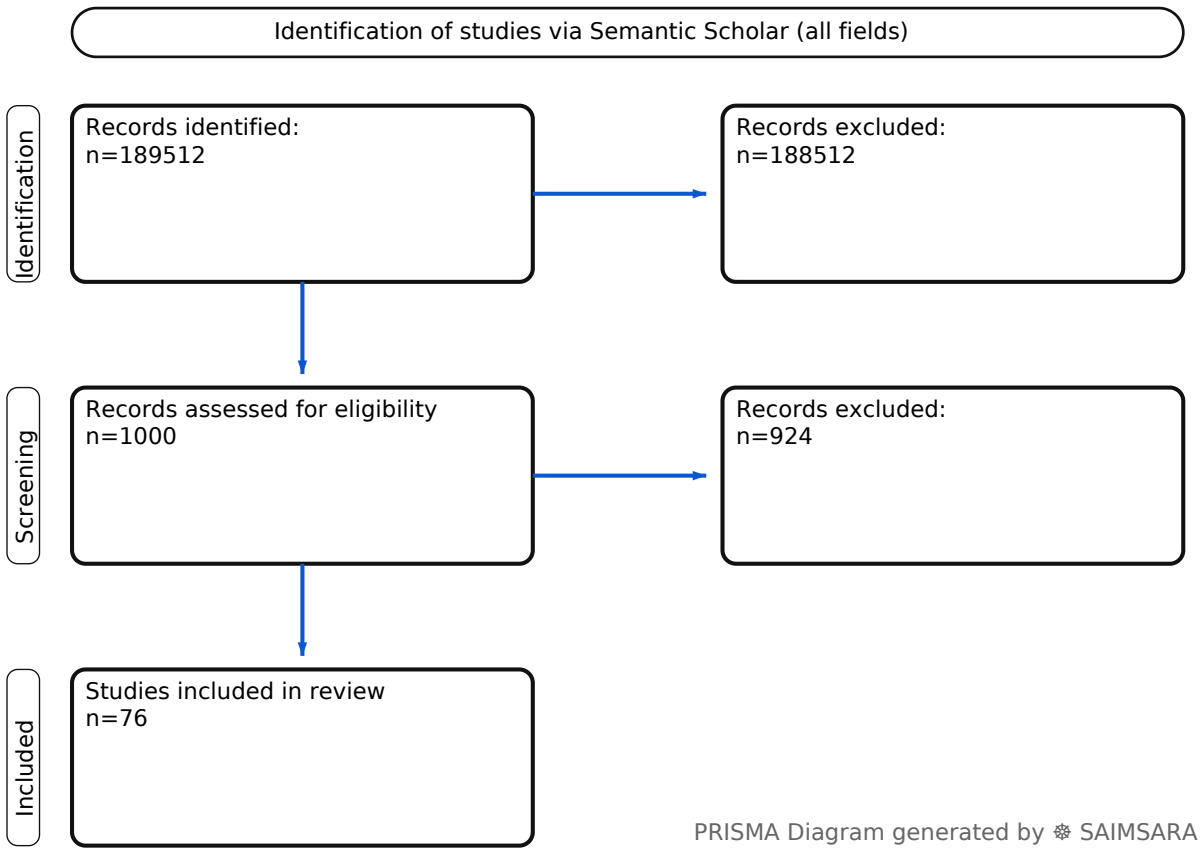
- Included original Abstracts/Papers: 76
- Total study participants (naïve ΣN): 23255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Records excluded:
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Screening
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Records excluded:
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Included
Studies included in review
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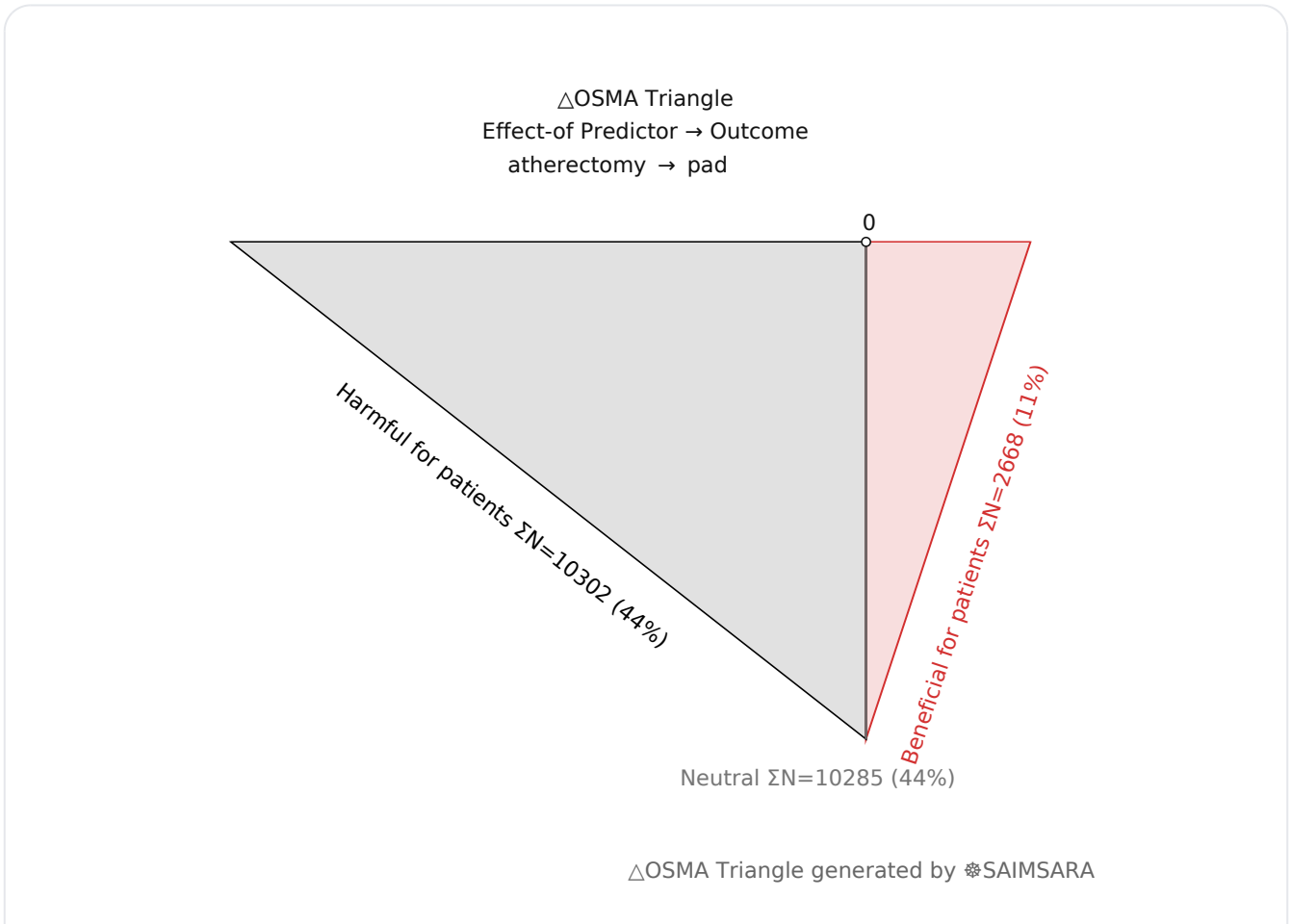
PRISMA Diagram generated by ☸ SAIMSARA


△OSMA Triangle
Effect-of Predictor → Outcome
atherectomy → pad
0
Harmful for patients ΣN=10302 (44%)
Beneficial for patients ΣN=2668 (11%)
Neutral ΣN=10285 (44%)
△OSMA Triangle generated by ☸SAIMSARA

Outcome-Sentiment Meta-Analysis (OSMA): *(LLM-only)*
Frame: Effect-of Predictor → Outcome • *Source*: Semantic Scholar
Outcome: pad Typical timepoints: 1-y, 12-mo. Reported metrics: %, CI, p.
Common endpoints: Common endpoints: complications, patency, mortality.
Predictor: atherectomy — exposure/predictor. Typical comparator: 6.1, dcb-only treatment in patients, 94.5, dcb angioplasty alone….

- **1) Beneficial for patients** — pad with atherectomy — [1], [2], [3], [4], [6], [7], [8], [9], [10], [11], [13], [14], [16], [20], [21], [24], [25], [29], [33], [35], [37], [38], [40], [45], [56], [60], [61], [62], [63], [69], [70], [74] — ΣN=2668
- **2) Harmful for patients** — pad with atherectomy — [15], [19], [32], [41], [48], [50], [76] — ΣN=10302
- **3) No clear effect** — pad with atherectomy — [5], [12], [17], [18], [22], [23], [26], [27], [28], [30], [31], [34], [36], [39], [42], [43], [44], [46], [47], [49], [51], [52], [53], [54], [55], [57], [58], [59], [64], [65], [66], [67], [68], [71], [72], [73], [75] — ΣN=10285

1) Introduction

Peripheral Artery Disease (PAD) represents a significant global health burden, characterized by stenotic or occlusive lesions in the peripheral arteries, often leading to claudication, critical limb ischemia (CLI), and a heightened risk of amputation. Endovascular interventions have revolutionized the management of PAD, with atherectomy emerging as a crucial adjunctive or primary technique for plaque modification and luminal gain. Atherectomy devices, encompassing directional, orbital, rotational, and laser systems, aim to physically remove atherosclerotic plaque, thereby improving vessel patency and facilitating subsequent therapies such as drug-coated balloon (DCB) angioplasty or stenting. This paper synthesizes current evidence on the efficacy and safety of various atherectomy modalities in diverse PAD patient populations and anatomical locations.

2) Aim

The aim of this paper is to systematically review and synthesize the available evidence regarding the performance, safety, and clinical outcomes associated with atherectomy procedures in the treatment of peripheral artery disease.

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. The included studies predominantly comprise retrospective cohort studies and mixed-design studies, alongside some prospective cohorts and randomized controlled trials (RCTs). The prevalence of retrospective designs and varied methodologies across studies introduces potential for selection bias and heterogeneity in outcome reporting. Small sample sizes in several studies further limit generalizability and statistical power, while the absence of specified study designs in many entries makes a comprehensive bias assessment challenging.

4) Results

4.1 Study characteristics:

The included studies predominantly consisted of retrospective and prospective cohort designs, with several mixed-design studies and a few randomized controlled trials. Populations frequently included patients with symptomatic PAD, often with moderate to severely calcified lesions, femoropopliteal (FP) artery disease, or below-the-knee (BTK) pathology. Follow-up periods varied widely, ranging from acute procedural assessment to 2-year and, in some cases, 5-year observations.

4.2 Main numerical result aligned to the query:

Procedural and technical success rates for atherectomy in PAD demonstrated a median of 97.3%, with a range from 84% to 100% across various studies [5, 7, 9, 37, 53, 57, 62, 70]. This indicates a consistently high rate of successful plaque removal and luminal gain during the initial procedure. Heterogeneity exists in the specific definitions of "procedural success" and "technical success" across studies, but the overall trend points to a high immediate efficacy of atherectomy techniques.

4.3 Topic synthesis:

- **Atherectomy Modalities and Efficacy:** Various atherectomy systems (directional, orbital, rotational, laser, BYCROSS™, Phoenix, Jetstream, TurboHawk) are employed, demonstrating significant luminal gain (e.g., minimal lumen area increasing from 0.0 mm^2 to 8.0 mm^2 after atherectomy [3], stenosis reduction from 86.6% to 48.4% [6], average increase of luminal volume by 6% [2], acute gain of 3.4 mm [28]). Laser atherectomy (Auryon system) showed 84% procedural success [7] and 83.7% freedom from target-lesion revascularization (TLR) at 1 year [45].
- **Combination Therapy Outcomes:** Atherectomy combined with drug-coated balloon (DCB) angioplasty consistently shows favorable outcomes, including low bail-out stenting rates (16% [1], 4% [25]), high patency rates (88.2% at 1 year, 74.8% at 2 years [4]; 80.8% at 1 year [60]; significantly higher than DCB-only at 12 and 24 months [8]), and low TLR rates

(26% at 2 years [1], 90.8% freedom from TLR at 1 year [4]). Rotational atherectomy with sirolimus-coated balloons achieved 95% primary patency at 12 months [62].

- **Complication Rates:** Atherectomy generally exhibits low complication rates, including vessel perforation (2% [1], 1.3-2.5% [9], 2.4% [19]), tibial embolism (12% [1]), dissection (3.4% [19]), and device fracture (1.2% [19]). Periprocedural complications for laser atherectomy (LA) were 4.9% and for orbital atherectomy (OA) 6.1% [5].
- **Anatomical Location and Lesion Characteristics:** Atherectomy is effective across various segments, including femoropopliteal (FP) lesions (high patency [4, 8], significant stenosis reduction [3, 6]), common femoral artery (CFA) lesions (83.3% primary patency at 1 year [70]), and below-the-knee (BTK) vessels (feasible with favorable outcomes [29, 35], but increased TLR and MALEs rates in mid-term [32]). It is particularly useful for moderate to severely calcified lesions [2, 5, 6, 17, 22, 28, 59, 66, 71].
- **Patient Subgroups and Risk Factors:** Atherectomy is utilized in diverse patient groups, including those in safety-net hospitals [1], patients with Rutherford class 3-4 PAD [5], and those with critical limb ischemia (CLI) [53, 75]. Type 2 diabetes mellitus (T2DM) was associated with a ~5.5-fold increased risk for major amputation in elderly patients [15]. Low BMI patients experienced worse in-hospital outcomes after endovascular therapy including atherectomy [50].
- **Comparison with Other Therapies:** Atherectomy is often compared to balloon angioplasty, with some evidence suggesting lower TLR at 24 months compared to percutaneous transluminal angioplasty (PTA) [38] and potential reductions in dissection and bailout stenting [23]. However, overall evidence on primary patency, mortality, and cardiovascular events compared to balloon angioplasty is very uncertain [18, 23]. Intravascular lithotripsy (IVL) is noted as an alternative for calcified lesions without the risk of dissection, perforation, or distal embolization [58].
- **Real-world Use and Trends:** Atherectomy is a common vessel preparation technique (20.7% in a cohort [43, 44]) and is increasingly used in complex cases [11, 25, 65]. Its use is influenced by factors like payment models (e.g., reduction in DCB usage potentially shifting to atherectomy [68]).

5) Discussion

5.1 Principal finding:

The central finding of this review is that atherectomy procedures in Peripheral Artery Disease consistently achieve high procedural and technical success rates, with a median of 97.3% (range 84-100%) [5, 7, 9, 37, 53, 57, 62, 70], indicating effective immediate plaque removal and luminal restoration.

5.2 Clinical implications:

- Atherectomy, particularly when combined with drug-coated balloons, offers a robust strategy for achieving high patency and low revascularization rates in femoropopliteal lesions [4, 8, 60].
- The technique is highly effective for calcified lesions across various arterial segments, minimizing the need for stenting and improving immediate luminal gain [3, 6, 17, 28].
- While generally safe, clinicians should be aware of potential complications such as embolization, dissection, and perforation, especially with specific atherectomy systems [19].
- Patient-specific factors, such as diabetes mellitus and low BMI, may influence outcomes, necessitating careful patient selection and risk stratification for atherectomy-assisted revascularization [15, 50].
- Atherectomy can be a valuable tool for complex PAD, including chronic total occlusions (CTO) and in-stent restenosis (ISR), offering alternatives to surgical revascularization [10, 16, 31].

5.3 Research implications / key gaps:

- **Comparative Effectiveness Trials:** Conduct large-scale randomized controlled trials directly comparing different atherectomy modalities (e.g., rotational vs. directional vs. laser) and atherectomy versus intravascular lithotripsy for specific lesion types and anatomical locations [18, 23, 66].
- **Long-Term Outcome Data:** Investigate long-term (beyond 2-3 years) primary patency, freedom from target lesion revascularization, and limb salvage rates for various atherectomy strategies, especially in challenging populations like those with critical limb ischemia and diabetes [32].
- **Subgroup Analysis:** Perform detailed subgroup analyses to identify optimal atherectomy strategies for specific patient characteristics (e.g., degree of calcification, lesion length, vessel diameter, diabetes status, renal insufficiency) and anatomical sites (e.g., BTK, CFA) [15, 49, 67].
- **Cost-Effectiveness Studies:** Evaluate the cost-effectiveness of atherectomy compared to other endovascular and surgical interventions, considering the increasing cost of PAD treatment due to technological advancements [30].
- **Standardized Outcome Reporting:** Develop and implement standardized outcome definitions and reporting metrics across studies to facilitate more robust comparisons and meta-analyses [18, 23].

5.4 Limitations:

- **Heterogeneous Study Designs** — The reliance on a mix of retrospective cohorts, prospective cohorts, and studies with unspecified designs limits the ability to draw definitive causal conclusions and introduces variability in data quality.
- **Limited Comparative Data** — Many studies lack direct head-to-head comparisons between different atherectomy devices or against alternative treatments like plain balloon angioplasty or intravascular lithotripsy, making it difficult to ascertain superior strategies.
- **Short-Term Follow-up** — A significant number of studies report only acute or short-term (e.g., 6-12 months) outcomes, which may not fully capture the durability of atherectomy interventions or late-term complications.
- **Small Sample Sizes** — Several studies involve small patient cohorts, which restricts the statistical power to detect meaningful differences and limits the generalizability of their findings to broader PAD populations.
- **Inconsistent Outcome Reporting** — Variability in the definition and reporting of key outcomes such as patency, revascularization, and complications across studies hinders direct quantitative synthesis and meta-analysis.

5.5 Future directions:

- **Standardized Outcome Reporting** — Implement uniform definitions for primary patency, target lesion revascularization, and major adverse limb events in future atherectomy studies.
- **Large-Scale Comparative Trials** — Conduct large, multicenter randomized controlled trials comparing different atherectomy devices and strategies against established endovascular treatments.
- **Long-Term Patency Studies** — Design prospective studies with extended follow-up periods (e.g., 3-5 years) to assess the durability and long-term clinical benefit of atherectomy.
- **Subgroup Analysis** — Focus on specific patient populations (e.g., diabetics, critical limb ischemia) and lesion characteristics (e.g., severe calcification, in-stent restenosis) to optimize treatment algorithms.
- **Cost-Effectiveness Analysis** — Perform economic evaluations to determine the value of atherectomy in the context of rising healthcare costs and alternative treatment options.

6) Conclusion

Atherectomy procedures in Peripheral Artery Disease consistently achieve high procedural and

technical success rates, with a median of 97.3% (range 84-100%) [5, 7, 9, 37, 53, 57, 62, 70]. These interventions are widely applicable across various anatomical sites and lesion complexities in PAD patients, including those with calcified lesions and critical limb ischemia. The primary limitation affecting certainty is the heterogeneity in study designs and outcome reporting, which complicates direct comparisons and comprehensive meta-analysis. A crucial next step is to conduct large-scale, randomized controlled trials with standardized outcome measures to definitively establish the long-term comparative effectiveness of different atherectomy modalities and their role in contemporary PAD management.

References

SAIMSARA Session Index — session.json

Figure 1. Publication-year distribution of included originals

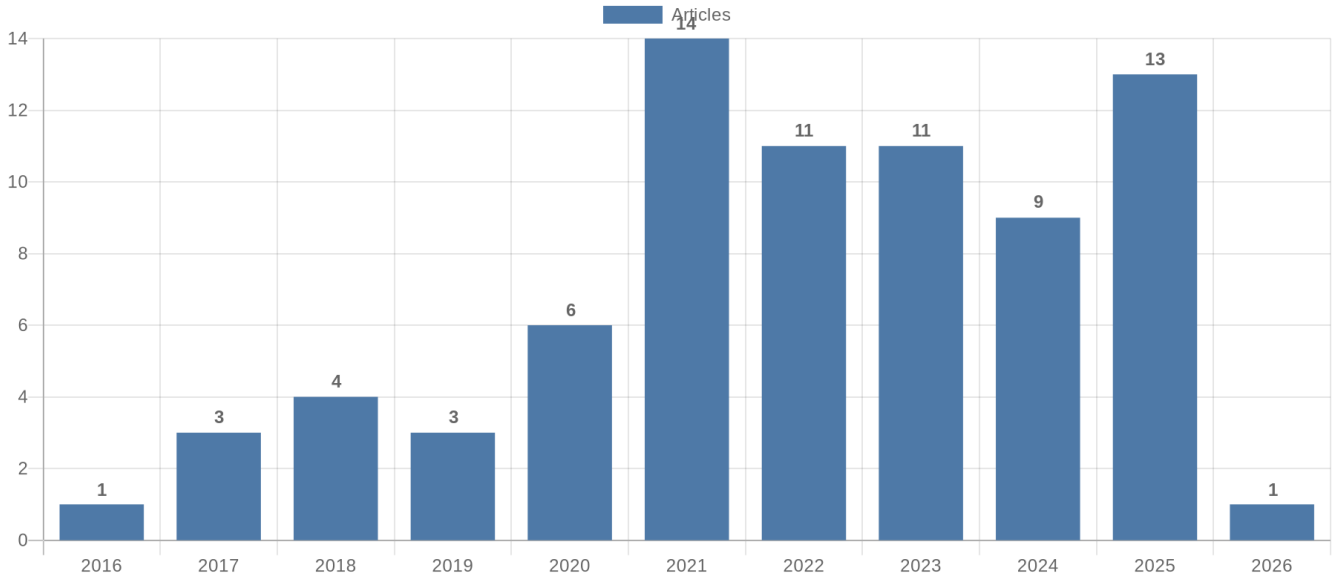


Figure 2. Study-design distribution of included originals

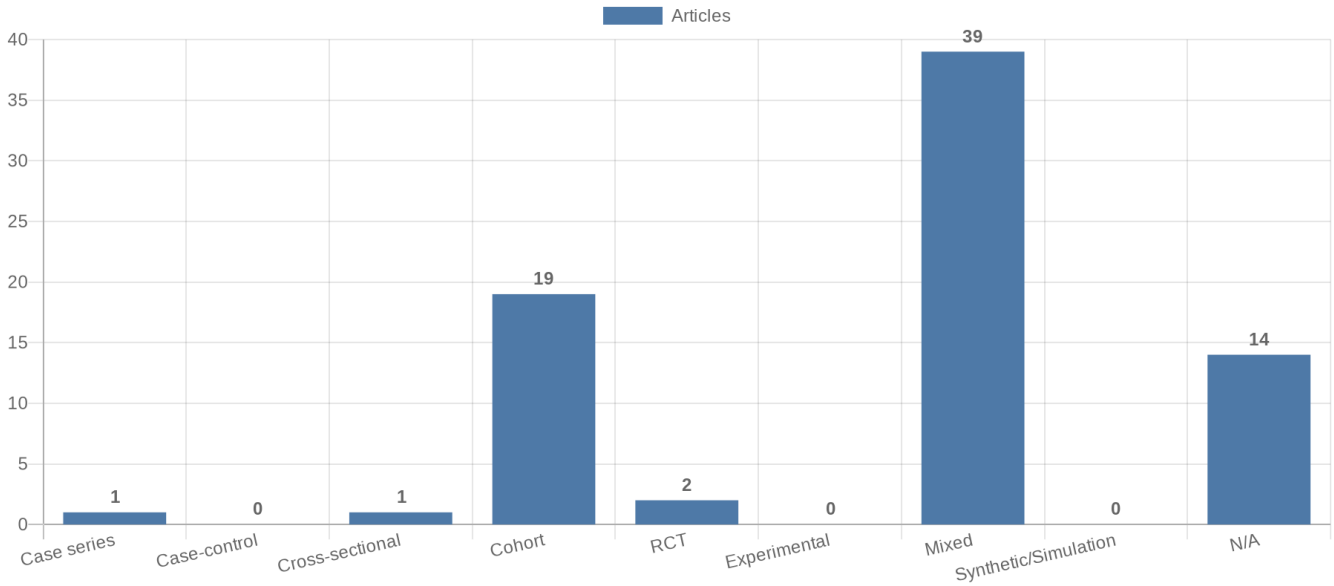


Figure 3. Study-type (directionality) distribution of included originals

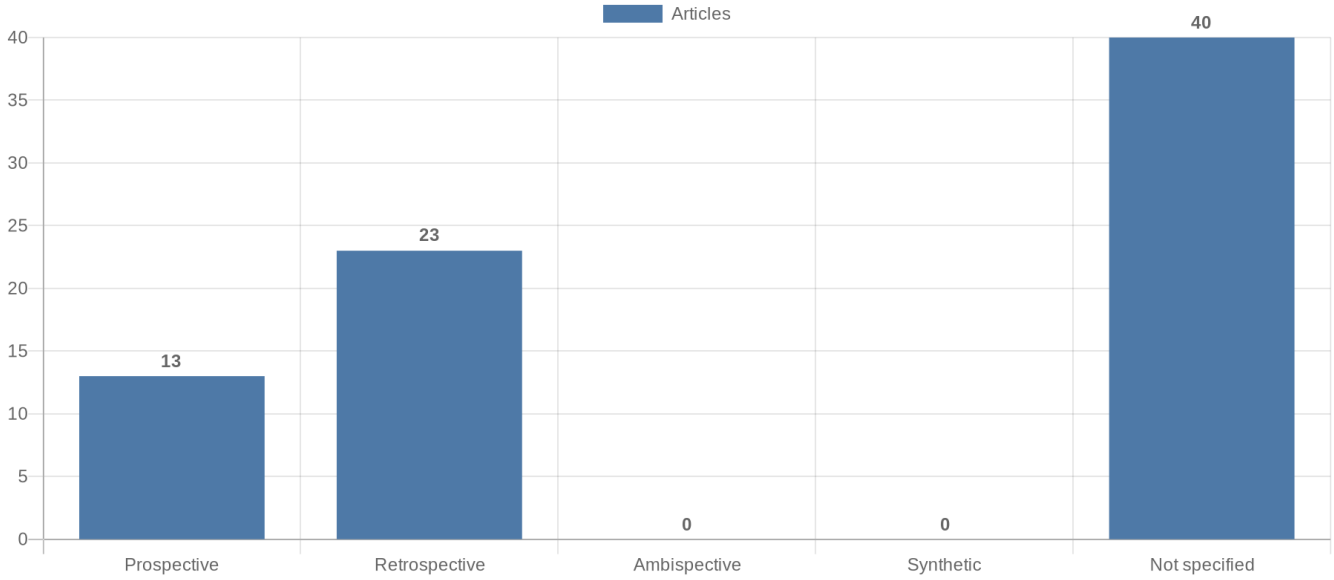


Figure 4. Main extracted research topics

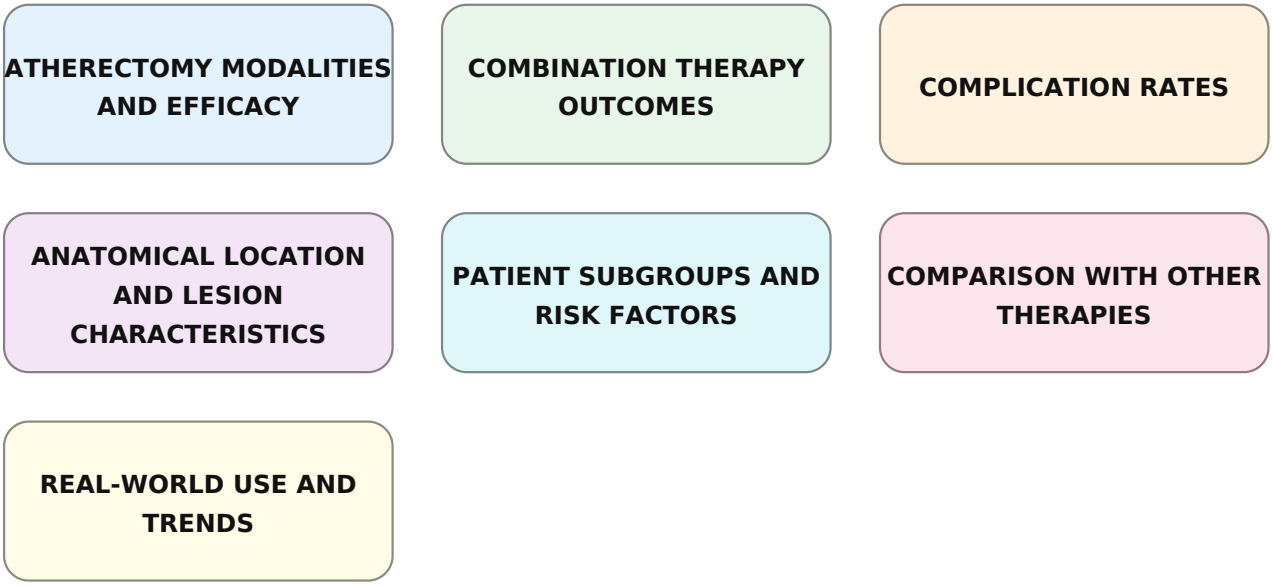


Figure 5. Limitations of current studies (topics)

Figure 6. Future research directions (topics)