

INPLASY

Protocol for "Independent Amputation Risk Factors in Patients with Concomitant Diabetes Mellitus and Peripheral Arterial Disease: A Systematic Review "

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ADMINISTRATIVE INFORMATION

Support - None.

Review Stage at time of this submission - Data extraction.

Conflicts of interest - None declared.

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Amendments - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 30 December 2023 and was last updated on 30 December 2023.

INTRODUCTION

Review question / Objective In patients with concomitant diagnoses of diabetes mellitus and peripheral arterial disease, what independent risk factors have been reported to influence the risk of amputation, as defined by any (major or minor) amputation, major adverse limb events (reintervention on the index arterial segment or amputation of the index limb) or amputation free survival?

Rationale Patients with concomitant diabetes mellitus and peripheral arterial disease represent a high-risk cohort for progression to rest pain, vascular interventions and amputation. While these populations have been extensively studied independently, the degree of their synergistic effect on amputation risk and limb events is unclear. This work is of particular importance given their high co-incidence and significant disease burden in the global population.

Condition being studied Diabetes mellitus (DM) is a leading cause of morbidity and mortality. It predisposes patients to atherosclerotic disease and amputation. Peripheral arterial disease (PAD) is common, affecting more than 230 million patients globally. Over time, PAD results in stenosis, impaired vasodilation and enhanced vasoconstriction of lower extremity vasculature. DM and PAD frequently coexist in comorbid patients and exert a synergistic effect on amputation risk.

METHODS

Search strategy A search of MEDLINE through PubMed from inception (January 1, 1946) to Dec, 2023 without language restrictions using the following MESH terms: "Peripheral Arterial Disease" AND "Diabetes Mellitus" AND "amputation, surgical" was performed. No language restrictions were included. References of

included articles were screened to assess for additional studies meeting eligibility criteria.

Participant or population Patients with concomitant diagnoses of diabetes mellitus and peripheral arterial disease.

Intervention Exposure of independent risk factor(s) of possible association with target outcome.

Comparator Not applicable.

Study designs to be included Randomized controlled trials, Cohort, Case-control and Cross-sectional studies.

Eligibility criteria All original studies assessing amputation as an outcome, including any (major or minor) amputation, major adverse limb events (MALE) and amputation-free survival (AFS) in patients specifically diagnosed with concomitant DM and PAD were included. Studies comparing risk of amputation based on intervention amongst this population, as well as studies with clearly defined subgroup analyses of patients with DM and PAD were included and screened for independent amputation risk factors. Studies including heterogeneous populations with and without diagnoses of DM and PAD without direct mention of, or allusion to, subgroup analysis of concomitant disease patients were excluded during screening.

Information sources MEDLINE (PubMed).

Main outcome(s) 'Amputation' as defined by the occurrence any amputation (major or minor), major adverse limb event (re-intervention on the index arterial segment or amputation of the index limb) or failure of amputation free survival.

Quality assessment / Risk of bias analysis Two independent reviewers (VB and BK) screened each title and abstract using the online platform Rayyan (<http://rayyan.qcri.org>). All discrepancies during the screening process were resolved by a third reviewer (PG). Study quality was assessed through the New-Castle Ottawa Scale (NOS) for non-randomized (cohort) studies and the Cochrane Revised risk-of-bias tool for randomized for randomized controlled trials (RoB 2) for randomized studies.

Strategy of data synthesis All included articles were screened for basic study characteristics and independent risk factors of amputation by two reviewers (VB and BK). Both reviewers used a data

spreadsheet in Excel 2016 (Microsoft Corporation, Redmond, Washington, USA) for data extraction and synthesis. Reviewers performed this step independently, then compared results.

Subgroup analysis No subgroup analysis was performed amongst patients already identified as having concomitant diabetes mellitus and peripheral arterial disease. Subgroups of heterogeneous patient populations, described as being entirely composed of patients with diabetes mellitus and peripheral arterial disease matching eligibility criteria, were analyzed for independent risk factors.

Sensitivity analysis None performed.

Language restriction None.

Country(ies) involved United States of America.

Keywords Diabetes Mellitus; Peripheral Arterial Disease; Amputation; Risk.

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