

# INPLASY

## Incidence and risk factors for amputation in patients with diabetic foot: systematic review and meta-analysis

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### ADMINISTRATIVE INFORMATION

**Support** - None.

**Review Stage at time of this submission** - Preliminary searches.

**Conflicts of interest** - None declared.

**INPLASY registration number:** INPLASY2024110059

**Amendments** - This protocol was registered with the International Platform of Registered Systematic Review and Meta-Analysis Protocols (INPLASY) on 13 November 2024 and was last updated on 13 November 2024.

### INTRODUCTION

**Review question / Objective** Population: Patients with diabetic foot. Study type: Cohort study, case-control study, cross-sectional study. Outcome measures: Incidence of amputation and factors influencing amputation. This study aimed to comprehensively analyze the incidence of amputation in patients with diabetic foot.

**Condition being studied** Diabetic foot (DF) stands as one of the most severe complications leading to death and disability in patients with diabetes mellitus (DM). According to the Global Diabetes Map 2021 (10th edition), diabetes-related deaths among individuals under 60 years old are projected to account for 32.6% in 2021. The global prevalence of diabetes among those aged 20-79 is estimated at 10.5% (536.6 million people), with a forecasted increase to 12.2% (783.2 million people) by 2045. It is estimated that approximately one in every 20 DM patients worldwide undergoes amputation due to DF, with a staggering 74.00%

amputation rate among new DF patients[3]. Yammine Ket al. reported that the amputation rate among patients with diabetic foot ulcers (DFUs) is 15%, with 9% involving severe amputations and 5% minor amputations. The mortality rate post-amputation is 4.4% within the first year and escalates to 24.5% by the fifth year. Amputation imposes significant economic and psychological burdens on diabetic foot patients.

### METHODS

**Participant or population** Patients with diabetic foot.

**Intervention** None.

**Comparator** None.

**Study designs to be included** Cohort study, case-control study, cross-sectional study.

**Eligibility criteria** Study type: Cohort study, case-control study, cross-sectional study.

Study population: Patients with diabetic foot.  
Outcome measures: Incidence of amputation and factors influencing amputation.  
Exclusion criteria: ① Repeatedly published literature; ② Literature not accessible by full text search or data extraction; ③ Non-English literature; ④ Literature with lower quality assessment results.

**Information sources** Computer searches of PubMed, Web of Science, Embase and the Cochrane Library databases were performed to identify observational studies of amputation in patients with diabetic foot, with a time frame of database construction to 30 October 2024.

**Main outcome(s)** Incidence of amputation and factors influencing amputation.

#### **Quality assessment / Risk of bias analysis**

① Newcastle Ottawa scale (NOS)  
② and Agency for Healthcare Research and Quality (AHRQ) Literature screening, data extraction and cross-checking were done independently by 2 researchers, and in case of disagreement, judgement was assisted by discussion or consultation with a third party. The data extraction included basic information of the literature, the incidence of amputation and influencing factors.

**Strategy of data synthesis** Meta-analysis was performed using STATA 17.0 software. If the data related to the incidence of amputation and the influencing factors were suitable to be combined, they were all treated as statistical effect sizes, and each effect size was provided with its 95% confidence interval (CI). Heterogeneity between the outcomes of the included studies was quantified using  $I^2$  to determine the magnitude of heterogeneity; if  $P > 0.1$  or  $I^2 < 50\%$ , it indicated that the heterogeneity between the studies was acceptable and was analysed using a fixed-effects model; if  $P \leq 0.1$  or  $I^2 \geq 50\%$ , it indicated that the heterogeneity between the studies was large and was analysed using a random-effects model. Publication bias was assessed using funnel plots and Egger's test. Literature screening, data extraction and cross-checking were done independently by 2 researchers, and in case of disagreement, judgement was assisted by discussion or consultation with a third party. The data extraction included basic information of the literature, the incidence of amputation and influencing factors.

**Subgroup analysis** Type of research, Region, Years.

**Sensitivity analysis** In order to test the stability and reliability of the research results, we conducted a sensitivity analysis.

**Country(ies) involved** China.

**Keywords** Diabetic Foot; Amputation; Incidence; Influencing factors.

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