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Hong, OY¹; Tang, Y²; Yang, F³; Ren, X⁴; Yang, J⁵; Ca, HY⁶; Yin, YF⁷.**ADMINISTRATIVE INFORMATION**

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Review Stage at time of this submission - Completed but not published.

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 01 November 2023 and was last updated on 01 November 2023.

INTRODUCTION

Review question / Objective With the increasing incidence of diabetes, diabetic foot ulcer (DFU) has become one of the most common and serious complications in people with diabetes. DFU is associated with significant morbidity and mortality, and can also result in significant economic, social and public health burdens. Due to peripheral neuropathy, peripheral vascular disease, hyperglycemic environment, inflammatory disorders and other factors, the healing of DFU is impaired or delayed, resulting in the formation of diabetic chronic refractory ulcer. Because of these pathological abnormalities in DFU, it may be difficult to promote wound healing with conventional therapies or antibiotics, whereas

platelet-rich plasma (PRP) can promote wound healing by releasing various bioactive molecules stored in platelets, making it more promising than traditional antibiotics. Therefore, the purpose of this systematic review is to summarize and analyze the efficacy of PRP in the treatment of DFU.

Condition being studied Diabetic foot ulcer (DFU) is one of the most common and serious complications in patients with diabetes [3-7] and is characterized by complex management, high morbidity, and high mortality [8]. The annual incidence of diabetic foot around the world ranges from 9.1 million to 26.1 million [9-10], with a global prevalence of about 6.3%, which mostly occurs in patients with type 2 diabetes, the elderly, and people with a longer duration of diabetes [11]. In

China, the prevalence of DFU is increasing with the increase of the incidence of diabetes year by year. According to statistics, the incidence of DFU in people over 50 years old in China is as high as 8.1%[12-13]. DFU continue to be an important cause of hospitalization in patients with diabetes and form the basis of 40-70% of diabetic non-traumatic lower limb amputations[14-15]. Relevant reports have also shown that nearly 88% of lower leg amputations are associated with diabetic foot ulcers[16]. In addition, the global annual cost of DFU treatment and amputation is approximately US \$10.9 billion[17], and the cost of DFU treatment in China will rise from the current US \$4.9 billion to US \$7.4 billion by 2030[18]. Thus, DFU is associated with significant morbidity and mortality, as well as significant economic, social, and public health burdens. The global incidence of diabetes is increasing rapidly. The International Diabetes Federation(IDF) estimates that the prevalence of diabetes will increase from 10.5%(536.6 million people in the 20-79 age group) in 2021 to 12.2%(783.2 million people in the 20-79 age group) by 2045[1]. It is projected that nearly half of adults (44.7 percent; 239.7 million people in the 20-79 age group) do not know they have diabetes, and people may be more susceptible to microvascular and macrovascular complications in an asymptomatic diabetic state[2]. Diabetic foot ulcer (DFU) is one of the most common and serious complications in patients with diabetes [3-7] and is characterized by complex management, high morbidity, and high mortality[8]. The annual incidence of diabetic foot around the world ranges from 9.1 million to 26.1 million [9-10], with a global prevalence of about 6.3%, which mostly occurs in patients with type 2 diabetes, the elderly, and people with a longer duration of diabetes [11]. In China, the prevalence of DFU is increasing with the increase of the incidence of diabetes year by year. According to statistics, the incidence of DFU in people over 50 years old in China is as high as 8.1%[12-13]. DFU continue to be an important cause of hospitalization in patients with diabetes and form the basis of 40-70% of diabetic non-traumatic lower limb amputations[14-15]. Relevant reports have also shown that nearly 88% of lower leg amputations are associated with diabetic foot ulcers[16]. In addition, the global annual cost of DFU treatment and amputation is approximately US \$10.9 billion[17], and the cost of DFU treatment in China will rise from the current US \$4.9 billion to US \$7.4 billion by 2030[18]. Thus, DFU is associated with significant morbidity and mortality, as well as significant economic, social, and public health burdens. Therefore, the treatment of DFU has become an urgent problem.

METHODS

Search strategy A literature search was undertaken in PubMed, Elsevier, CNKI, EMBASE, the Cochrane Library, the WanFang Database and the WeiPu Database by computer. The retrieval time was from the establishment of the database to June 2023, using the combination of subject terms and free words. The search terms included "Diabetes", "Diabetic foot ulcer", "Platelet-rich plasma", "Diabetic complications" and "Efficacy".

Participant or population The included studies were clinical trials (including randomized controlled trials, case-controlled trials, prospective observational) and retrospective studies (there were no language or location restrictions). We excluded case reports, letters, reviews. We included studies evaluating the efficacy of PRP in the treatment of DFU. Since the conventional first-line treatment of DFU includes blood glucose control, infection management, debridement, wound undressing, dressing, and vascular surgery for PAD[19], therefore, the relevant efficacy indicators included in our study mainly included wound healing rate, healing time, ulcer area reduction rate, ulcer recurrence rate, amputation rate or follow-up surgical treatment rate, infection rate, adverse event, length of stay, hospitalization cost, etc.

Intervention PRP.

Comparator Saline or standard treatment.

Study designs to be included Randomized controlled trials, case-controlled trials, prospective observational) and retrospective studies.

Eligibility criteria We included studies evaluating the efficacy of PRP in the treatment of DFU. Since the conventional first-line treatment of DFU includes blood glucose control, infection management, debridement, wound undressing, dressing, and vascular surgery for PAD[19], therefore, the relevant efficacy indicators included in our study mainly included wound healing rate, healing time, ulcer area reduction rate, ulcer recurrence rate, amputation rate or follow-up surgical treatment rate, infection rate, adverse event, length of stay, hospitalization cost, etc.

Information sources PubMed, Elsevier, CNKI, EMBASE, the Cochrane Library, the WanFang Database and the WeiPu Database by computer.

Main outcome(s) wound healing rate, healing time, ulcer area reduction rate, ulcer recurrence rate, amputation rate or follow-up surgical treatment rate, infection rate, adverse event, length of stay, hospitalization cost, etc.

Quality assessment / Risk of bias analysis The Centre for Evidence-Based Medicine at Oxford University, UK (2005).

Strategy of data synthesis Therapeutic effect and preparation method.

Subgroup analysis No.

Sensitivity analysis No.

Country(ies) involved China.

Keywords Diabetes; Platelet-rich plasma; Diabetic foot ulcer Therapeutic effect and preparation method.

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