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Meta-analysis of clinical efficacy and safety of autologous platelet-rich plasma in the treatment of diabetic foot ulcers

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ADMINISTRATIVE INFORMATION

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Review Stage at time of this submission - Data analysis.

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 05 January 2024 and was last updated on 05 January 2024.

INTRODUCTION

Review question / Objective This study's objective was to evaluate Au-PRP's clinical efficacy and safety in diabetic foot ulcers through systematic evaluation, so as to provide better evidence-based medical evidence for future clinical applications.

Condition being studied DFU is an infection, ulceration, and / or deep tissue destruction of the lower extremities in patients with diabetes mellitus due to concomitant neuropathy and various degrees of peripheral vascular lesions. Surveys showed that the annual incidence of DFU worldwide is approximately 6.3% . In China, the incidence of DFU in people over 50 years old is as high as 8.1% . Unfortunately, once a DFU ulcer wound has formed, it can develop into a chronic refractory wound due to a variety of factors such as microangiopathy, neuropathy, and

immunosuppression that do not heal, and the final treatment result is that the patient will have a lower extremity amputation or will be dead. About 5.1% of DFU patients in China need amputation every year, which is much higher than in Western countries.

METHODS

Participant or population 15 studies included 780 patients, with 381 in Au-PRP group and 399 in control group. The minimum sample size was 14 and the maximum was 103. Countries included in the studies were China, Italy, Egypt, Greece, Etawah, India, and America.

Intervention None.

Comparator Au-PRP group and control group.

Study designs to be included Meta-analysis.

Eligibility criteria (1) explicitly reported the efficacy and safety of Au-PRP or AGP in patients with DFU and were randomized control trials; (2) included indicators of therapeutic effects such as healing rate, healing time, rate of lower extremity (or toe) amputation, and safety indicators such as recurrence rate, incidence of adverse reactions, etc.

Information sources By using databases such as Web of science, Embase, and PubMed, a comprehensive literature screening was conducted on published literature of RCTs of Au-PRP applied in treating DFU. Literature published before August 2022 were included. The search strategies of literature screening were as follows: ("Platelet-Rich Plasma" OR "PRP" OR "Autologous platelet-rich plasma" OR "Au-PRP" OR "Autologous platelet-rich gel" OR "APG") AND ("Diabetic foot, Diabetic" OR "DF" OR "Diabetic foot ulcer" OR "DFU") AND ("Randomized controlled trial" OR "Randomized" OR "Placebo"). References to relevant articles were also consulted for more comprehensive analysis.

Main outcome(s) 780 patients were included in the studies, including 381 in Au-PRP group and 399 in control group. Meta analyse showed higher healing rates in the Au-PRP group compared to those in the control group [RR=1.26, 95%CI(1.15, 1.39), $P < 0.00001$]. Compared with control group, Au-PRP group spent significantly lesser healing time [SMD=-2.04, 95%CI(-3.21, -0.86), $P < 0.00001$], and the ulcer area in the Au-PRP group was reduced [SMD=0.76, 95%CI(0.20, 1.32), $P=0.008$]. And the incidence of adverse reactions remained unchanged [RR=0.96, 95%CI(0.57,1.60), $P=0.87$].

Quality assessment / Risk of bias analysis According to the comprehensive assessment of the seven aspects of Cochrane's tool, the risk of bias and the overall risk of bias in each study were relatively low.

Strategy of data synthesis By retrieving such data bases as Web of science, Embase, and PubMed, studies of randomized controlled trials that Au-PRP was applied in treating DFU were collected for meta-analysis. In comparison to conventional treatment, the effectiveness and safety of Au-PRP in the treatment of DFU were comprehensively evaluated in such aspects as healing rate, healing time, reduction of ulcer area, rate of lower extremity (or toe) amputation, recurrence rate, incidence of adverse reactions, and length of hospital stay. Risk rate (RR) and STM mean difference (SMD) were used as the combined

effect size of binary variables and continuous variables respectively in statistics analysis.

Subgroup analysis (1) Healing rate: Au-PRP group had higher healing rate compared to control group. (2) Healing time: Au-PRP can shorten the healing time for patients with DFU. (3) Reduction of ulcer area: Au-PRP can accelerate the reduction of diabetic foot ulcer area and wound healing. (4) Incidence of adverse reactions: compared to conventional treatment, Au-PRP did not increase the incidence of adverse reactions. (5) Length of hospital: the length of hospital stay in Au-PRP group was shorter than that in control group. (6) Rate of lower extremity (or toe) amputation: Au-PRP can lower the rate of lower extremity (or toe) amputation. (7) Publication bias: the number of studies in the left side of the funnel plot were more than those in the right side, which indicated that the possibility of publishing bias existed.

Sensitivity analysis RevMan 5.4 software.

Country(ies) involved China.

Keywords Autologous platelet-rich plasma; Diabetic foot ulcer; Healing rate; Recurrence rate; Incidence of adverse reactions.

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