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REVIEW ARTICLE

THE SCOPING REVIEW OF CHINESE AND WESTERN MEDICINE TREATMENT OF DIABETIC FOOT IN ASIA

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Abstract

Diabetic foot is a common and serious chronic complication of diabetes due to the simultaneous occurrence of diabetic peripheral neuropathy and vascular lesion. Among all complications, foot ulcers in diabetic ulcers account for the first place among the reasons for hospitalization and treatment of diabetic patients. 15% of diabetic patients may have foot diseases, and 85% of patients may have foot ulcers as the cause of amputation. Diabetic foot seriously affects the quality of life of patients. Although there are many methods to treat diabetic foot, the therapeutic effect of diabetic foot is not ideal in general. The main purpose of this scoping review was analyzing the existing loopholes of researches on diabetic foot in Asia. Used Pub Med, CNKI, Wangfang data, CQVIP to search and select 5 traditional Chinese medicine literatures and 5 western medicine literatures, through the comparison of various conditions between literatures to analyze the lack of research. Ten pieces of literature were retained through 183 records and included 9 drugs or decoction, they were adipose-derived stem cell–hydrogel complex, hyperbaric oxygen therapy, Xenogeneic (porcine) a cellular dermal matrix, alprostadil, salvia miltiorrhiza polyphenols for injection and collagen sponge, Taohong Siwu Decoction, Simiao Yong an Decoction, Jiawei Simiao Yong an Decoction, Huangqi Guizhi Wuwu Tang, and Wuwei Xiaodu Drink. The obvious problems found by this scoping review were the quantity and quality deficiency of the research in the diabetic foot in Asia. Scoping review is an effective method of evidence identification and synthesis, which can provide a basis for the further development of a certain field. In the further study of the diabetic foot, more attention should be paid to the verification of experimental data as well as the feasibility of the researches on oral drugs.

Keywords: Diabetic foot, Traditional Chinese medicine, Western medicine.

INTRODUCTION

Diabetic foot is a general term for a series of clinical manifestations of the foot caused by peripheral vascular disease, neuropathy, and infection in diabetic patients due to long-term and chronically elevated blood glucose, including foot ulcers, infection and deep tissue destruction. Once diabetic foot occurs, it is difficult to treat, with the high cost and poor prognosis. If the treatment is not timely or adequate, there is often a risk of amputation. Diabetic foot is one of the main complications of diabetes. According to the IDF diabetes map (9th edition), about 463 million adults worldwide suffered from diabetes in 2019, and it is estimated that 700 million people could have diabetes by 2045 Figure 1 shows the global distribution of diabetes patients in 2019[1]. At the national level, the top three countries with diabetes in 2019 were China, India and the United States, with about 118 million, 78 million and 30 million diabetics (20-79 years old), respectively. And China and the United States also have a high expenditure with diabetics 1. Figure 2 shows the top 10 countries with the highest number of diabetes in 2019. Based on the above data, the number of diabetes patients in Asia is the first in the world. In global diabetes research, the study of American forces dominates. Diabetes research in China in the number of papers and patents statistics on has and Germany are close to, or more than these countries, but from the paper quality in new drug research and clinical research level, with Europe and the United States and other developed countries have a certain gap[2]. Because Asian countries the number of diabetes and the number of concurrent with diabetic foot ulcers are more, but at this stage of clinical research level is not high, the number of new drug research, research direction is

fuzzy, therefore decided to Asian drug therapy for diabetic foot ulcers group scoping review, to provide reference for drug treatment for the future research direction. A scoped review is a design approach "to rapidly map the key concepts underpinning the research field as well as the key resources and types of available evidence"[3]. This scoping review is to summarize the current clinical research literature on Chinese medicine and western medicine for diabetic foot treatment in Asia, so as to provide new ideas for the future research direction of diabetic foot medicine in Asia and facilitate the further development of research.

Table 1: Nine drugs or prescriptions and their effects in treating diabetic foot.

Drug therapy	Effects	literature
Adipose-Derived Stem Cell–Hydrogel Complex	Promote granulation tissue formation, epithelialization, and angiogenesis, thereby promoting wound healing.	Potential of Allogeneic Adipose-Derived Stem Cell–Hydrogel Complex for Treating Diabetic Foot Ulcers[6]
Hyperbaric oxygen therapy	Increase tissue oxygen level, accelerate wound healing, reduce edema, kill anaerobic bacteria.	A Pilot Study of Short-Duration Hyperbaric Oxygen Therapy to Improve HbA1c, Leukocyte, and Serum Creatinine in Patients with Diabetic Foot Ulcer Wagner 3-4[7]
Xenogeneic (porcine) acellular dermal matrix(ADM)	Prevent pollution, promote blood supply reconstruction and increase cell regeneration.	Application effect of the xenogeneic (porcine) acellular dermal matrix in the repair of diabetic foot ulcer[8]
Alprostadil	By activating adenylate cyclase to promote vascular dilation, inhibit platelet aggregation, improve microcirculation.	Analysis of the effect of alprostadil on diabetic foot[9]
Salvia miltiorrhiza polyphenols	Effectively improve microcirculation, increase microvascular blood flow, and anticoagulation effect.	Effects of Salvia miltiorrhiza polyphenols for injection Adipose-Derived Stem Cell–Hydrogel Complex and collagen sponge in the diabetic foot[10]
Taohong Siwu Decoction	Vasodilation,anti-inflammation, anti-fatigue, anti-shock, regulation of immune function, lipid reduction, supplementation of trace elements, anti-allergic effect.	The clinical curative effect of modified peach Tao Hong Siwu decoction and lipoic acid injection on diabetic foot (DF) in 50 cases[11]
Jiawei Si Miao Yong An Decoction Or Simiao Yong an Decoction	Resist inflammation, regulate blood coagulation and immunity, reduce blood glucose and inhibit bacteria, strengthen erythrocyte deformability, improve microcirculation and scavenging free radicals.	Clinical Observation of Jiawei Si Miao Yong An Decoction in the Treatment of Diabetic Foot Ulcer of Lower limb[12] Research of intervention by Simiaoyong'an decoction for vascular endothelial function in the diabetic foot[13]
Huangqi Guizhi Wuwu Tang	Improve the vascular function and hemodynamics of lower limbs, have certain anti-inflammatory and oxidative stress effects and reduce the injury of vascular endothelial cells.	Clinical Effect of Modified HuangqiGuizhiWuwu Tang on Patient with Lower-extremity Arterial Disease[14]
Wuwei Xiaodu Drink	Play an active role in antibacterial and anti-inflammatory, and inhibits the inflammatory response of patients.	Clinical observation on treatment of type 2 diabetic foot ulcer by adding or subtracting Wuwei Xiaodu Drink combined with tissue engineering full-thickness skin[15]

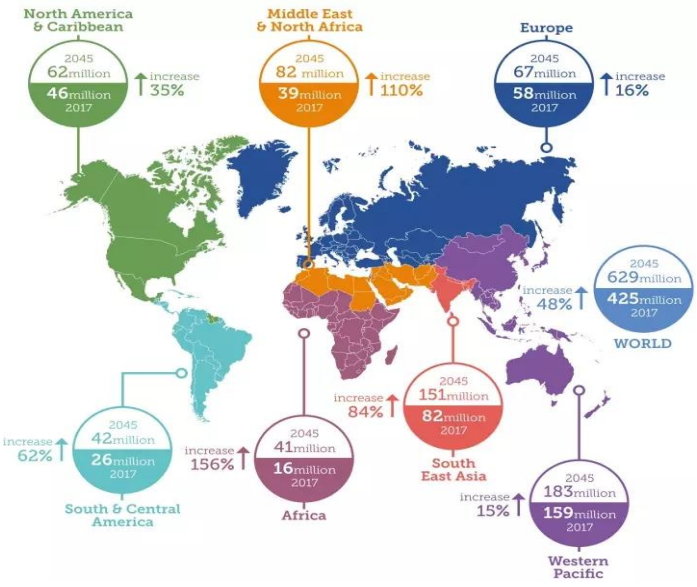

Figure 1: Number of diabetes patients worldwide (20-79 years old) in 2019.

METHODS

Eligibility Criteria

Literature including nearly five years (2015-2019) in four databases of free text articles. Literature type limited to the clinical trial. Intervention limited to drugtreatment. Study design limited to randomized controlled trials. The population limit for Asians, any gender, most was over 35 years old, and the study population was limited to 30 or more (N > 30).

Search Strategy

The databases used are CNKI (China National Knowledge Infrastructure), PubMed and CQVIP (China Science and Technology Journal Database), Wanfang Data Knowledge Service Platform. In the process of visual search of three databases, the search of the literature will be stopped until the literature in the database does not conform to the content of the literature required by the re problem which is researched. The search strategy is based on the review of the clinical research progress of Chinese and western medicine in treating diabetic foot and the management of diabetic foot ulcers and extends to the differences in the treatment of diabetic foot with Chinese and western medicine[4,5]. The common terms used in different databases include diabetic foot (including diabetes foot); broad terms such as non-surgical debridement agents; narrower terms such as hydrogels. The literature published after 2015 was searched until all the required literature was retrieved.

Study Selection

Three researchers examined the search records of the first layer cooperatively, at the first place screening by the published date, title and abstract, secondly, by full text. When a disagreement arises between the researchers, the controversial papers should first be retained and then screened according to drug type of the papers as well asa comparison of the literature describing the same classification of drugs.

Table 2: The basic information of all the experiments.

	Number of participants	Age of participants (Unit: year-old)	Experimental location	Country	Degree of lesion of patients
Adipose-Derived Stem Cell–Hydrogel Complex6	44	18-80	1. Yonsei University Severance Hospital 2. Eulji General Hospital 3. Asan Medical Center 4. Korea University Guro Hospital	Korea	Type of diabetes: type 1 or type 2 diabetes; Ulcer duration: longer than 4 weeks for the history of ulcer at screening; Wound size: between 1 and 25 cm^2; Wound depth of Wagner grade 1 and 2
Hyperbaric Oxygen Therapy7	30	20-79	Institutional Review Board of Medical Faculty of Udayana University and Sanglah General Hospital Denpasar	Indonesia	Diabetic foot ulcer (DFU) Wagner 3-4
Xenogeneic(porcine) acellular dermal matrix8	76	18-68	Shizuishan first people's hospital of Ningxia hui autonomous region	China	Diabetic foot ulcer (DFU) Wagner 2-3 DFU Wagner2: 47 DFU Wagner3: 29
Alprostadil9	100	Male: 48-81 Female: 43-78	Shanghai Ruijin rehabilitation hospital	China	
Salvia miltiorrhiza polyphenols for injection and collagen sponge[10]	115	44-72	Metabolic disease hospital of Tianjin medical university	China	Diabetic foot ulcer (DFU) Wagner 2-3
Taohong Siwu Decoction[11]	100	44-76	Pinghu hospital of traditional Chinese medicine	China	Diabetic foot ulcer (DFU) Wagner 0-1
Simiao Yong ' an Decoction[13]	50	>60	Henan Province Hospital of TCM	China	
Jiawei Simiao Yong ' an Decoction[12]	86	58-74	People's hospital of Wuhan university	China	Diabetic foot ulcer (DFU) Wagner 1-4
Huangqi Guizhi Wuwu Tang[14]	128	64-74	Weifang People's Hospit al	China	Fontaine stage I to III
Wuwei Xiaodu drink [15]	150	41-63	Department of dermatology, Cangzhou central hospital, Hebei province	China	Diabetic foot ulcer (DFU) Wagner 3-4

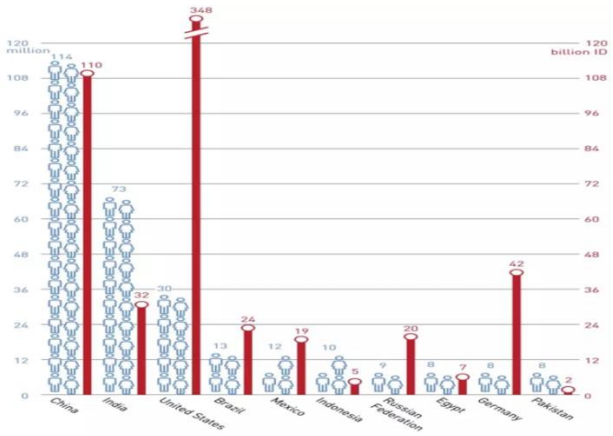

Figure 2: Top 10 countries with the highest number of diabetics in 2017 (the red bar represents health spending).

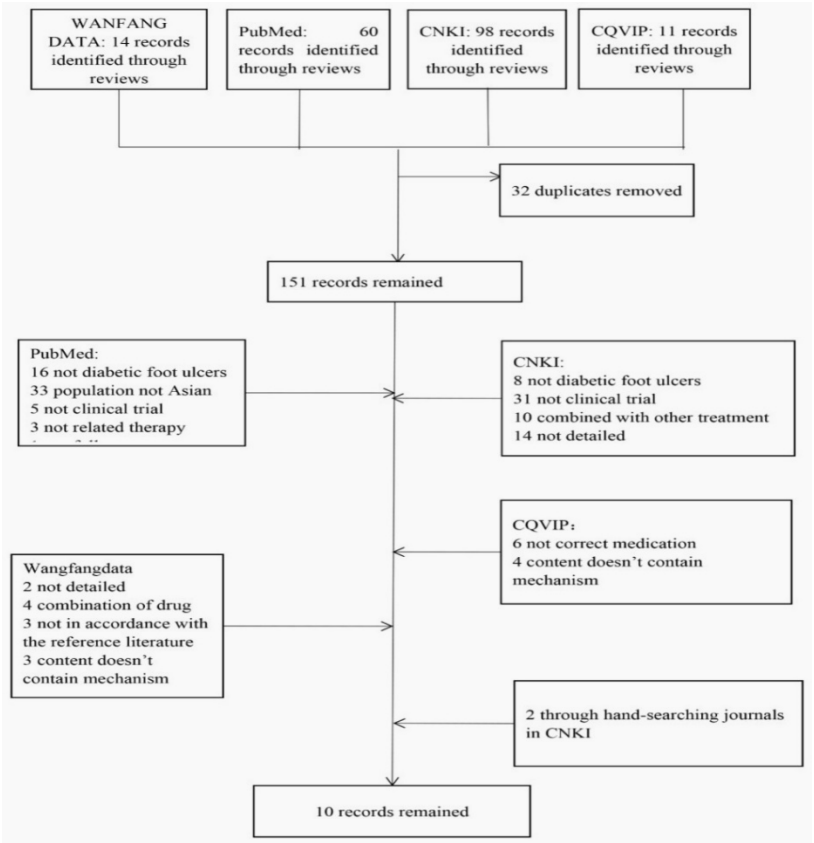

Figure 3: Process of identifying, screening, including, and excluding literature.

Charting the Data

Before the data analysis, two articles were used to discuss the process of data analysis. After collecting the data, three researchers summarized, analyzed and compared, and agreed on the types of data items including drug therapy, study method, inclusion and exclusion criteria of participants (not included in the report) and treatment results.

RESULTS

The purpose of this scoping review is to summarize the existing studies on drug therapy (western medicine and Chinese medicine) for diabetic foot patients in Asia, so as to provide references for future research directions on drug therapy and the combination of Chinese and western medicine. Figure 3 shows the process of identifying, screening, including, and excluding literature.

Components of Drug Therapy

After screening, 10 articles and 9 drugs for treating diabetic foot ulcers were retained. There were 5 kinds of western medicines, including Adipose-Derived Stem Cell–Hydrogel Complex, Hyperbaric oxygen therapy, Acellular dermal matrix, Alprostadil, Salvianolate. Chinese medicine prescription 4 kinds, including Taohong Siwu Decoction, Simiao Yong Decoction, Huangqi Guizhi Wuwu Tang, Wuwei Xiaodu drink. Taohong Siwu Decoction has two pieces of literature, while other medicines only have one. Table 1 shows the nine drugs and their effects in treating diabetic foot.

Experimental design

The experimental designs were based on the route of drug use, different experimental sites, and the degree of

disease. Comparing different experimental designs needed to be done from different aspects, thus the following Table 2 and Table 3 discussed the ten literature from the number of participants, age of participants, experimental location, country, degree of the lesion in patients and specific experimental operation.

Table 3: The details of all the experimental designs.

	Specific experimental operation
Adipose-Derived Stem Cell–Hydrogel Complex6	Of the 44 participants, 25 were assigned to the experimental group and 19 were assigned to the matched group. 3 participants in the experimental group and 2 participants in the matched group were excluded because they did not reach high blood glucose levels (>450). Patients of both groups were treated with 3% hydrogen peroxide and a saline solution to remove dirt and other debris from their ulcers, and both groups were covered with polyurethane foam. The difference between the two groups' patients was that the experimental group used allograft ASC sheets as the primary dressing and the matched group used mesh polyurethane films with silicone adhesives as the primary wound dressing. In both groups, drugs were changed once a week.
Hyperbaric Oxygen Therapy7	Blood tests were performed on all patients to detect HbAlc levels, white blood cell counts and serum creatinine levels before debridement, and they were divided into two groups. Among them, the experimental group conducted ten courses of HBOT (One session of HBOT uses oxygen at 2.4 ATA for 90 minutes per day at several hyperbaric chambers) and the matched group adopted the standard treatment. Five courses of treatment per week, it took two weeks altogether.
Xenogeneic(porcine) acellular dermal matrix8	All participants were given anti-infection, nutritional support treatment, diabetes specialist guidance diabetic diet, insulin treatment, monitoring and regulating blood sugar, wound secretion culture-sensitive antibiotics guide treatment as well as other comprehensive systemic treatment. The wound surface was washed with 1.5% hydrogen peroxide solution, iodine-volt solution and 0.9% sodium chloride solution in turn, and the wound surface was wrapped and fixed with gauze, and the dressing was changed once a day. Experimental group: One week later, under subarachnoid anesthesia and spinal anesthesia, the Sonoca180 low-frequency ultrasonic debridement device (produced by Germany surin-cieser company) was applied to debridement of the diabetic foot, and the wound surface was expanded and created stealthily. Matched group: The matched group was treated with sulfadiazine silver cream (1% sulfadiazine silver, 60 g, Guangdong Hengjian pharmaceutical co., LTD.).
Alprostadil9	Of the 100 participants, 50 were assigned to the experimental group and 50 to the matched group. Patients in both groups received conventional treatment and were treated with hypoglycemic drugs. The wounds were washed with normal saline and hydrogen peroxide, and the wound was wrapped with iodoform gauze. Patients were treated for 2 weeks and the results were reviewed.
Salvia miltiorrhiza polyphenols for injection and collagen sponge[10]	Of the 115 participants, 60 were assigned to the matched group and 55 to the experimental group. Patients in both groups were treated with conventional type 2 diabetic foot therapy, wound cleaning, and spraying 0.9% sodium chloride solution on the wound with the same type of antibiotic. The difference between the two groups was that the patients in the experimental group were treated with collagen dressing, dissolved 200 mg Danshen polyphenols in 5% glucose injection, and given intravenous infusion once a day. For four weeks of one course of treatment, patients' ulcer recovery before and after treatment and during treatment were observed after two courses of treatment.
TaohongSiwu Decoction[11]	All participants received basic treatment for diabetes, including diet control, insulin control of blood glucose, and decompression therapy. Foot superficial ulcer was disinfected with iodophor, local antibiotics were given wet compress, and on this basis, the experimental group was given Tao Hong Siwu Decoction(Tao Ren 30g, Hong Hua 30g, Dang Gui 30g, Chuanxiong 20g, Shu Di Huang 20g, Shen Jin Cao 30g, Hai Feng Teng 30g, Ai Ye 30g), which was fried and soaked in feet once a day for 15 minutes each time.
Simiao Yong ' an Decoction[13]	All patients were given diabetes education and a diabetic diet, and the experimental group was given Simiao Yong ' an Decoction (Dang Gui 30g, Xuan Shen 15g, Huang Qi 15g, Jin Yin Hua 15g, Ji Xue Teng 15g, Gan Cao 6g) which was fried in water, one dose per day and separated one dose for two times. In the meantime, the matched group was not given any medication.
Jiawei Simiao Yong ' an Decoction[12]	Of the 86 participants, 43 were assigned to the experimental group and 43 to the matched group. Patients in the two groups were first given conventional treatment to control their blood glucose, and the same antibiotics were selected to control infection. Physical methods and drugs were used to improve the blood circulation in the lower extremities of the patients. The ulcer of the patients was changed once a day and the patients were given cilostazol tablets twice a day, 100mg each time.
HuangqiGuiZhi Wuwu Tang[14]	Of the 128 participants, 64 were assigned to the experimental group and 64 to the matched group. Two groups of patients simultaneously received non-drug treatment, control of blood glucose, blood pressure, blood lipid, and other drug treatment. Patients were given probucol tablets at breakfast and dinner with 0.5g each time. Oral aspirin enteric-coated tablets were taken 100mg per day for 3 months. Intravenous infusion of alprostadil injection, 10 mg a day, plus 10ml normal saline, continuous injection for 15 days, 15 days rest for a course of treatment, a total of 3 courses of treatment. Patients with hot chest, palm and foot were added to Xuan Shen 15g and Mu Dan Pi 15g. Soak the medicine in water for 30min and cook it twice a day.
Wuwei Xiaodu Drink[15]	Of the 150 participants, 75 were assigned to the experimental group and 75 to the control group. Patients in the two groups were given insulin injection at the same time, 20 units a day, and subcutaneously injected at 3 times in the morning, the middle and the evening 30 minutes before the meal, and the patients were given tissue engineering full-layer skin treatment. The difference between the two groups was that the experimental group was treated with Wuwei Xiaodu drink

Table 4: The total effective rate of all the experiments.

Drug therapy	Total effective rate
Adipose-Derived Stem Cell–Hydrogel Complex6	Matched group: 47%(8/17) Experimental group: 73% (16/22)
Hyperbaric oxygen therapy7	Matched group: HbA1c levels: Baseline: 10.98± 2.37; Effect size: 1.28± 1.54 Leukocyte count: Baseline: 14.27± 6.79 Effect size: 3.26± 7.76 Serum creatinine levels: Baseline: 0.73± 0.25 Effect size: 0± 0.13 Experimental group: HbA1c levels: Baseline: 9.42± 1.96 Effect size: 2.34± 1.57 Leukocyte count: Baseline: 13.97± 6.24; Effect size: 5.13± 6.72 Serum creatinine levels: Baseline: 2.10± 2.88 Effect size: 0.05± 0.45
Xenogeneic(porcine) acellular dermal matrix8	Matched group: 78.95% (30/38) Experimental group: 94.74% (36/38)
Alprostadil9	Matched group: 78% (39/50) Experimental group: 98% (49/50)
Salvia miltiorrhiza polyphenols for injection and collagen sponge[10]	Matched group: 30.91% (22/60) Experimental group: 60% (33/55)
Taohong Siwu Decoction[11]	Matched group: 68% (34/50) Experimental group: 84% (42/50)
Simiao Yongan Decoction[12]	Matched group: ET-1 (pg/ml): 52.06± 5.32 NO(μmol/L): 67.15± 2.93 TXB_2(pg/ml): 84.02± 3.99; 6-Keto-PGF1α(pg/ml): 72.55± 3.89 Experimental group: Before the treatment: ET-1 (pg/ml): 74.09± 4.87 NO(μmol/L): 54.18± 7.97; TXB_2(pg/ml): 101.60± 9.78; Keto PGF1α(pg/ml): 65.07± 5.83 After the treatment: ET-1 (pg/ml): 62.05± 4.78; NO(μmol/L): 65.81± 3.83 TXB_2(pg/ml): 91.84± 8.90; 6-Keto-PGF1α(pg/ml): 70.77± 7.00
Jiawei Si Miao Yong An Decoction[13]	Matched group: 86.05% (37/43) Experimental group: 93.02%(40/43)
HuangqiGuizhiWuwu Tang[14]	Matched group: 92.2% (59/64) Experimental group: 100% (64/64)
WuweiXiaodu drink combined with tissue engineering full-thickness skin[15]	Matched group: 73.33%(55/75) Experimental group: 86.67%(65/75)

DISCUSSION

Nine different Chinese medicines and western medicines were used to treat diabetic foot. In the above paragraphs, different Chinese medicines and western medicines were compared one by one. Next, this section will analyze 10 articles used to determine the research direction of treating diabetic foot in the future.

In "The Potential of Allogeneic Adipose-Derived Stem cells - Hydrogel Complex for Treating Diabetic Foot Ulcers"[6], the author said research is likely to be the first report to prove Allogeneic Adipose-Derived Stem Cell for the effectiveness of the treatment of diabetic foot ulcers. So, the study has limitations, the action mechanism of allogeneic adipose-derived stem cells still need to be further confirmed. In the study of short-duration hyperbaric oxygen therapy[7], the author found that the glucose metabolism and the mechanism of improving human renal function were still unclear, and further studies were needed to determine the effect of short-duration hyperbaric oxygen therapy on diabetic foot ulcer patients. When using the xenogeneic (porcine) acellular dermal matrix to repair diabetic foot ulcers[8], it can not only shorten the wound healing time, reduce the number of dressing changes, but also reduce the psychological and economic burden of patients and reduce the infection rate. At the same time, it has wide sources, simple operation, and low price, and is worthy of clinical promotion. In the study of alprostadil[9], it has been determined that alprostadil has a better clinical effect and higher safety. Research shows that alprostadil is worthy of extensive application in clinical practice. In the process of studying salvia miltiorrhiza polyphenols for injection and collagen sponge[10], the direct therapeutic effect of salvianolic on diabetic foot still needs further study, but it can improve microcirculation, prevent microthrombosis, regulate vascular endothelial dysfunction and other effects have been able to play a positive role in the treatment of diabetic foot. The combination of salvianolic and collagen sponge played an active role in the treatment and healing of diabetic foot.

In the process of studying of the Taohong Siwu Decoction[11], it has proved flavoured Taohong Siwu Decoction combined thioctic acid injection on diabetic foot has good effect, but the author use samples is limited, did not add the diabetic foot higher severity of patients, so in further research, more data are needed to determine the curative effect of Taohong Siwu Decoction. In the two articles of Simiao Yong an Decoction, Jia Wei Simiao Yong an Decoction can improve the microvascular lesions of diabetic foot by repairing the damaged intima of arteries[12], inhibiting inflammation[13] , and so on, so that diabetic foot can be relieved. However, the literature on Simiao Yong 'an Decoction is still very limited, and the molecular

mechanism of Simiao Yong 'an Decoction remains to be further studied. In the study of Huangqi Guizhi Wuwu Tang[14], it was proved that Huangqi GuizhiWuwu drink could improve the vascular function and hemodynamics of the lower extremities, reduce the injury of vascular endothelial cells, and thus play a role in alleviating the progression of diabetic lower extremity vascular diseases. It is worthy of clinical promotion and application of such drugs. In the process of studying Wuwei Xiaodu drink combined with tissue engineering full-thickness skin[15], it has been determined that it can improve the efficacy, improve the patient's condition and play an anti-inflammatory role without obvious adverse reactions. Therefore, it is a drug worthy of clinical promotion.

CONCLUSIONS

The purpose of the scoping review is to review the general situation of a certain research field, based on this paper; the principal contradiction discussed in this paper is comparing the researches of partial traditional Chinese medicine and western medicine treatment of the diabetic foot. Through studied and thought of these ten pieces of literature, some problems emerged obviously. The first problem was that the literature of diabetic foot in China was deficient. On the one hand, the quantity of literature in China may be considerable; on the other hand, the quality was dissatisfactory. These were two pieces of literature that had some statistical errors; both of these two pieces of literature were written by Chinese researchers. Proportionately, this kind of error maybe not only existed in the 10 literature but had a big amount in the published literature in China. The second problem was that the research of diabetic foot in Asia was not enough. According to the approach of PUBMED searches, a total of 60 articles were excluded from 33 because of geographical conditions. The third problem was that most of the literature that meets the requirements of this theme was cited fewer times, even some literature hasn't been cited before. That confirmed the lack of research on diabetic foot in Asia from another perspective and the low quality of that literature. To sum up, this scoping review proves that there was still a big loophole in the quality of research on diabetic foot in Asia.

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AUTHOR'S CONTRIBUTION

Wang X: writing original draft, methodology, investigation. **Wang Y:** formal analysis, data curation, conceptualization. **Yu H:** writing, review and editing. **Aslam MS:** formal analysis. All authors read and approved the final manuscript for publication.

DATA AVAILABILITY

Data will be made available on request.

CONFLICT OF INTEREST

No conflict of interest associated with this work.

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