

TRADITIONAL CHINESE MEDICINE COMPOSITION, PREPARATION METHOD AND APPLICATION THEREOF

FIELD OF TECHNOLOGY

[0001] The present invention relates to the technical field of rash treatment, and particularly to a traditional Chinese medicine composition, preparation method and application thereof.

BACKGROUND

[0002] At present, the expected annual incidence and mortality rates of colorectal cancer rank among the highest for malignant tumors, and both are showing a significant upward trend. Recent studies have identified the epidermal growth factor (EGF) signaling pathway as a key target pathway in tumor therapy. Monoclonal antibody cetuximab, which targets the epidermal growth factor receptor (EGFR), is widely used for the treatment of various solid tumors such as metastatic colorectal cancer, non-small cell lung cancer, and squamous cell carcinoma of the head and neck. However, rash is a common cutaneous adverse reaction to cetuximab injection, with an incidence rate of over 80%, characterized by acneiform lesions, causing distress to patients and even affecting the smooth progress of treatment. Currently, the treatment methods for cetuximab-induced rash include topical antibiotics (such as fusidic acid), corticosteroids (such as hydrocortisone), moisturizers, oral antibiotics (such as doxycycline), short-term corticosteroids and antihistamines, as well as supportive treatments like photoprotection and immunomodulators. However, these methods are mainly symptomatic treatments with limited efficacy and are difficult to reverse cutaneous toxicity. Some treatments may cause side effects with long-term use, such as skin thinning from corticosteroids and antibiotic resistance from antibiotics, leading to poor patient compliance. It is evident that current approaches lack targeted prevention and treatment for EGFR inhibitor-induced cutaneous toxicity, and preventive measures are insufficient.

The treatment process is complex and costly, resulting in many patients discontinuing therapy due to insufficient efficacy or adverse reactions, which affects their quality of life and anticancer outcomes.

[0003] For example, Chinese Patent Publication No. CN113350438A discloses a traditional Chinese medicine composition for treating rash, which includes the following raw materials in parts by weight: 12–18 parts *Portulaca oleracea*, 8–10 parts green Sichuan pepper, 6–12 parts *Atractylodes*, 7–11 parts *Saposhnikovia divaricata*, 28–32 parts mirabilite, 8–12 parts alum, 14–16 parts *Forsythia suspensa*, 8–10 parts raw *Platycladus orientalis* leaves, and 3–7 parts scallion white. However, this traditional Chinese medicine composition demonstrates limited therapeutic effect in practical applications and has certain limitations. Additionally, Chinese Patent Publication No. CN118717905A discloses the use of a traditional Chinese medicine composition in the preparation of a medicament for treating skin diseases. This composition consists of concentrated water buffalo horn powder, moutan bark, *Scrophularia ningpoensis*, raw gypsum, *Imperata cylindrica* root, *Gentiana macrophylla*, *Coptis chinensis* tablets, roasted peach kernel, dried *Dendrobium*, honeysuckle, safflower, and raw *Rehmannia glutinosa*. Similarly, this traditional Chinese medicine composition is insufficiently effective in treating cetuximab-induced rash in practical applications. Therefore, there is an urgent need for a novel treatment regimen that is safe, effective, highly targeted, and economically viable to address the problem of rashes caused by cetuximab injection.

SUMMARY

[0004] The main objective of the present invention is to provide a traditional Chinese medicine composition, its preparation method, and applications, aiming to solve the technical problem of poor efficacy of existing traditional Chinese medicine compositions in treating rashes caused by cetuximab injection.

[0005] To achieve the above objective, the present invention provides a traditional Chinese medicine composition comprising *Taraxacum mongolicum* (dandelion), *Sophora flavescens*, *Lonicera japonica* (honeysuckle), *Paeoniae Radix Rubra* (red peony root), and *Kochia scoparia* fruit, wherein, by weight, dandelion is 20–30 parts, *Sophora flavescens* is 20–30 parts, honeysuckle is 30–100 parts, red peony root is 10–30 parts, and *Kochia scoparia* fruit is 20–30 parts.

[0006] Optionally, by weight, dandelion is 30 parts, *Sophora flavescens* is 30 parts, honeysuckle is 30 parts, red peony root is 30 parts, and *Kochia scoparia* fruit is 30 parts.

[0007] In addition, to achieve the above objective, the present invention further provides a preparation method for the aforementioned traditional Chinese medicine composition, comprising the following steps:

[0008] Step 1: Weigh dandelion, *Sophora flavescens*, honeysuckle, red peony root, and *Kochia scoparia* fruit according to the preset weight ratio, place them in a clean container, and add cold water to soak, allowing the herbs to fully absorb water;

[0009] Step 2: Pour the soaked herbs together with the soaking liquid into a decoction pot, add cold water with a volume of V_1 so that the water covers the herbs by 2–3 cm, then decoct for 1.5–3 hours. After decoction, filter the herbal residue with gauze and collect the decoction, with the volume of the decoction being V_2 , where V_2 is 15–25% of V_1 ;

[0010] Step 3: Subject the decoction to a second decoction for 30 minutes to concentrate the volume to V_3 , obtaining the secondary decoction, where V_3 is 20% of V_2 ;

[0011] Step 4: Cool the secondary decoction to room temperature, allow it to stand and precipitate, then filter to remove residual impurities, collect the clarified decoction, and refrigerate for later use.

[0012] Optionally, in step 1, the soaking time is 1 hour.

[0013] Optionally, in step 2, the decoction procedure is to first bring to a boil over high heat, then switch to low heat to maintain a gentle simmer.

[0014] Optionally, in step 3, the second decoction is performed over low heat to maintain a gentle simmer, facilitating the concentration of active ingredients.

[0015] Optionally, in step 4, fine gauze or a decoction filter is used for filtration.

[0016] In addition, to achieve the above objective, the present invention further provides the use of the above traditional Chinese medicine composition in the preparation of a medicament for treating rashes caused by cetuximab injection.

[0017] Optionally, the dosage form of the medicament is liquid.

[0018] In addition, to achieve the above objective, the present invention further provides the use of the traditional Chinese medicine composition in the preparation of a medicament for treating oral ulcers.

[0019] Beneficial Effects:

[0020] The present invention adopts a predetermined proportion of honeysuckle, dandelion, *Sophora flavescens*, red peony root, and *Kochia scoparia* fruit, with heat-clearing and detoxifying, cooling blood and removing dampness, reducing swelling and relieving itching as the core therapeutic effects, targeting the pathogenesis of cetuximab-induced rash. Through sequential operations such as soaking, decoction, concentration, and filtration, and by providing standardized and reproducible preparation processes—such as the soaking time of herbs, decoction conditions, concentration ratio, and specific parameters of the filtration step—the invention ensures maximum extraction rate of active ingredients and stability of efficacy. The entire production process is environmentally friendly and feasible, avoids the use of chemical additives, offers low cost, and is suitable for large-scale industrial promotion. Compared with existing treatment methods, it has comprehensive advantages in terms of efficacy, safety, and cost-effectiveness.

BRIEF DESCRIPTION OF THE DRAWINGS

[0021] FIG. 1 is a schematic flow diagram of an embodiment of the preparation method for the traditional Chinese medicine composition of the present invention;

[0022] FIG. 2 is an image of the affected area after cetuximab injection in a patient;

[0023] FIG. 3 is an image showing the recovery of the affected area after one week of applying the traditional Chinese medicine composition of the present invention in the patient from Figure 2.

DESCRIPTION OF THE EMBODIMENTS

[0024] It should be understood that the specific embodiments described herein are merely for illustrating the present invention and are not intended to limit the invention.

[0025] The traditional Chinese medicine composition prepared according to the present invention is used to treat rashes caused by cetuximab injection. Such acneiform rashes and other skin diseases are caused by the invasion of wind, dampness, heat, and toxic pathogens, mainly due to lung heat and blood heat as well as damp-heat in the gastrointestinal tract. The treatment focuses on cooling the blood, clearing lung heat, and detoxification. The traditional Chinese medicine composition comprises dandelion, *Sophora flavescens*, honeysuckle, red peony root, and *Kochia scoparia* fruit. Honeysuckle is a commonly used Chinese medicinal material, cold in nature and sweet in taste, entering the lung, stomach, and large intestine meridians. It has the effects of clearing heat and detoxifying, dispersing wind-heat, and is rich in organic acids, volatile oils, and flavonoids, with antibacterial, antiviral, and immunomodulatory properties. The human subcutaneous blood vessels are abundant, and topical application allows the medicine to penetrate through the skin, directly reach the meridians, and integrate into body fluids to exert its meridian-targeting effects. Dandelion, *Sophora flavescens*, red peony root, and *Kochia scoparia* fruit are also commonly used for clearing heat and detoxifying, drying dampness, and relieving itching. Therefore, the formula of the present invention is composed of pure Chinese medicinal materials in a rational proportion, in line with the monarch-minister-assistant-courier principle of traditional Chinese medicine and modern pharmacology. The combined use of dandelion, *Sophora flavescens*, honeysuckle, red peony root, and *Kochia scoparia* fruit achieves the effects of clearing heat and detoxifying, cooling blood and removing dampness, relieving itching and reducing swelling. It is mainly used for rashes and related symptoms caused by damp-heat and toxic pathogens, such as erythema, pruritus, papules, and burning sensation, and also improves local microcirculation, repairs the skin barrier, and alleviates inflammation. The synergistic action of the above medicinal materials can solve skin and related problems caused by damp-heat and blood heat.

[0026] Furthermore, by weight, the traditional Chinese medicine composition comprises 20–30 parts dandelion, 20–30 parts *Sophora flavescens*, 30–100 parts honeysuckle, 10–30 parts red peony root, and 20–30 parts *Kochia scoparia* fruit; preferably, 30 parts dandelion, 30 parts *Sophora flavescens*, 30 parts honeysuckle, 30 parts red peony root, and 30 parts *Kochia scoparia* fruit. More preferably, 20 parts dandelion, 20 parts *Sophora flavescens*, 50 parts honeysuckle, 15 parts red peony root, and 20 parts *Kochia scoparia* fruit; or 25 parts dandelion, 25 parts *Sophora flavescens*, 100 parts honeysuckle, 10 parts red peony root, and 25 parts *Kochia scoparia* fruit.

[0027] Furthermore, the present invention also proposes a preparation method for the above traditional Chinese medicine composition. Refer to Figure 1. The method includes the following steps:

[0028] Step 1: Weigh dandelion, *Sophora flavescens*, honeysuckle, red peony root, and *Kochia scoparia* fruit according to the preset weight ratio, place them in a clean container, and add cold water to soak, allowing the herbs to fully absorb water; preferably, the soaking time is 1 hour.

[0029] Step 2: Pour the soaked herbs together with the soaking liquid into a decoction pot, add cold water with a volume of V_1 so that the water covers the herbs by 2–3 cm, then decoct for 1.5–3 hours. After decoction, filter the herbal residue with gauze and collect the decoction, with the volume of the decoction being V_2 , where V_2 is 15–25% of V_1 ; the decoction procedure is to first bring to a boil over high heat, then switch to low heat to maintain a gentle simmer.

[0030] Step 3: Subject the decoction to a second decoction for 30 minutes to concentrate the volume to V_3 , obtaining the secondary decoction, where V_3 is 20% of V_2 ; the second decoction is performed over low heat to maintain a gentle simmer, facilitating the concentration of active ingredients.

[0031] Step 4: Cool the secondary decoction to room temperature, allow it to stand and precipitate, then filter to remove residual impurities, collect the clarified decoction, and refrigerate for later use. Fine gauze or a decoction filter is used for filtration.

[0032] The present invention adopts a predetermined proportion of honeysuckle, dandelion, *Sophora flavescens*, red peony root, and *Kochia scoparia* fruit, and through sequential operations such as soaking, decoction, concentration, and filtration, ensures the efficient extraction of active ingredients and the stability of the formulation. After decoction, the above medicinal materials are used to prepare a decoction for soaking, which is then applied externally to the corresponding area of the patient. The principle is based on the heat-clearing, detoxifying, anti-inflammatory, and antipruritic effects of components such as dandelion, *Sophora flavescens*, and honeysuckle. The above preparation method allows the active ingredients produced after processing the medicinal materials to act directly on the skin surface, rapidly alleviating symptoms such as redness and itching, effectively improving inflammatory reactions of the skin, and accelerating the healing process. Furthermore, the formula targets the mechanisms of skin barrier damage, immune dysregulation, and inflammation induced by EGFR inhibition, providing significant symptom relief, reducing the risk of treatment interruption due to rash, and markedly improving patient compliance and quality of life. The prepared decoction can be used to treat rashes caused by drugs such as cetuximab, and can also be used to treat oral ulcers.

[0033] Furthermore, the clarified decoction thus prepared can be applied in the treatment of rashes caused by drugs such as cetuximab. The specific usage method is as follows:

[0034] Use clean, soft medical gauze or absorbent cotton, cut into pieces suitable for the size of the affected area, ensuring complete coverage of the rash. Completely soak the gauze or absorbent cotton in the decoction, gently wring out after fully absorbing the decoction to keep it moist but not dripping. Initially, apply 3 times per day, 1 hour each time; if symptoms improve, reduce to 2 times per day, 1 hour each time; during the stabilization period, apply once per day, 1 hour each time; subsequently, apply once every 3 days, 1 hour each time. One week constitutes one treatment course. During wet application, keep the gauze moist; if it dries out, replace or re-soak it in the decoction.

[0035] Example 1: Tong, male, 54 years old, developed multiple scattered rashes on the head, face, and neck after three infusions of cetuximab injection, involving less than 10% of the body surface area, without pruritus.

After applying the traditional Chinese medicine composition of the present invention, the rash improved by approximately 30% after 1 day, 50% after 2 days, 70% after 5 days, and 90% after 1 week.

[0036] Example 2: Zhang, male, 45 years old, after five infusions of cetuximab injection, developed multiple scattered rashes on the head, face, neck, chest, and back, covering more than 30% of the body surface area, accompanied by pruritus. After applying the Chinese medicine composition of the present invention, the rash improved by approximately 20% after one day, 30% after two days, 60% after five days, and 80% after one week.

[0037] Example 3: Leng, female, 60 years old, after four infusions of cetuximab injection, developed multiple scattered rashes on the head, face, chest, and both upper limbs, covering 10% to 30% of the body surface area, accompanied by pruritus. After applying the Chinese medicine composition of the present invention, the rash improved by approximately 20% after one day, 50% after two days, 80% after five days, and 90% after one week.

[0038] Example 4: Wan, male, 60 years old, after four infusions of cetuximab injection, developed multiple scattered rashes on the neck, chest, and both upper limbs, covering 10% to 30% of the body surface area, accompanied by pruritus. After applying the Chinese medicine composition of the present invention, the rash improved by approximately 20% after one day, 50% after two days, 80% after five days, and 90% after one week. Among them, FIG. 2 shows an image of the affected area before treatment, and FIG. 3 shows an image of the affected area after one week of treatment. As can be seen from the figures, there was significant improvement in the patient after application of the above Chinese medicine composition.

[0039] Comparative Example 1

[0040] 50 grams of honeysuckle decocted in water and applied externally. No improvement was observed in the patient after use.

[0041] According to the above Examples 1-3, the Chinese medicine composition of the present invention achieved an improvement rate of greater than 80% after one week of use, with no other side effects observed.

[0042] Furthermore, for the treatment of oral ulcers, the specific method of use is to rinse the mouth with the Chinese medicine composition. This not only effectively reduces inflammation and relieves pain, but also promotes the healing of oral ulcers, improves the repair capacity of the oral mucosa, and achieves symptom relief and accelerated recovery. The principle is that oral ulcers are mostly caused by excessive internal heat and toxins or abnormal immune function. Honeysuckle, dandelion, and red peony root have significant effects in clearing heat and detoxifying, which can relieve the pain and inflammation of oral ulcers.

[0043] In summary, the Chinese medicine composition prepared in this application can effectively treat cetuximab-induced rash through both external application and oral rinsing, and also demonstrates good therapeutic effects on other types of rashes and oral ulcers, thus possessing significant clinical application value.

[0044] It should be noted that, in this document, the terms "comprise," "include," or any other variants thereof are intended to cover non-exclusive inclusion, such that a process, method, article, or system that comprises a list of elements not only includes those elements, but may also include other elements not expressly listed, or may also include elements inherent to such process, method, article, or system. Without further limitations, an element defined by the phrase "comprising a..." does not exclude the presence of additional identical elements in the process, method, article, or system that includes that element.

[0045] The serial numbers of the embodiments of the present invention are for descriptive purposes only and do not represent the merits of the embodiments.

[0046] The above are only preferred embodiments of the present invention and do not limit the scope of the present patent. Any equivalent structural or process modifications made based on the content of the specification and drawings of the present invention, or direct or indirect applications in other related technical fields, shall be included within the scope of patent protection of the present invention.