Examining Serum Biomarkers and Standardised Measures to Measure Changes in Pruritus in Eczema

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Introduction

In traditional Japanese herbal medicine (Kampo medicine) clinics, one of the most common presentations is psoriasis, or itching, which is frequently caused by atopic dermatitis or any other type of eczema. It can be accompanied by a number of symptoms, like trouble sleeping and mental stress and patients have a lower quality of life overall. As a form of integrative medicine, physicians in outpatient Kampo medicine clinics should address issues other than itching while also providing lifestyle guidance and customized Kampo formulations in addition to the standard treatment provided by dermatologists. The traditional diagnoses (called patterns) of the patients, associated symptoms and constitutional aspects should all be taken into consideration when selecting traditional Kampo formulas.

Description

After prescribing Kampo formulas, it is challenging to collect precise and comprehensive follow-up data. Several standardized scales are frequently used in clinical studies to evaluate patient-reported eczema and atopic dermatitis pruritus; Skindex-16, the patient-oriented eczema measure (POEM) and the visual analog scale (VAS) are a few examples. The eczema area and severity index (EASI), serum Th2 allergy markers, peripheral eosinophil counts, total (nonspecific) immunoglobulin E (IgE) levels, lactate dehydrogenase (LDH) levels, thymus and activation-regulated chemokine (TARC) levels and interleukin (IL)-31 levels are additional objective markers that are utilized.

Based on the gut-skin axis or leaky gut concept, it has been reported that increased intestinal permeability affects various symptoms, including atopic dermatitis, pruritus, anxiety and stress, in various chronic diseases, particularly autoimmune diseases. As a result, we also focused on circulating zonulin and diamine oxidase (DAO; associated with decreased tight junction binding in the intestinal epithelial cell pores) as indicators of increased intestinal permeability. formerly known as histaminase), which is a sign of permeability in the small intestine. However, especially after Kampo treatment, it is unclear which scale or parameter is best for evaluating the patients' subjective symptoms and objective findings.

As a result, the goal of this study was to see how outpatients treated with customized Kampo formulas' pruritus symptoms and severity changed using standardized scales and serum biomarkers. Consequently, standardized pruritus scales and several serum biomarkers were used to investigate temporal changes in symptoms and eczema severity in daily Kampo medicine outpatients. Our evaluations were based on how traditional Kampo medicine is

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currently used in Japan. Our goal was to emphasize a "real-world approach," which has become more and more important in recent years.

A Kampo formula was given to the participants for 12 weeks. Following a traditional medicine-based diagnosis, one of the three doctors in charge of the Kampo medicine outpatient clinic examined the participants and prescribed a customized Kampo formula. We did not intend to evaluate the physicians' interrater agreement, so each participant was evaluated by a single physician. In addition to being board-certified Kampo specialists with more than five years of clinical experience following board certification at the Keio University Hospital's Kampo Clinic, the three doctors have held Japan's active biomedicine licenses for more than ten years. Although the recommended daily dose was adhered to, these doctors were free to alter the dosage as they saw fit. During the course of their treatment, the participants were permitted to combine two or more Kampo formulations or to alter the Kampo formulations, depending on their clinical course. Allopathic medications, such as topical glucocorticoids, topical tacrolimus and oral antihistamines, were recommended to be continued for stable patients by the participating physicians, but not oral or injectable glucocorticoids. On the reports of the patients, compliance was noted [1].

As measured by the POEM, 5D and Skindex-16 questionnaires, which contain 7, 8 and 16 items, respectively, as well as an improvement in pruritus (as measured by the VAS), pruritus improved over time. This indicates that participants experienced an improvement in their quality of life. Additionally, we assessed the participants' objective eczema severity using the EASI. From the initial consultation to 12 weeks later, the score showed significant improvement. These findings suggest that Kampo treatment might be a good option for lessening the severity of eczema and pruritus. Outside of Japan, kampo formulas have not been widely distributed; However, our findings suggest that Kampo formulations may be effective against eczema pruritus [2].

With regard to the crude values at each consultation, changes in the crude values and responsiveness, there were moderate or at least weak correlations among the subjective symptom scales—the VAS, POEM, 5D and Skindex-16. Based on these findings, it may be possible to evaluate the patients' subjective symptoms following treatment with Kampo formulas using any or all of these questionnaires. In contrast, there was no relationship found between the EASI and the subjective symptom scales. Our participants had relatively lower EASI scores than those in other phase III trials utilizing nemolizumab (an anti-IL-31 antibody) or dupilmab (an antibody against the IL-4/13 receptor). In addition, when compared to the changes in the scores of the subjective scales, the magnitude of changes in the EASI score was relatively small. However, our findings demonstrated that Kampo formulations may have a concomitant effect on subjective pruritus-related quality of life even in patients with mild or moderate rashes [3].

We were unable to evaluate the efficacy of Kampo formulas or which medicines produced subjective and objective changes because this was an observational study with no comparators and the choice of the Kampo formulas was left to the discretion of specialist doctors. It was not possible to evaluate the significance of selecting the Kampo formula or the differences among experts. Additionally, because the majority of cases had relatively lower scores at the time of the initial examination, it was challenging to evaluate the changes in EASI scores. It was difficult to evaluate other diseases because atopic dermatitis accounted for the majority of the enrolled cases. The power might not be sufficient to demonstrate significant differences in the serum markers due to the small sample size. Lastly, we only measured intestinal hyperpermeability biomarkers in the serum; Therefore, in future research, tissue or feces samples ought to be evaluated [4,5].

Conclusion

After treatment with Kampo formulas, our findings suggested that the VAS, POEM, 5D, Skindex-16 and EASI could be utilized to assess subjective symptoms and eczema severity. Serum IL-31 levels decreased in tandem with these scale changes. The initial value of DAO was correlated with a lower level of IL-31; However, neither the DAO nor the zonulin levels in the serum altered over time. Nevertheless, additional research is required to confirm the findings of the study.

Acknowledgment

None.

Conflict of Interest

No conflict of interest.

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