Editorial

Clinical Trials and Kampo

Clinical trials have become extremely difficult to perform in recent years, even in Western medicine. Strong emphasis is placed on protecting privacy, ensuring proper storage of clinical data and maintaining authenticity without risk of manipulation. Furthermore, it goes without saying that heavy weight is placed on managing sensitive personal information such as genetic information, depending on the data that is handled. In evidence-based medicine (EBM), randomized control trials (RCT) with a high level of evidence are valued, because researchers' bias is not reflected, and subjective evidence can be acquired. In Europe and USA, RCT is thus actively performed. However, in these clinical trials it is necessary to note in particular that the criteria of choosing subject patients will necessarily form a group of subjects who are readily able to participate, and that the trial would be performed under a limited patient. In other words, the problem lies in the fact that cases included in such trials represent only a portion of all patients. Nonetheless, our Kampo specialists wish to answer to doubts by Western doctors of whether Kampo really works (we, personally, do not need such data, because we have no doubt that Kampo is effective). The problem, however, is that Kampo diagnosis is characteristically based on proof and evidence (*sho*), and emphasizes individualization. RCT and similar trials are intrinsically unsuited for evaluating Kampo drugs. To preserve *sho* used for Kampo medicine is difficult to perform clinical trials of Western medicine by Kampo medicine method. One of a clinical study design is to classify the diseases in Western medicine. When performing an RCT under this method, the effects of Kampo drugs are likely to be underestimated, but if RCT could prove effects of them, it would be considered valid to administer Kampo drugs by disease name (that means these diseases exhibit homogenous conditions (*sho*)). On the other hand, studies have also been performed by combining the selection of a disease name and the *sho* concept in Kampo medicine. For example, there are ways to choose patients by physical data, health conditions and the patient's complaints. There are some previous reports proved the efficacy of Kampo drugs by these method.

Now, the question is why Japanese Kampo is able to perform clinical trials at a high level of quality. The greatest reason lies in the consistent and stable extract products made by Japanese pharmaceutical companies. This means that Kampo clinical studies particularly for short-term trials of a few cases could be performed by using Kampo extracts preparations decocted with the same rod and contained same ingredients Additionally, unlike decoctions, extract preparations could be considered drugs that can maintain their quality for a long period (years) if they are stored appropriately. When examining decoctions in a study, it is necessary to unify the quality and amount of herbs, and using the addition and subtraction method would render the study unsuitable for RCT. Severe paying attention also is needed at the method of decoction. In a certain study, it was found that the same decoction prepared at home by a patient had largely varying ingredients on different occasions. While there are apt to be differences in the quality of herbs, even taking this into consideration, it can be said that each patient takes a different decoction every day. Decoction studies thus require extremely careful attention.

To perform clinical studies of Kampo drugs at a high level of quality, we adopt principles that lean toward Western medicine. However, while this has proven that Kampo drugs as a whole have pharmaceutical effects, the largest issue lies in how to apply the interpretation of EBM results to the treatment of individual patients at hand. I offer that concurrently adopting the Kampo concept of *sho* is a possible solution to such individualization, and intend to study examination methods and administration of medicine toward making *sho* reproducible.

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