

Kampo Medicine - Current Research

Can Hypertension be Controlled with Kampo Medicine?

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Introduction

“Whether or not hypertension or high blood pressure can be controlled with Kampo medicines” is an important and interesting question. To this question, studies conducted in the past have provided almost no answers. On the other hand, there are not a few case reports describing the results of its successful control using Kampo medicines. Further there are the results of case-series studies available, although very limited in number. Thus it cannot definitively be said that Kampo medicines have necessarily no effect at all.

Current situation in hypertension treatment with Kampo medicines

Namiki of Chiba University says about the indication of Kampo therapy for hypertension as follows:

[Hypertension for which Western-style medicines are the first-line agents]

- a. Essential hypertension without subjective symptoms
- b. Hypertension with severe complications
- c. Secondary hypertension

[Hypertension for which Kampo medicines has the indication]

- a. Grade I (mild) Hypertension (140-159/90-99mmHg)
- b. Hypertension with an intense psychosomatic tendency (for instance, some cases of white coat hypertension)
- c. Hypertension in the elderly with its accessory symptoms
- d. As a particular case, hypertension complicated by visceral fat obesity

In Kampo therapy that uses conventional extract formulations, the Namiki's standards are regarded as being very common for Japanese practitioners. However, if Kampo practitioners are very able specialists, they could produce much better

performance with decoction formulations.

Hypertension treatment started only when an environment was built to enable the measurement of blood pressure. Thus, it makes sense that hypertension treatment did not exist in ancient China. Fine-tuned delicate treatment of hypertension has eventually become practicable in the present time when blood pressure can be measured with a sphygmomanometer. Furthermore, today disorders caused secondarily by hypertension have become known and various antihypertensive drugs of fine quality have emerged.

As it stands now, Kampo medicines are rarely used “as antihypertensive drugs” in the typical healthcare setting. It is often the case, however, that Kampo medicines have effects on mild hypertension accompanying a variety of symptoms. For the condition under which antihypertensive drugs cannot be used in anticipation of side effects, the use of Kampo medicine needs to be taken into account.

Introduced hereunder is Yoshinori OTSUKA's own case. Otsuka showed, for the first time in Japan, effectiveness and potentiality of hypertension treatment with Kampo medicines.

Experience by Yoshinori OTSUKA (1900-1981)

Yoshinori Otsuka, one of the most distinguished physicians who played a leading role in the Japanese Kampo medicine during a period from the middle to the latter half of the 20th century, realized for the first time that his blood pressure was high when he had fundal hemorrhage. In his days, many things about hypertension were not elucidated as in the present days, and good antihypertensive drugs were seldom available. In such condition, having a visual threat, he devised a formulation and got over the difficulty. There is a well known episode about him as below:

I (Otsuka) began to feel dizzy, sigh in the afternoon, and have hot flashes leading to headache between times from about summer of 1951 when I was 51 years old. In autumn, lowback pain occurred and it became difficult to roll over. Even putting on my socks in the mornings also became painful. At the time, my blood

pressure might have been very high, but I thought that these would go away before long as they were from fatigue, and I continued to see patients as usual.

On March 20 of the following year, it was raining. I was not able to see things clearly and thought it unusual. But I persuaded myself to think that it was so because the weather was not clear and I was still uncaredful. It was in the morning of May 31; when I looked at words on a framed picture from the bed's position, something was apparently strange. With the right eye closed, I was able to see almost nothing. Although it was very odd, I still did not realize it was ocular fundal hemorrhage.

However, I felt uneasy about it and visited a nearby ophthalmologist. The physician told me that it was severe fundal hemorrhage, bleeding was seemingly taking place for quite a long time, and a part of the blood formed connective tissues. Everything was too late. The eyesight did not get recovered but rather deteriorated at an accelerating pace. Two months later, I was unable to distinguish whether it was light or dark.

The records of my blood pressure in those days showed no records till April 4th, 147/90mmHg on April 5, April 10 175/105mmHg, April 15 158/90mmHg, and May 25 170/104mmHg. The highest levels were marked on April 10 and May 25. What concerned me was the high diastolic pressure.

During that time, I used the formulations such as *hachimijiogan*, *orengedokuto*, *yokukansan*, *shakanzoto*, *saikokaryukotsuboreito*, and *kairosan*. However, they were unable to stop the progress of the condition. So, after thinking a lot, I created my own new formulation with the composition of *shimotsuto* plus *Uncaria Uncis Cum Ramulus*, *Astragali Radix*, and *Phellodendri Cortex*.

I started using my formulation on May 30. The blood pressure on the day was 140/90mmHg. Then 126/86mmHg on June 3, 136/86mmHg on June 4, 114/80mmHg on June 5, and 120/80mmHg on June 6 – the systolic pressure became below or above 120mmHg, and the diastolic pressure also became below or above

80mmHg.

When I told Dr. Baba, then Prime Minister's doctor, about this, he named the formulation as *shichimotsukokato*.

This Otsuka's experience has assured Japanese Kampo physicians that hypertension can be controlled with Kampo medicines. After this, many cases were reported and many studies were conducted, including the one by Mori and Miyazaki. Their study reports only successful cases. I will present their study, although not RCT, as it will serve as a useful reference for future studies.

Study by Mori and Miyazaki

Mori and Miyazaki selected the patients with hypertension based on the following criteria for conducting a study. They added their consideration to their study.

The subjects were 57 patients with hypertension (male 17 cases, female 40 cases, average age 66.6) who visited their clinics during a month from July 1, 2003 to July 31, 2003, had treatment with Kampo medicines alone and achieved the target blood pressure levels.

Mori and Miyazaki studied on classification of hypertension, risk classification Table1, improvement of associated symptoms, dosing pattern, dosing method, and side effects based on the "Hypertension Treatment Guidelines 2000" prepared by the Japanese Society of Hypertension. Target blood pressure levels were set at below 130/85mmHg for young adults, the middle aged, and individuals with accompanying diabetic disease; in the elderly, below 140/90mmHg for 60s, below 150/90mmHg for 70s, and 160/90mmHg for 80 or more.

The age distribution of the subjects was 45 to 87, and the elderly of 60 or more accounted for 71.9%. (Table2)

Table 1 Classification of Hypertension & Risk Classification

Risk factors other than blood pressure of classification of hypertension	Mild hypertension (140-159/90-99mm Hg)	Moderate hypertension (160-179/100-109mmHg)	Severe hypertension ($\geq 180/\geq 110$ mmHg)
No risk factors exist.	Low risk	Intermediate risk	High risk
Risk factors other than diabetes exist.	Intermediate risk	Intermediate risk	High risk
Diabetes or organ disorder or cardiovascular disease exists.	High risk	High risk	High risk

Classification of hypertension, risk classification, and details of complications of the subjects are shown in Table 3. Under the classification of hypertension, there were 50 subjects in the mild group (87.7%), 7 in the moderate group, and nil in the

Table 2 Age Distribution of Subjects

45 to 59 years old:	16 subjects (male 5/female 11)
60 to 69 years old:	20 subjects (male 6/female 14)
70 to 79 years old:	15 subjects (male 4/female 11)
80 to 87 years old:	6 subjects (male 2/female 4)

severe group. In terms of the risk classification, 38 subjects were classified under the low risk group (66.7%), 14 under the moderate risk group, and 5 under the high risk group. There were complications in 18 subjects or 30% of all subjects, including neuropsychiatric disease in 4 subjects and hyperlipidemia in 3.

Table 3 Details of Subjects

Classification of Hypertension:
Mild- 50 subjects / Moderate-7 subjects/ Severe-not applicable.
Risk Classification:
Low risk-38 subjects / Moderate risk-14 subjects / High risk-5 subjects
Complication of Other Diseases:
Neuropsychiatric disorder-4 subjects / Hyperlipidemia-3 subjects / Diabetes-2 subjects / Cardiac disease-2 subjects / Bronchial asthma-2 subjects / Others – 5 subjects

Improvement factors of collateral symptoms associated with the treatment with only Kampo medicine are shown in Table 4. The number of subjects who had associated symptoms was 56, except for one. Associated symptoms were mostly headaches, stiffness in the nape, stiff shoulders, and insomnia, and the severity of these symptoms improved by more than half in all subjects, and the rate of improvement from “substantially improved” to “resolved” was 82.9%. Longer the administration, greater the improvement.

Table 4 Improvement Factors of Collateral Symptoms Associated with Treatment with Kampo Medicines alone

Symptoms improved by nearly half (The condition became 5 from 10):		
Male-2 subjects / Female-4 subjects		Total 6 subjects
Symptoms substantially improved (The condition became 2-4 from 10):		
Male-9 subjects / Female-16 subjects		Total 25 subjects
Symptoms mostly resolved – Resolved (The condition became 0-1from 10):		
Male-5 subjects / Female 20 subjects		Total 25 subjects

* Assuming the condition before the use of Kampo medicines is 10, degrees of improvements with Kampo treatment are shown in figures.

Dosing pattern is shown in Table 5. Group A, or the group of Kampo medicines alone from the outset, had 32 subjects (56%). Group B, or the group that

initially used Kampo medicines and Western-style medicines in combination but later changed to Kampo medicines alone, had 13 (23%). The severity of disorders in many of the subjects in Groups A and B was mild with a high or intermediate risk. And Group C, the group that discontinued the previously prescribed Western-style medicine and switched to Kampo medicines, had 12 (21%).

Table 5 Dosing Pattern

Group A (The group that used Kampo medicines alone):
32 subjects /56% (Male 9 : Female 23)
Group B (The group that initially used Kampo medicines and Western-style medicines in combination and later changed to Kampo medicines alone):
13 subjects / 23% (Male 5 : Female 8)
Group C (The group that discontinued the previously prescribed Western-style medicines and switched to Kampo medicines):
12 subjects / 21% (Male 3 : Female 9)

Details of used formulations are shown in Table 6. Varieties of formulations as many as 21 were used from *shichimotsukokato* for 16 subjects to *shimbuto* for 11, *chotosan* for 10 and *orengedokuto* for 10.

Table 6 Used Formulations

1: <i>shichimotsukokato</i> for 16 subjects (Male 1 vs. Female 15)
2: <i>shimbuto</i> for 11 subjects (Male 2 vs. Female 9)
3: <i>chotosan</i> for 10 subjects (Male 4 vs. Female 6)
4: <i>orengedokuto</i> for 10 subjects (Male 5 vs. Female 5)
5: <i>hachimijiogan</i> for 9 subjects (Male 4 vs. Female 5)
Other 16 formulations including <i>keishibukuryogan</i> for 4 subjects, and <i>bofutsushosan</i> for 2 subjects.

These patients began to take Kampo medicines at some point due to hypertension and their blood pressure thereby gradually lowered and reached the normal pressure range when the investigation was conducted. So, the administration period was inconsistent and the patients did not clearly

say how soon the effect appeared.

However, the result of this study suggests that the application of Kampo medicine alone is useful in the elderly/mild hypertension/low risk. These are mostly matches with Namiki's criteria.

Study by Nagata, et al.

Nagata administered Extract of *chotosan* 7.5g/day to 24 patients with essential hypertension (age 49.2±5.6) for two weeks and observed changes before and after the administration in subjective symptoms and changes in the results of Shellong's tilting test.

Changes of statistical significance ($p < 0.05$) were observed in systolic blood pressure after the standing position for 10 minutes (before→after; 192±25→178±14), diastolic blood pressure in the recumbent position (98±3→86±7), diastolic blood pressure after the standing position for 10 minutes (104±10→99±11), cardiac index in the recumbent position (3.8±1.0→4.1±0.8), total peripheral resistance in the recumbent position (1960±410→1450±440), and total peripheral resistance after the standing position for 10 minutes (2160±620→1720±510).

Items of significance in subjective symptoms were concern about patient's own health, appetite, sleep, pain, sex life, fulfillment of daily life, and fulfillment of family life.

Nagata conducted one more similar study with his collaborator, in which Extract of *chotosan* 7.5g/day was

administered to 72 patients with essential hypertension (age 52.6 ± 7.5) to observe changes in subjective symptoms and in Shellong's tilting test. They obtained similar results as those shown above.

Summary

Some of the studies conducted in Japan on hypertension treatment with Kampo medicines were introduced as above. These studies show that blood pressure often lowers secondarily when Kampo medicines are administered to target symptoms. This does not make a denial of the hypertension treatment with antihypertensive drugs, but rather suggests that a combination use of Kampo medicines and antihypertensive drugs will provide better results. This also indicates that mild hypertension can possibly be controlled by making better use of Kampo medicines. However, extract preparations have their limits. If better results are required, decoction preparations need to be used. *Shichimotsukokato* that Otsuka used for his own treatment was also in the form of decoction.

References

- 1) NAMIKI T.: Junkanki shikkan (*cardiovascular diseases*), Kamp Chiryō Manual, Gendai Shuppan Planning Co.,Ltd. 2010
- 2) OTSUKA Y.: Kampo Shinryō Jissai, Sogen-Sha
- 3) MORI K., MIYAZAKI R.: Study of Cases of Hypertension that could successfully controlled with Kampo Medicines alone. *Journal of Kampo Medicine* VOL52 No.6 29-36 2005
- 4) NAGATA K., OKAMOTO A., KAMANO Y., et al.: *Chotosan* niyoru Koketuatsu no Chiryō to QOL (Jinsei no Shitsuteki Level). *Journal of Traditional Medicines*, 6:426-427, 1989.
- 5) NAGATA K., HARA K., KINOSHITA T., et al.: Koketsuatsu niokeru QOL to *Chotosan* no Kouka. *Journal of Traditional Medicines*, 8:252-253, 1991.