

2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)**11. Gastrointestinal, Hepato-Biliary-Pancreatic Diseases****Reference**

Oh-oka H. The clinical usefulness of gargling with hangeshashinto for treatment of oral mucositis caused by sunitinib in patients with metastatic renal cancer. *Kampo Medicine* 2018;69: 1-6 (in Japanese with English abstract). Ichushi Web ID: 2018142526 [J-STAGE](#)

1. Objectives

To evaluate the clinical usefulness of gargling with hangeshashinto (半夏瀉心湯) for treatment of oral mucositis caused by sunitinib in patients with metastatic renal cancer.

2. Design

Randomized controlled trial (RCT).

3. Setting

One hospital (department of urology) (the author belongs to National Hospital Organization, Kobe Medical Center), Japan.

4. Participants

Twenty-two patients (11 men and 11 women) with metastatic renal cancer whose global response to sunitinib was assessed as “stable disease (SD) or better” as of January 2016, and who had sunitinib-induced oral mucositis. These participants had onset of oral mucositis despite oral hygiene instructions (e.g., tooth brushing, gargling, caries treatment) given to all patients before the start of oral sunitinib therapy.

5. Intervention

Arm 1: Gargling with TSUMURA Hangeshashinto (半夏瀉心湯) Extract Granules 2.5 g three times daily, for 30 seconds after each meal, followed by refraining from eating and drinking for 30 minutes (n=12).

Arm 2: Non-gargling group (n=10).

6. Main outcome measures

Changes from baseline in the Karnofsky Performance Status (KPS), oral mucositis grade, body weight, albumin level, hemoglobin level, global self-assessment (GSA) of eating status, etc. in the treatment cycle with highest severity of oral mucositis were analyzed.

7. Main results

Patient baseline characteristics did not statistically differ between the two groups. In Arm 1, the KPS ($P=0.046$), oral mucositis grade ($P=0.002$), and GSA ($P=0.002$) significantly improved after the start of treatment, but body weight, albumin level, and hemoglobin level showed no significant changes. In Arm 2, the oral mucositis grade was not significantly improved, while GSA ($P=0.005$) significantly improved, but the KPS ($P=0.007$), body weight ($P=0.005$), albumin level ($P=0.005$), and hemoglobin level ($P=0.005$) significantly decreased.

8. Conclusions

Gargling with hangeshashinto is very effective for treating oral mucositis associated with sunitinib for metastatic renal cancer.

9. From Kampo medicine perspective

None.

10. Safety assessment in the article

No clinically relevant adverse effects were observed.

11. Abstractor's comments

This clinical study is of interest in that it was designed to determine the effect of gargling with hangeshashinto on oral mucositis associated with sunitinib for metastatic renal cancer. This article failed to specify whether or not the gargled hangeshashinto was ingested after gargling. This study makes us wonder whether similar results can be obtained with irinotecan or the fluorinated pyrimidine class of anticancer drugs, as with the multi-kinase inhibitor sunitinib. Further study results from more patients are awaited.

12. Abstractor and date

Kato Y, 1 September 2019.