Task Force for Evidence Reports, the Japan Society for Oriental Medicine

Note) The quality of this RCT has not been validated by the EBM committee of the Japan Society for Oriental Medicine. 2. Cancer (Condition after Cancer Surgery and Unspecified Adverse Drug Reactions of Anti-cancer Drugs)

References

Tsunezuka Y. The efficacy of bakumondoto on prolonged cough after lung cancer surgery. *Kampo to Meneki Arerugi (Kampo and Immuno-Allergy)* 2008; 22: 43-55 (in Japanese with English abstract). Tsunezuka Y. The efficacy of bakumondoto on prolonged cough after lung cancer surgery — QOL analysis with 36-Item Short Form (SF-36) v2^{*}.. *Progress in medicine* 2010; 30: 100-1 (in Japanese). MOL, MOL-Lib

1. Objectives

To evaluate the efficacy of bakumondoto (麦門冬湯) on improvement in cough after lung cancer surgery.

2. Design

Randomized controlled trial using sealed envelopes for allocation (RCT-envelope)

3. Setting

One hospital, Japan.

4. Participants

Thirty-two outpatients with prolonged cough for more than three weeks after lung cancer surgery, who were recruited between November 2005 and December 2007. Patients with apparent respiratory disease or antitussive drug use were excluded.

5. Intervention

The duration of administration was 4 weeks.

Arm 1: Tsumura Bakumondoto (麦門冬湯) Extract Granules (TJ-29) 9.0 g/day, n=17.

Arm 2: Medicon (dextromethorphan) 90 mg/day, or Astomine (dimemorfan) 60 mg/day, n=15.

6. Main outcome measures

Cough points, QOL score (36-Item Short Form [SF-36] v2 Health Survey).

7. Main results

Cough points showed significant decrease after 5 days of administration in arm 2, and after 3 days in arm 1 (P<0.05). Also, cough frequency was significantly less in arm 1 compared to arm 2 after 6 days of treatment until the end of the 4-week observation period (P<0.05). As for effect of improvement in cough, cough points decreased from 7 to 3.76 in arm 1, and from 7.2 to 4.58 in average after 4 weeks of administration. Cough disappeared in 3 patients in arm 1. Of 5 non-responders in arm 1, 3 showed improvement with proton pump inhibitor (PPI). QOL scores of the patients at the baseline were much lower than that of national standard. After the treatment, arm 2 showed improvement only in physical components, whereas arm 1 showed statistical improvements in general health, in both physical and mental components; mental health was significantly better in Arm 1 compared to arm 2.

8. Conclusions

Bakumondoto is effective in improving not only prolonged cough after lung cancer surgery, but also mental health components in QOL, when compared with Medicon or Astomine.

9. From Kampo medicine perspective None.

10. Safety assessment in the article

Not mentioned.

11. Abstractor's comments

Tsunezuka (2008) demonstrated that bakumondoto not only has efficacy in reducing cough frequency in cases of prolonged cough after lung cancer surgery but also has efficacy in reducing psychological stress. Bakumondoto treatment eliminated the symptoms of cough in 3 patients and use of PPI improved cough in 3 patients; the high rates were interesting. Another report by Tsunezuka (2010) based on this study, which added three months to the registration period and two patients to arm 2, also shows the same efficacy.

12. Abstractor and date

Fujisawa M, 1 June 2010, 14 January 2011, 31 December 2013