The use of Chinese Herbs (CH) Formula in patients with advanced lung cancer: a feasibility study

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Conflict of Interest: None

Introduction

Background

- Unregulated and unsupervised CH use among patients with cancer is increasing.
- Despite numerous prior studies there are no standardized CH formula available for treatment of symptoms in cancer patients.
- There is an urgent need to better define both the safety and potential benefits of CH in patients undergoing cancer treatment.

The aims of the study:

- To evaluate the interest in CH in lung cancer patients
- To determine prevalence of adverse events due to a specific standardized CH formula
- To assess if CH leads to improved quality of life

Materials and Methods

Study design:

- A single-arm, prospective 6-week intervention study
- A University teaching hospital and tertiary referral center (Peter Brojde Lung Cancer Centre (PBLCC), Jewish General Hospital, Montreal).

Inclusion criteria:

- Confirmed stage 4 NSCLC
- ECOG PS 0-2
- Not already using CH
- Not taking TKI
- Stable after at least one cycle of chemotherapy or have no plans to start treatment within the next 6 months

Intervention

- The CH formula contained 23 herbs and was based on the classical **Shu Yu Wan (*Chinese Yam Pill*)** formula
- The herbs for this formula were imported from Sun Ten Pharmaceutical Company in Taiwan and manufactured as a single batch by BEMA Botanicals
- BEMA Botanicals also performed testing for potentially toxic contaminants as required by Health Canada's Good Manufacturing Practices
- Take CH dose (1 sachet or 4 capsule) three times a day.

Tools

- Symptom and adherence diary
- CBC and Biochemistry every 2 weeks
- FACT-L and ESAS every 2 weeks

Results

Interest, Adherence & Completion rate

Adverse events

- In total 7/15 patients reported 26 adverse events (AE)
- All grade 1 or 2 and most (22/26, 85%) were grade 1
- The majority of AEs reported were pre-existing and occurred in patients (6/7) who were receiving active treatment and thus deemed not related to CH
- Only 3/26 AEs were deemed related to CH and occurred in only one patient: nausea, dermatitis and eye infection
- No evidence of liver toxicity on blood tests

Quality of Life

Changes in Trial Outcome Index (FACT-L)

- Significant improvement in Physical well-being (p=0.03) and Trial Outcome index (TOI) (p=0.04)
- TOI is a composite measure of the functional well-being, (FWB), PWB and the lung cancer symptoms subscale (LCS)
- 6-point change in TOI is a cut-off point for clinically meaningful change

Symptoms changes (ESAS)

- The 2 points difference for the ESAS responses considered clinically meaningful changes (CMC)
- 9(64%) of patients felt less tired and 5(36%) less sleepy and in fact 6(43%) patients reported improvement in overall well-being
- The other symptoms didn't change significantly

Conclusions

- Interest in Chinese herbs among lung cancer patients was high
- Patients found this CH formula acceptable and easy to tolerate
- Very few adverse events were related to use of CH formula
- Significant improvement in physical well-being, FACT-TOI, tiredness, drowsiness and overall well-being
- Randomized placebo-controlled study to assess the potential beneficial effects of Shu Yu Wan formula is feasible and being planned

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