Safety of Chinese herbal medicine

Information & risk management of adverse events

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HERBAL SAFETY FROM THE TCM PERSPECTIVE

Chinese herbal medicine (CHM) has long appreciated herba l safety and emphasizes the use of herbs from the right sources, with proper post-harvest treatment and pre-dispense processing. In the very beginning of CHM practice, herbs were classified based on safety considerations. “Shen Nong Ben Cao Jing” (Classic of Materia Medica), the first Chinese herbal classic published nearly 2000 years ago, classifies herbs into upper, middle and lower grades according to their safety profiles. The upper grade herbs nourish life and can be taken frequently over a long period of time. The middle grade herbs nourish constitutional types. The lower grade herbs expel diseases and should not be taken for a prolonged period of time.

Strategies and procedures to minimize the adverse effects of herbs have been developed to further safeguard the use of Chinese herbs. Thus, toxicity can be reduced by proper pre-dispense processing. Toxicity can also be neutralized by adding another herb to counter the toxicity of an herb.

Interactions between herbs have also been observed and documented in Chinese herbal medicine. There are herbal combinations that produce synergistic actions resulting in clinically beneficial effects. There are also combinations that diminish each other’s actions or lead to unforeseen toxicity. Combinations of herbs that may lead to harmful interactions are to be avoided (Zhu & Woerdenbag, 1995). In classical CHM texts, herbs with different degrees of toxicities are graded and are clearly marked d in their “property” section in herbal texts.

CHINESE HERBAL SAFETY IN WESTERN COUNTRIES

In general, adverse reactions due to CHM treatment are low and mild. An investigation in a German TCM hospital found that of 1519 patients (95.1% of the 1597 patients admitted to and discharged from the hospital between February 1992 and August 1993) receiving treatment with decoctions of Chinese herbs, 2% of the patients reported side effects such as flatulence, nausea, vomiting, diarrhea and allergic erythema. Seven patients (0.46%) had moderate temporary increase of liver enzyme (transaminases) levels. A total of 305 herbs were used in the hospital (Melchart et al., 1999). This investigation provides a fairly good indication as to the incidence and severity of adverse reactions due to CHM treatment in well-managed CHM practices.

Data from Australia also demonstrated that Chinese herbal medicine has a much safer profile than chemical drugs (Bensoussan et al., 2000).

Problems arise when herbs are substituted or adulterated with toxic herbs. The latter problem is particularly acute in the West due to confusing nomenclature of Chinese herbs, as was the case with herbs of Aristolochia origin such as Gunag Fang Ji (Aristolochia fangchi) and Guan Mu Tong (Aristolochia manshuriensis) (Vanherwhem et al., 1993). In the case of Guan Mu Tong this is because the sources of this herb has changed over time from Akebia species to Clematis species to Aristolochia manshuriensis (Zhu, 2002).

CHM USE IN SPECIFIC POPULATIONS

Use of CHM during pregnancy

Use of herbal medicines during pregnancy is not uncommon. 9.1-15% of pregnant women use herbs in western countries. In the Chinese community, the percentage is much higher (Ong et al., 2005). Herbal medicine is frequently used by pregnant women and very frequently used by those with a threatened abortion in the Chinese community (Chuan et al., 2007). Chinese herbal remedies are effective in preventing threatened abortion and reducing abortion rate in women receiving in vitro fertilization and embryo transfer (IVF-ET) (Liu & Wu, 2006; Qu & Zhou, 2006; Ushiroyama et al., 2006).

On the other hand, there are herbs that should not be used during pregnancy and those that must be used with caution. Warnings are given for herbs that are not to be used or should be used with caution during pregnancy (Zhu, 1998).

A Hong Kong university hospital survey of women who took Chinese herbs and Western pharmaceutical products one month before or during pregnancy found no significant difference in the teratogenicity between those took Chinese herbs and those took Western pharmaceutical products. No women who took Chinese herbs underwent termination of pregnancy because of anxiety whereas 2.7% of women who took Western pharmaceutical products did so (Leung et al., 2002).

Chuang et al. investigated the use of CHM during pregnancy and their effects on fetal growth in 9895 pregnancies. It was found that CHM did not increase the adverse risk on fetal growth. There was a non-significantly slightly decreased mean of birth weight and increased risk of low birth weight and small for gestational age when taking Huang Lian (Rhizoma Coptidis) for more than 8 weeks (Chuang et al., 2006a).

Taking Huang Lian during the first trimester of pregnancy was found to be associated with increased risk of congenital malformations of the nervous system. Use of An-Tai-Yin (Bei Mu, Gan Jiang, Dang Gui, Gan Cao, Chuan Xiong, Bai Shao Yao, Huang Qi, Qiang Huo, Hou Po, Jing Jie, Zhi Shi, Ai Ye and Tu Si Zi) during the first trimester was associated with an increased risk of congenital malformations of the musculoskeletal and connective tissues and eyes. However, it is clear whether the increased risk is associated with direct toxicity of herbs, or contaminations or other uncontrolled confounding. Further research is therefore needed to draw a clearer conclusion. Without further data, it should be cautioned to use these herbs during the first trimester of pregnancy. It should also be pointed out that An-Tai-Yin is more appropriately used in the third trimester because its main function is to help deliver smoothly. Similarly, advice for using Huang Lian to improve skin conditions is to take it in the second or the third trimester. No adverse effects were associated with the other herbal use (Ren Shen, Si Wu Tang and Dang Gui Shao Yao San) during pregnancy (Chuang et al., 2006b).

Teratogenesis due to herb in humans has been occasionally reported with a few Chinese herbs. A woman who took Lei Gong Teng (Tripterygium wilfordii) early in her pregnancy gave birth to a baby with a huge cystic mass protruding from the occiput which was diagnosed as occipital meningoencephalocele and cerebellar agenesis (Takei et al., 1997).

A woman who allegedly took Eleutherococcus senticosus during her pregnancy gave birth to a baby with neonatal androgenisation (hairy baby syndrome) (Koren et al., 1990). It was later suggested that the mother had consumed Periploca sepium, which had been substituted for Eleutherococcus senticosus (Awang, 1991).

Use of CHM in surgical patients

Studies suggest that more than 30% of the surgical population has used herbs (Moss & Yuan, 2006). In the Chinese population the percentage is higher.

In a Hong Kong cohort study, 601 patients undergoing major elective surgery were asked about their Western medicine and TCHM use in the 2 weeks before surgery. Of the 601 patients, 483 patients (80%) took selfprescribed TCHM, and 47 (8%) took TCHM by prescription (with or without

self-prescribed TCHM) in the 2 weeks before surgery. The crude incidences of any combined endpoints of preoperative, intraoperative, and postoperative events were 23%, 74% and 63%, respectively. Compared with nonusers, patients who took CHM by prescription were more likely to have a preoperative event. In contrast, there was no significant association between the use of any type of TCHM and the occurrence of either intraoperative or postoperative events.

Four of the 530 patients who used CHM 2 weeks before admission had "probable" preoperative events caused by TCHM by prescription. Preoperative TCHM-related hypokalemia occurred in three patients, with one requiring oral potassium chloride supplements before surgery. TCHM-related coagulopathy occurred in one patient, requiring a change in anesthetic plan, additional preoperative hemostatic tests, and abandonment of epidural analgesia.

The use of TCHM by prescription near the time of surgery should therefore be discouraged because of the increased risk of adverse events in the preoperative period. There was no clinically significant negative impact on intraoperative and postoperative care (Ang-Lee et al., 2001; Lee et al., 2006).

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