PREVALENCE AND MICROSCOPIC STUDY OF THE HERBS USED IN PREGNANCY

by

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Thesis submitted in fulfilment of requirement for the Degree of Master of Science (Health Science)

JUN 2011

DECLARATION

I certify that this thesis does not incorporate without acknowledgement any material previously submitted for a degree or diploma in any university; and that to the best of my knowledge and belief it does not contain any material previously published or written by another person except where due reference is made in the text.

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CERTIFICATE

This is to certify that the dissertation entitled '*Prevalence and Microscopic Study of the Herbs Used in Pregnancy*' is the bonafide record of research work done by Ms. Law Kim Sooi, Matric Number: S-HSM0086 during the period of January 2007 to June 2011 under our supervision. This dissertation submitted in fulfilment for the degree of Master of Science (Health Science – Gender and Health) research work and collection of data belongs to Universiti Sains Malaysia.

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LIST OF ABBREVIATIONS

CAM	Complementary and Alternative Medicine
HM	Herbal Medicines
HUSM	Hospital Universiti Sains Malaysia
RM	Ringgit Malaysia
WHO	World Health Organization
TM	Traditional Medicine
LM	Light Microscopic
VPSEM	Variable Pressure Scanning Electron Microscope
SEM	Scanning Electron Microscope
EDX	Energy Dispersive X-Ray
FDA	Food and Drug Administration
USM	Universiti Sains Malaysia
NHMRC	National Health and Medical Research Council
CADs	Complementary Alternative Drugs
ТСМ	Traditional Chinese Medicines
SD	Standard Deviation
SVD	Spontaneous Vertex Delivery
%	Percentage
HMDS	Hexamethyldisilazane
AHL	Anastatica Hierochuntica L.
SPSS	Statistical Package for the Social Sciences
g	Gram

mm	Millimeter
kv	Kilovolt
US\$	United States Dollar
С	Carbon
Al	Aluminium
0	Oxygen
Si	Silica
Ca	Calcium
Mg	Magnesium
К	Potassium
Zn	Zinc
Fe	Iron

Definition of key terms

The following key terms are highly contested notions. Some terms are the subject of ongoing debate about their theoretical construction, meanings and applications in practice. Therefore, it is necessary to give definitions of the way the terms are used in the context of this thesis.

Herbal medicine - a plant-derived material or preparations with therapeutic or other human health benefits, which contains either raw or processed ingredients from one or more plants (World Health Organization, 2000).

Herbal medicine user - users were defined as those who took the herbal medicines orally. Other route of administration such as topical application was excluded. Preparations consumed as nutriments and within routine meal preparation such as solutions, capsules or raw form, at any frequency, duration and amount at any trimester of pregnancy.

Pregnancy - the time period from the date of conception to the date of birth. It is divided into three trimesters. First trimester is the time period from the date of conception, taken as the first date of last menstrual period (LMP) to day 90 of gestation. Second trimester is from day 91 to day 180 and third trimester is from day 181 to the date of birth (DOB).

Traditional - ancient ethno-cultural-religious beliefs and practices that have been handed down through the generations (WHO, 2002).

Traditional medicine - Traditional medicine is based on theory, beliefs and experiences that are indigenous to the different cultures, and that is developed and handed down from generation to generation (WHO, 2000).

Variable Pressure Scanning Electronic Microscopy (VPSEM)

The scanning electron microscope (SEM) is a type of electron microscope that images the sample surface by scanning it with a high-energy beam of electrons in a raster scan pattern. The electrons interact with the atoms that make up the sample producing signals that contain information about the sample's surface topography, composition and other properties.

Morphology - The shape and size of the particles making up the object; direct relation between these structures and materials properties.

KAJIAN PREVALEN DAN MIKROSKOPI KE ATAS PENGGUNAAN HERBA DALAM TEMPOH MENGANDUNG

ABSTRAK

Penggunaan ubat herba sangat biasa di Malaysia termasuk penggunaannya semasa mengandung. Namun begitu, penyelidikan secara mendalam mengenai penggunaan herba semasa mengandung sangat terhad dan tiada sesiapa yang mengkaji sifat ultra-struktur berkenaandan logam surih dalam ubatan herba ini. Kajian ini bertujuan menentukan prevalens dan ciri-ciri kimia asas dan struktur morfologikal ubatan herba yang paling utama digunakan di kalangan wanita Melayu yang mengandung di Kelantan dengan menggunakan mikroskop elektron berskan. Persampelan rawak digunakan dan seramai 460 orang wanita Melayu di wad antenatal dan posnatal Hospital USM dari bulan September hingga Disember 2007 telah mengambil bahagian. Data dikumpul dengan menggunakan borang soal selidik berbentuk tertutup yang ditemubual oleh penyelidik. Ubatan herba (Anastatica Hierochuntica L.) juga dilihat melalui Variable Scanning Electron Microscope (VPSEM) dan analisis logam surih juga dilakukan dengan menggunakan *Energy* Dispersive X-Ray (EDX). Seramai 460 wanita telah ditemubual, 55.7% suri rumahtangga, 61% berpendidikan sekunder, 85% berumur di antara 21 hingga 40 tahun dan 57.2% adalah berpariti 2 hingga 5. Prevalens penggunaan ubatan herba semasa mengandung adalah sebanyak 34.3% dan 73% dilaporkan menggunakan ubatan herba semasa bersalin untuk memudahkan proses kelahiran. Anastatica Hierochuntica L.(Sanggul Fatimah) (60.1%), minyak kelapa (35.4%) dan ubat herba disediakan oleh bidan kampung (6.3%) adalah ubatan herba yang biasa digunakan. Majoriti dari wanita (89.2%) menggunakan satu jenis ubatan herba dan satu kapsul setiap hari (38%) serta mengambilnya apabila diperlukan (53.2%). Majoriti wanita (81%) menggunakan ubatan herba tanpa pengetahuan doktor dan 60.7% mendapat informasi penggunaan ubatan herba daripada ibubapa serta mendapatkannya dari bidan kampung (32.2%) dan 77% wanita pasti tentang kemujaraban dan keselamatan herba yang diambil. Struktur yang dilihat melalui VPSEM juga dibincangkan. Analisis EDX ke atas ubatan herba ini juga terdapat mineral yang berguna seperti magnesium, aluminium, potassium, zink, zat besi, kalsium, karbon, oksigen dan silika. Penggunaan ubatan herba masih tinggi dalam komuniti wanita Melayu Kelantan. *Anastatica Hierochuntica L.* adalah herba yang paling sering digunakan boleh membantu dalam pembentukan kolagen dan tisu tulang. Penyelidikan lebih menyeluruh dan terperinci tentang kemujaraban dan keselamatan serta cara menggunakan ubat herba perlu dilakukan agar kesejahteraan ke atas ibu dan janin.

PREVALENCE AND MICROSCOPIC STUDY OF THE HERBS USED IN PREGNANCY

ABSTRACT

The use of herbal medicine is common in Malaysia including its use during pregnancy. However, there have been very few formal studies of herbal consumption in pregnancy and even fewer looking at ultra-structural features and trace elements of herbal medicine. This study was to determine the prevalence of use and to identify possible chemical properties and morphological structure of herbal medicine found to be popularly used among the Kelantanese Malay women during the pregnancy period. A study was conducted among 460 Kelantanese Malay women at antenatal and postnatal ward Hospital USM from September to December 2007 using structured close-ended questionnaires. The surface morphology and the microstructure of Anastatica Hierochuntica L. were captured by Supra 50 VPSE-SEM LEO and Olympus SZ40 Stereomicroscope with image analyzer. Elemental analysis was done by using Energy Dispersive X-Ray (EDX). Of these 460 women, 55.7% were housewives, 61% had attended secondary education, 85% were aged between 21 to 40 years and 57.2% were para 2 to 5. Herbal medicine used during pregnancy was 34.3% while 73% utilized herbal in labor because in the belief that it can shorten labor and makes labor easier. The most commonly used herbal medicine in pregnancy was Anastatica Hierochuntica L. (Sanggul Fatimah) (60.1%) followed by coconut oil (35.4%) and herbs prepared by traditional midwives (6.3%). The majority of women (89.2%) used only one type of herbal medicine and took it when necessary (53.2%) with one capsule/glass (38%) per day. Herbal medicines used by pregnant women were commonly unsupervised (81%),

with most women getting information from their parents (60.7%) and buying the products directly from traditional midwifes (32.2%) and 77% agreed upon its efficacy and safety. *Anastatica Hierochuntica L.* structures were viewed under VPSEM and were discussed. Micro diffraction analysis (EDX) of the herb revealed inert significant presence of useful mineral such as magnesium, aluminium, potassium, zinc, iron and calcium as well as elements like carbon, oxygen, silica. Herbal medicine is still being commonly used among the Malay Kelantanese women communities. A detailed study is therefore needed to establish among others, the efficacy and safety of these herbs where the well-being of mother and fetus are of paramount.

CHAPTER 1

INTRODUCTION

1.1 Introduction

This chapter outlines the background of this quantitative study into the prevalence and microscopic findings of commonest herbs used among Kelantanese child bearing women in pregnancy. The rationale of the study, its objectives, intended outcomes, and significance of the study are included. It also provides an outline of the thesis structure. Definitions of key terms used throughout the thesis in relation to traditional herbal medicine utilisation were provided in the definition of key terms prior to this chapter.

1.2 Background to the study

Traditional medicine or complementary and alternative medicine (TM/CAM) is an integral part of the practice of ancient civilization to improve health and well-being in countries such as India, China and Malaysia (Hassan & Shaaban, 2005) and in many developed countries (Ernst, 2003). The various modalities currently practised are based on theory, beliefs and experiences that are indigenous to the different cultures, developed and handed down from generation to generation (World Health Organization, 2000). Amongst one of the popular practices of TM/CAM is herbal medicine (Chuang, Lai, Wang, Chang & Chen, 2005).

Herbal medicines were favoured in human daily life due to its acclaimed medicinal and nutritional value. Herbal medicines usage were not only popular among the individual use but also had been practiced by primary health care providers in developing countries such as India, China and Malaysia. Herbal medicines were also practiced in countries where conventional medicines are predominant (World Health Organization, 2000). World Health Organization (WHO) (2002) reported that 70 to 80 per cent of the world population relied mainly on herbal sources for their primary care. In the study of Nordeng and Havnen (2005), they found that non-conventional medicines such as herbal medicines were used in many countries to treat pregnancy related illness and to encourage a healthy pregnancy and well-being. However, Pinn and Pallett (2002) indicated that although the practice of herbal consumption in pregnancy was very popular, they reported that there was a lack of evidence for the safety and efficacy of herbal medicines utilized in pregnancy and for other reason. Similarly, other studies also showed that although herbal medicines were unproven scientifically, 7 to 55 per cent of pregnant women continued to consume herbal medicines over the pregnancy period even with the lack of knowledge about its safety and benefit (Chuang, Chang, Hsieh & Tsai, 2009; Nordeng & Havnen, 2004; Tiran, 2003).

Malaysia is a multicultural country that has rich traditional practice modalities. Among these modalities is the use of herbal medicine for the treatment of various ailments and in pregnancy (Hassan & Shaaban, 2005; Mustafa, 2003). In Malaysia, herbal medicines are becoming increasingly popular and regarded as important to the public as well as to the scientific communities. The deluded beliefs by the majority of ethnic groups in the Malaysian population is that herbal products does not contain harmful chemical and free of any side effects as compared to commercially available pharmaceutical drugs (Hussin, 2001).

Malaysia is well-known for its tropical rain forest which possesses one of the most complex and diverse botanical ecosystems in the world that avails substantial amount of herbal medicines. However, only a limited number of local herbs were used as herbal medicines and had been analyzed for their pharmacological activity and active substances (Hussin, 2001). Herbal remedies possess various beneficial properties and effects but it may also result in adverse effects or may cause drug interactions (Vickers, Jolly & Greenfield, 2006; Barrett, Kiefer & Rabago, 1999). Peer-reviewed medical journals have acknowledged herbal medicine's unique position in the growing field of complementary and alternative medicine (CAM). These journals have provided a guide for clinicians to approach patients in using herbal medicines with caution as the practice of combining conventional and herbal products may yield drug interactions (Cathryn, 2003). According to Ernst (2003) and Eisenberg, Davis, Ettner, Appel, Wilkey and Van Rompay (1998), the use of herbal medicines is different from the scientific approach as it is based on the promotion of health and does not limit its treatment to only one part of the body. One of the most important reasons for the utilization of herbal medicines is the notion that 'natural' substances like herbs are safer compared to the synthetically prepared substances. Therefore, due to the perceived beliefs that it may confer to health, herbal remedies have been used extensively as medicine for the treatment of various ailments since pre-historical times (Hamayun, Khan & Khan, 2003; Drew & Myers, 1997).

1.3 Rationale for the study

The result of this study will provide a database on the prevalence of traditional herbs usage over the pregnancy period among Kelantanese Malay women. Information gained from this study can provide an appropriate interventions and/or strategies to improve knowledge, attitude and practice on herbal medicine practice. It also can be used to design seminars, workshops, and continuing education courses to increase awareness amongst health care professionals and help to increase knowledge about herbal medicine's safety and efficacy during pregnancy. It is especially important for nurses and midwives who provide care to pregnant women in the clinical setting. Information obtained from this study will provide a greater understanding of herbal medicines utilisation and also provide a better evidence-based health education to the pregnant women in Malaysia. Findings from this study might also be used by schools of nursing, medicine, and pharmacy to review and/or justify curriculum changes that incorporate principles and methods of TM/CAM into the required courses.

1.4 Problem statement

In Malaysia, the use of herbs was based on practical experience, observations and rituals derived from socio-religious beliefs passed down from one generation to another generation. These utilization and practices have been observed within the communities and claimed to be important for reason of health and well-being, including beneficial to pregnancy (Hassan & Shaaban, 2005). Although various studies had been published on medications used during pregnancy, there is a lack of evidence for safety and efficacy on

these herbal medicines in pregnancy (Tieraona, 2009; Simpson, Parsons, Greenwood & Wade, 2001; Gallo, Sarkar & Au, 2000). Since many women use herbal medicines during the pregnancy period which might produce potential adverse effects on mother and fetuses, such practice modalities should raise concerns among healthcare professionals and consumers on the issue of safety and efficacy (Donald & Wayne, 2005; Westfall, 2004). In addition, there are limited and in many cases lack of data on the extent of Malaysian women's use of herbs over the pregnancy period. To date, there is a lack of scientific evidence on herb use among Malaysian women and study that has been performed and/or conducted in Malaysia. This study focused only on the Malay pregnant women because they represent the majority of Kelantanese women population. Investigations of the most commonly consumed herb by these women would be beneficial as it may be related to the women's antepartum care.

1.5 Purpose of the study

The use of herbal medicines in pregnancy is common (Chuang *et al.*,2009, Azriani, Zulkifli, Naing, Siti Amrah, Abdul & Wan, 2007; Tiran, 2003). Several studies have shown that herbs used in pregnancy are associated with congenital malformations, which may lead to perinatal mortality (Noordalilati, Sulaiman, Sembulingam & Afifi, 2004; Chan, Chiu & Lau, 2003; Takei, Nagashima & Suzuki, 1997). There are limited data on the extent of antenatal women's use of herbal medicines in pregnancy, despite the fact that knowledge of the potential benefits or harms of many of these herbal medicines is sparse, particularly with respect to their use in pregnancy. In conjunction with this evidence, some herbs must be regarded as harmful and some may be protective for the

fetus (Azriani *et al.*, 2007). This study is expected to provide information to the health care providers about the strategies to improve health educational services by making them more informative among the antenatal women in Malaysia. It is hoped that information provided by this study will provide a better understanding about herbal medicine utilisation in the Malaysian healthcare system.

1.6 Objective of the study

The general objective of this study was to determine the prevalence and microscopic evidence of herbs used among the Kelantanese child bearing women in pregnancy.

1.6.1 Specific objectives

- a) To determine the prevalence of herbal medicines usage over the pregnancy period among the Kelantanese Malay women.
- b) To describe the pattern of herbal medicines usage over the pregnancy period among these women.
- c) To determine the most popular herb used by these pregnant women.
- d) To determine the relationship between socio demographic factors and herbs used among the pregnant Kelantanese Malay women.

- e) To compare the knowledge score of the pregnant Kelantanese Malay women with their socio demographic factors.
- f) To describe the morphological structure and elements present in the most popular traditional herbs using VPSEM and SEM-EDX.

1.7 Research questions

- a) What is the prevalence of herbs usage over the pregnancy period among the Kelantanese Malay women?
- b) What is the pattern of herbal medicines usage over the pregnancy period among these women?
- c) What is the most popular herb used by these pregnant women?
- d) Is there any relationship between the socio demographic factors and herbs used among the pregnant Kelantanese Malay women?
- e) Is there any difference between the knowledge score of the pregnant Kelantanese Malay women and their socio demographic factors?
- f) What are the morphological structures and elements present in the selected traditional herbs using VPSEM and SEM-EDX?

1.8 Research hypothesis

- a) There is no significant relationship between the socio demographic factors and herbs used among the pregnant Kelantanese Malay women.
- b) There is no significant mean difference between the knowledge score of the pregnant Kelantanese Malay women and their socio demographic factors.

1.9 Justification for and significance of the study

To date, many antepartum women in Malaysia continued to use herbal medicines during pregnancy. Furthermore, many of these women are not aware of the potential danger and the adverse effect of these herbs on their health and well-being on their pregnancy. According to Titilayo, Rasaq and Ismail (2009), Nordeng and Havnen (2004), Tiran (2003) and Drew and Myers (1997), pregnant women often assumed traditional use of herbs over the pregnancy period is safe.

To the best of the researcher's knowledge, there has been limited study on traditional herbal usage by Kelantanese Malay women over the pregnancy period, including microscopic and elemental characterization study of the traditional herbs. Therefore, this study can be useful as a source of information pertaining to the types of herbal medicines used by the Kelantanese women over the pregnancy period.

Documentation of knowledge regarding the use and elements found in this common herb is needed as information gathered could help in educational intervention essential in the Malaysian healthcare system. This study will provides the foundation for further research on the possible side effects of herbs. Healthcare professional, particularly nurses and midwives in Malaysia, who provide care for antepartum women in the clinical setting need to be cognizant of the herbal medicines practices. Part of the nurses' roles and responsibility is to educate the antenatal woman regarding the potential benefits and dangers of herbal medications on them and the unborn fetus.

1.10 Thesis structure

This thesis comprised of six chapters. This introductory chapter is meant to explain the study and give a brief overview of its background; the rationale for the study; the purpose of the study and its objectives, including the research questions; and justification for, and significance of the study. Following this introductory chapter, Chapter 2 sets a review of the literature pertinent to this study topics. This is followed by a discussion of the research methods and material in Chapter 3, including describing how the VPSEM and SEM-EDX studies were conducted on the selected herbal medicine found to be popular in order to determine the morphological structures of the herb and to identify possible elemental properties. Chapter 4 is a presentation of the findings while Chapter 5 details the discussion and Chapter 6 is conclusion. Chapter 7 is suggested strategies for nursing practice, education, future research and the study's limitations.

CHAPTER 2

LITERATURE REVIEW

2.1 Introduction

Malaysia is an amalgam of segregated ethnicities. Economically, it is a mixture of stratified classes; and culturally, a composite of languages, beliefs and practices. One of the popular beliefs and practices of Malaysian population is herbal medicine (Hassan & Shaaban, 2005; Mustafa, 2003). As stated earlier, in chapter one, herbal medicine has been used extensively as medicine for the treatment of various ailments and in pregnancy (Chuang *et al.*, 2009; Hassan & Shaaban, 2005; Mustafa, 2003). In this context, some understanding of herbal medicine, specifically in relation to the utilization of herbal medicine pattern during the pregnancy period is required to appreciate the content of this study. This study also provides an overview of the VPSEM and SEM-EDX technique.

2.2 Herbal medicine

According to WHO (2002), the utilisation of TM/CAM practices is classified as alternative medicine. For reasons of treatment in health and for well-being, human seek TM/CAM. The widespread use and positive attitude toward TM/CAM is because it is considered natural and safe. Therefore, this deterred human to explore for better options and treatment in their health care. With the increased use of TM/CAM and the

emergence of new diseases, more scientific knowledge of TM/CAM application is needed.

Herbal medicine and traditional medicine is usually defined as a plant-derived material or preparation used as therapeutic or other human health benefits and contains ingredients, either raw or processed, from one or more plants. In some preparations, materials or animal origin may also be present (WHO, 2000). Herbal preparations are either used for treatment of certain diseases or just for normal health and vitality; and some are used as aphrodisiac (Mustafa, 2003). According to Pirmohamed (2003), herbal and traditional medicines have played a significant role in maintaining human health and improving the quality of human life. The medicinal value of plants is inestimable. Vishwanath's (2002) study indicated that plants are biologically and chemically diverse resources as they synthesize various chemicals to defend themselves against pests, diseases and predators. Thus, plants are also an excellent reservoir of medicines and chemical leads.

Herbal medicines are also referred to as phytomedicine which has become an integral part of society's daily practices and the growing self-medicating trend among consumers (WHO 2002). According to WHO (2002), there is a global resurgence in the herbal medicine utilization. Herbal medicine is used as food and dietary supplements or natural health products, including those employed during the antepartum period, however, a dearth of information about the potential effects of these herbal medicines is profound.

It is noted that its utilisation has caused a crisis where it is subjective to questioning and debate regarding its safety and efficacy (WHO 2002).

In United States, it has been estimated that one third of Americans used herbal products (Johnstone, 1997) with herbal medicine sales in United States reaching an estimated total of about US\$3.24 billion equivalent to 12.3 billion Malaysia Dollar (Ringgit Malaysia or RM) in 1997. In 1999, Malaysians were indicated to spend about RM 3.8 billion on herbal medicines. This amounts to about RM45.00 spent on herbals per person per year in the United States compared to about RM91.00 per person per year in Malaysia taking into account populations of 273 million and 22 million respectively (Hussin, 2001). About 17.1 per cent of Malaysians used herbs to treat their health problems while 29.6 per cent consumed herbal medicine for their health maintenance (Mahmud, 1993). According to Malaysia Health Minister Datuk Liow Tiong Lai, many Malaysians used traditional medicines to treat their ailments and for reason of health purposes, however, to date these medicines are still not fully exploited especially in research and development (Liow, 2008). He indicated that Malaysia herbal industry was estimated to be worth approximately RM8 billion in 2007 and is expected to grow at a rate of 10 percent per year (Liow, 2008).

In 1999, more than 8000 herbal products were registered with the Malaysian Ministry of Health (MOH) (Hussin, 2001). Similar to WHO (2002) on herbal medicines and traditional medicines safety and efficacy report, Kozyrskyj (1997) also argued over the question on how safe are the herbal products available in the commercial market and points out that the safe usage of herbal medicines is of utmost importance. Majority of

these herbal products are self prescribed and only few are properly standardized by scientific accredited methods that ensured consistent controlled products of safety and efficacy (Kozyrskyj,1997).

The utilization of TM/CAM practices were transferred from generation to generation. In recent time more scientific knowledge has become more concrete and with the emergence of new diseases, the classical knowledge and their application has become limited. With the emergence of new diseases and the failure of treatment with modern drugs, people have begun to look for more options in their health care. One alternative for them is to use herbal medicine as most of the people have a strong belief that natural product is always safe. With this ideology, the trend in pharmaceutical industries and business is booming as more and more products are labeled as natural. What is worrying is that some TM contains element that is detrimental for health. Most alarming is that most people are unaware that certain TM/CAM which is natural can also be harmful (Mustafa, 2003).

Herbal medicine is classified as an alternative medicine in Western based medicine. Today herbal medication and traditional medicine finds itself in a unique situation. The increased utilization of herbal and medicinal plants in human daily life is significant. Howell, Kochhar, Saywell, Zollinger, Koehler, Mandzuk, Sutton, Sevilla and Allen's (2006) study on non-pregnant Hispanic women indicated that herbs were most often used to treat cough, stomach pain, sore throat, menstrual cramps, head ache and chest pain. In reality, lack of information about the potential effects of herbal plants and traditional medicine had caused its widespread use as food and dietary supplements or natural health products, including those employed during the antenatal period. Studies by Titilayo *et al.*, (2009) and Barbara, McFarlin, Gibson and Patsy's (1999) indicated that herbal medicines were perceived by many as natural, safer, gentle and lower in cost than synthetic pharmaceutical products. In addition to that, over the counter products and herbal medicine offered more freedom for many individuals in self treatment compared to prescription medicines (Sharma, Kapoor & Verma, 2006; Barbara *et al.*, 1999).

2.3 Herbal medicines used during pregnancy

According to Nordeng and Havnen (2005), herbal medicine utilisation has been used in many countries by pregnant women to treat pregnancy related illnesses and to encourage a healthy pregnancy and well-being among the fetus. In an Australian study on antenatal women by Tiran (2003), she found that 7 per cent to 55 per cent of the antenatal women consumed herbal medicines over the pregnancy period. However, a dearth of study had been examined for evidence of safety and efficacy in herbal medicine consumption. She indicated that these women consumed herbal medicines before and during pregnancy; and many of these herbal medicines are still uncertain and unproven scientifically. Moreover women who consume herbal medicines before pregnancy may continue to use it even when they are pregnant. Shankar, Partha and Shenoy (2002) indicated that women used herbal medicines to counter discomforts and as dietary supplements during the pregnancy period. Concurring with Tiran's (2003) and Shankar *et al.*, *'s*. (2002)

medicine were used during pregnancy. They reported that these herbal medicines can cause congenital anomalies and were risk factors for perinatal mortality.

According to Pinn and Pallet (2002), there had been very few studies of herbal consumption in pregnancy and even fewer looking at outcomes. They reported that there were traditional beliefs that certain kinds of traditional medicines and herbal plants were beneficial to pregnancy. Although the use of herbal medicine among pregnant women is important, to date it is poorly studied. According to Ong, Chan, Yung and Leung (2005), fifty-six per cent of the women in China consumed traditional Chinese medicines (TCM) during pregnancy due to consultation fee were much cheaper as compared to western medicine. Ong *et al.*,'s (2005) study also found that Chinese women in China consumed herbal medicine during pregnancy period to improve their health, to assist in fetal growth development in utero and to prevent premature delivery. A study done by Chuang *et al.*,'s (2005) also concurred that women consumed herbal medicine to prevent recurrent spontaneous abortion or stillbirth.

Studies from other countries specifically report on the use of herbal medicines in pregnancy, ranged from 7 percent to 96 percent (see Table 2.1). However, there was a trend that smaller studies had found high prevalence of herbal medicine usage. The results of other studies were summarized in Table 2.1.

S/N.	Author, Year, Country	Design	Sample	Prevalence
1	Westfall (2004), Canada	Structured interview	27 women in 3 rd trimester	96 % used herbal medicine in pregnancy
2	Byrne, Semple & Coulthard (2002), Adelaide, Australia	Structured interview	48 antenatal inpatients	56% used herbal medicine
3	Maats & Crowther (2002), Adelaide, Australia	Structured interview	211 pregnant women 26 weeks gestation onwards	20% used ginger and 9% raspberry lead tea
4	Pinn & Pallett (2002), Nambour, Australia	Surveys, self completed questionnaire	305 women (16-24 weeks gestation)	12% used herbs in pregnancy
5	Hepner, Harnett, Segal, Camann, Bader & Tsen (2002), USA	Structured questionnaires	734 pregnant women	7.1% used herbs in pregnancy
6	Hollyer, Boon, Georgousis, Smith & Einarson (2002), Canada	Structured questionnaires	70 pregnant women	51% used ginger
7	Gibson, Powrie & Star (2001), USA	Cross sectional survey	250 pregnant women	9.1 % used herbs in pregnancy
8	Hemminki, Mantyranta, Malin & Koponen (1991), Finland	Structured questionnaires	180 postpartum women	14% used alternative drugs during pregnancy

 Table 2.1: Prevalence of use of herbal medicine in pregnancy from several studies

Several cross-sectional surveys in one Australian state in 1993 and 2002 reported the used of herbal medicines in pregnancy. The reports demonstrated high levels of use of CAMs and CAMs therapist (MacLennan, Wilson & Taylor 1996, 2002; MacLennan, Myers & Taylor, 2004). Nordeng and Havnen (2004) found that the use of herbal medicines increased as pregnancy progressed, supporting trends noted in a previous Finnish study (Hemminki, Mantyranta, Malin & Koponen, 1991).

2.4 The most commonly used herbal medicines by pregnant women

A detailed search of the MEDLINE, CINAHL, EMBASE, PROQUEST and the WHO Reproductive Health Library databases were conducted for articles published between 1996 and 2007. Search items included the keywords: herbal medicines, prevalence and predictors of herbal used, childbearing women and pregnancy. In the search covered no information regarding herbs used by local childbearing and pregnant women in Malaysia was found. However, information regarding some herbs community used by pregnant women in other studies was indicated (see Table 2.2).

Table 2.2: The most commonly used herbal medicines by pregnant women from other studies

Author, Year, Country	Herbs used during pregnancy
Nordeng & Havnen (2004), Norway	46 herbs used. Most common: Echinacea, iron-rich herbs, ginger, chamomile, cranberry, aloe, herbal teas (mixed), horsetail, black elderberry, wheat germ oil
Westfall (2004), Canada	Herbs used for nausea: ginger, peppermint and cannabis
Glover, Amonkar, Rybeek & Tracy (2003), USA	Most common used herbs: peppermint, cranberry, aloe, herbal tea
Maats & Crowther (2002), Adelaide, Australia	Ginger, raspberry leaf tea, chamomile, echinacea, evening primrose oil, slippery elm
Pinn & Pallett (2002), Nambour, Australia	15 herbs used. Most common: raspberry leaf, Chinese herbs, ginger, St John's wort, evening primrose oil, echinacea
Byrne, Semple & Coulthard (2002), Adelaide, Australia	46 herbs used. Most common: chamomile, ginger, peppermint, raspberry leaf, valerian
Hepner, Harnett, Segal, Camann, Bader & Tsen (2002), USA	Echinacea, ephedra, St Johns's wort, ginger, gingko biloba, ginseng, primrose, garlic, cranberry
Gibson, Powrie & Star (2001), USA	Garlic, aloe, chamomile, peppermint, ginger, Echinacea, pumpkin seeds, ginseng
Tsui, Dennehy & Tsourounis (2001), USA	45 herbs used. Most common: Echinacea, teas, ginger, multivitamin with herbs, raspberry leaf
Henry & Crowther (2000), Adelaide, Australia	Evening primrose oil, antioxidants (no others reported)
McFarlin <i>et al.</i> (1999), USA	Most common herbal preparations used by certified nurse- midwives to stimulate labor: black cohosh, blue cohosh, red raspberry leaf, castor oil, evening primrose oil

2.5 The indications of the used of herbal medicines during pregnancy

The use of herbal medicine among pregnant women is important but to date the studies is still limited. There are traditional beliefs that certain kinds of traditional medicines and herbal plants are beneficial to pregnancy. Chinese women who take herbal medicines generally consider that these medicines can improve health or may help fetal growth and prevent premature delivery. Some of them also tried to use herbal medicines during pregnancy to prevent recurrent spontaneous abortion or stillbirth (Chuang *et al., 2009;* Chuang *et al., 2005*). According to (Ong *et al., 2005*) more than half (55.8%) of the women in mainland China had consumed traditional chinese medicines (TCM) during pregnancy. The reason for usage due to consultation fee is much cheaper for TCM practitioners compared with western medicine.

A study in North Carolina (Allaire, Moos & Wells, 2000) reported 98% certified nurse midwives are using, recommending or referring patients for complementary and alternative medicine therapies in the past year. Sixty of 82 (73.2%) respondents suggested herbal therapy. Indications for use of herbal therapies by nurse midwives were nausea and vomiting, preterm labor, labor stimulation, perineal discomfort, labor analgesia, malpresentation, lactation disorders and postpartum hemorrhage (Allaire, Moos & Wells, 2000). However, McFarlin *et al.*, (1999) reported that the most common indication for using herbal medicines is to stimulate labour. While the study of Nordeng and Havnen (2005) reported that the most common reason of herbal medicines used was for colds and respiratory tract illness, need for nutritional supplement, skin problems,

pregnancy related problems such as nausea and vomiting, urinary tract infections and central nervous system disorders.

The study done by Vickers *et al.*, (2006) found that the main factors women in their study consumed herbal medicines were unsuccessful conventional treatment and concerns about side effects and the belief that herbal medicine is natural and free from chemicals and they are safer. The three most common reasons why women used herbal medicines during pregnancy in the study by Ong *et al.*, (2005) were good for pregnancy, good for general health and for common cold.

Majority of the pregnant women used herbal medicines for pregnancy related reasons. For example, Australian pregnant women used raspberry leaf tea as a uterine tonic (Forster *et al.*, 2006). Herbal medicines also used by majority of the pregnant women for pregnancy related problems and for relaxation. For example, Canadian women used ginger to alleviate the problem of nausea and vomiting during pregnancy (Forster *et al.*, 2006; Hollyer *et al.*, 2002). Pregnant women used all of kind herbal medicines during pregnancy for so many reasons and it was crucial to look for the safety and efficacy of the herbal medicines that was commonly use to prevent adverse reaction or the side effects of the herbs to both mother and fetus. Table 2.3 showed summaries of common reasons for using herbal medicines during pregnancy.

Table 2.3: The indications/reasons of the use of herbal medicines	during pregnancy
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Herbs	Most common reasons for use of herbs during pregnancy
Raspberry leaf	Strengthen or tone uterus ready for labour (Forster <i>et al.</i> , 2006), stimulant effect on the uterus (Parsons, Simpson & Ponton, 1999).
Ginger	Nausea (Forster <i>et al.</i> , 2006)
Chamomile	Relax/ calming/ help to sleep, aid digestion/ nausea (Forster <i>et al.</i> , 2006)
Cranberry juice	Prevent/treat urinary tract infections, vitamin c intake (Forster <i>et al.</i> , 2006)
Echinacea	Cold/flu, increase immunity (Forster <i>et al.</i> , 2006), upper respiratory tract ailments (Gallo <i>et al.</i> , 2000)
Slippery elm	Digestive disorders (Forster <i>et al.</i> , 2006)
Kgaba remedies (used in South Africa by pregnant women of Tswana population)	Stimulate prolonged labour, induce labour when overdue, protect from evil and harm (Van der kooi & Theobald, 2006)
St John's wort	As an antidepressant to avoid using synthetic antidepressants (Grush, Nierengerg, Keefe & Cohen, 1998)
Black cohosh	Induce labor (McFarlin <i>et al.</i> , 1999)
Blue cohosh	Induce labor (McFarlin <i>et al.</i> , 1999)
Castor oil	Induce labor (Scarpa, 1982; Davis, 1984)

2.6 The outcomes of using herbal medicines in pregnancy

There have been very few formal studies of herbal consumption in pregnancy and even fewer which looking at the outcomes (Pinn & Pallett, 2002). Table 2.4 was the summaries of some studies that look into the outcomes of using herbs in pregnancy. The evidence summarized below shows that some herbs have been associated with risks to pregnant women and their babies. Therefore, pregnant mothers need to be aware that herbs are 'natural' but not entirely risk free. Health care professionals also need to be alert of the usage of herbal medicines by pregnant women.

Herbs	Studies	The outcomes of using herbal medicines in pregnancy
Echinacea (Echinacea purpurea)	112 pregnant women used Echinacea in 1 st trimester for improving upper respiratory tract symptoms (Gallo <i>et al.</i> , 2000)	No statistical difference was found between the two groups in terms of pregnancy outcomes, delivery method, maternal weight gain, gestational age, birth weight or fetal distress. There were 13 spontaneous abortions in the Echinacea group, compared with 7 in the control group. Gestational use of Echinacea during organogenesis is not associated with an increased risk for major malformations. 81% of the subjects reported that Echinacea was effective in improving upper respiratory tract symptoms.

Table 2.4: The outcomes of using herbal medicines in pregnancy

Ginger (Zingiber officinale)	27 pregnant women at a mean gestational age of 11 weeks took 1 g of ginger daily as a treatment for hyperemesis (Fischer- Rasmussen, Kjaer, Dahi & Asping, 1990)	As compared with placebo, more patients had relief from their symptoms with ginger. Outcomes included one therapeutic abortion, one spontaneous abortion and 25 normal living infants.
	32 pregnant women took a daily supplement containing 1 g of ginger for four days (Vutyavanich, Kraisarin & Ruangsri, 2001)	Pregnant women reported feeling less nauseous and had fewer vomiting episodes than a group of women who took inactive placebo pill. Ginger is effective for relieving the severity of nausea and vomiting of pregnancy.
	13 pregnant women ingested prepared ginger syrup for 2 weeks during first trimester of pregnancy (Keating & Chez, 2002).	After 9 days, 10 of 13 (77%) subjects receiving ginger had improvement on the nausea scale. Only 2 of 10 (20%) subjects in placebo group had the same improvement. 67% women in ginger group who were vomiting daily at the beginning of the treatment stopped vomiting by day 6. While only 20% women in the placebo group who were vomiting stopped by day 6.
Castor Oil	107 pregnant women with premature rupture of membranes receive castor oil to induce labor (Davis, 1984).	75% of the subjects who received castor oil went into labor as compared to 58% control subjects who went into labor spontaneously. The author concluded that castor oil can be used safely and effectively to stimulate labor and more economical and convenient than oxytoxin.

Raspberry leaf	51 pregnant women had taken raspberry leaf during pregnancy (Parsons <i>et al.</i> , 1999).	Raspberry leaf was not associated with any childbirth complications and no evidence of long term teratogenic effects were found.
	192 pregnant women were randomized to receive either raspberry leaf tablets (2x1.2g/day) or placebo during 32 nd week of pregnancy until labor.	No adverse effects for mother or baby were noted. Raspberry leaf did not shorten the first stage of labor but a small shortening of second stage (10 minutes on average) and less (19% vs. 30%) forceps deliveries were observed in the treatment compared with the control group.
Evening Primrose oil (EPM)	54 pregnant women taking EPM orally from the 37 th gestational week until birth (Dove & Johnson, 1999).	EPM intake did not shorten gestation or decrease duration of labor. It was associated with an increase in the incidence of prolonged rupture of membranes, oxytocin augmentation, arrest of descent and increased frequency of vacuum extraction.

2.7 The safety and effectiveness of herbal medicines used during pregnancy

Studies of maternal drug consumptions during pregnancy showed that there was generally a lack of evidence for safety and efficacy about use of herbal medicines in pregnancy. Most of the study focused on simple herb products such as Echinacea or Raspberry (Simpson *et al.*, 2001; Gallo *et al.*, 2001). Among the poor evidence in the use of herbal medicines are misidentifications of herbs, contamination from microbes, heavy metals, or pesticides; including possibilities of adulterated with western medicines, and potential herbal toxicity (Chuang, Doyle, Wang, Chang, Lai & Chen, 2006).

Antenatal mother and their health care providers are increasingly aware that they should avoid unnecessary exposure during the pregnancy period. This has resulted in a decrease in the use of prescription drugs during pregnancy, but ironically, it has also led to an increase in the quantity on herbal and over the counter medications that are self administered (Elizabeth, 2003). According to Glover *et al.*, (2003), 92.6% of the pregnant women had self medicated with over the counter medication products. However, there was little information on the safety but still more than 90% of the pregnant women used at least one drug/herbal medication during pregnancy (Tieraona, 2009; Beyens, Guy, Ratreman & Ollagnier, 2003). A study done by Mabina, Pitsoe & Moodley (1997) showed that use of herbal medicines in South Africa may lead to fetal distress as indicated by the frequency of meconium stained and high caesarean section rates in a group of pregnant women presenting in labour. Fifty five point six percent of pregnant women who used 'Isihlambezo' during labor had grade II-III meconium