العنوان:	استخدام الاستروجينات النباتية في علاج اعراض فترة اليأس من المحيض: (دراسة عشوائية ذات مجموعة ضابطة)
المؤلف الرئيسي:	موسى، نهى أحمد السيد
مؤلفين آخرين:	علي، منصور يوسف، محمد، ماهر صلاح محمد، نصر، أحمد محمد علي(مشرف)
التاريخ الميلادي:	2004
موقع:	اسيوط
الصفحات:	1 - 244
رقم MD:	535540
نوع المحتوى:	رسائل جامعية
اللغة:	English
الدرجة العلمية:	رسالة ماجستير
الجامعة:	جامعة اسيوط
الكلية:	كلية الطب البشري
الدولة:	مصر
قواعد المعلومات:	Dissertations
مواضيع:	الطب البشري، علاج فترة اليأس، المحيض، الاستروجينات
رابط:	http://search.mandumah.com/Record/535540

Acknowledgment

ACKNOWLEDGMENTS

First, I am greatly honored to express my deepest gratitude and thanks to ***Prof. Dr. Mansour Youssef Aly***, Professor of Obstetric and Gynecology, Faculty of Medicine, Assiut University, for his constructive supervision and keen interest in directing, observing and guiding my effort in this work.

My sincere thanks to ***Prof. Dr. Maher Salah Mohammed***, Professor of Obstetrics and Gynecology, Faculty of Medicine, Assiut University, for his kind endless help and tutorial guidance throughout the study from the early beginning till full accomplishment. He spent a lot of his time and effort in reading and revising every word of this thesis, and for him the all words of praise and thanks will never be sufficient.

I would like to express my deep gratitude and thanks to ***Dr. Ahmed Mohamed Aly Nasr***, Lecturer of Obstetrics and Gynecology, Faculty of medicine, Assiut University, for exerting much of his time for the fine adjustment and monitoring of every tiny step in the thesis with his creative and comprehensive advice.

My cordial thanks should be offered to ***Prof. Dr. Hossam Th. Salem*** Professor of Obstetrics and Gynecology, and Head of Obstetrics and Gynecology Department, Faculty of medicine, Assiut University, for his keen effort in adjusting all the research and work in the department.

I would like to express my cordial thanks to ***Dr. Nagham Nabil Omar*** Assistant Lecturer of Diagnostic Radiology, Faculty of medicine, Assiut University, for her great help to me in conducting an important section of this study which is the breast ultrasonography, she spent time and effort without limits in this work. She added to me in addition to her help, a new useful experience in learning the breast ultrasonography.

My sincere thanks to ***Prof. Dr. Ahmed M. Makhloof,*** Assistant Professor of Obstetrics and Gynecology, Faculty of medicine, Assiut University, for his great help in performing the statistical analysis of this study. He was so patient with solving all the statistical problems I faced during this study. My cordial thanks to ***Dr. Mohamed M.F. Fathalla,*** Lecturer of Obstetrics and Gynecology, Faculty of medicine, Assiut University, for his sincere effort in teaching me the basics of statistical science and computer based statistical analysis that helped me to proceed through this part of study.

I would like to express my deep gratitude to all staff members of Obstetrics and Gynecology Department, Faculty of medicine, Assiut University. My cordial thanks should be offered to my colleagues of the Obstetrics and Gynecology Department for their valuable help and assistance.

Lastly, the deepest gratitude to all women who participated in this study.

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LIST OF ABBREVIATIONS

ACOG	The American College of Obstetricians and Gynecologists
BCPT	Breast Cancer Prevention Trial
CAMS	Council of Affiliated Menopause Societies
CHD	Coronary Heart Diseases
FDA	Food and Drug Administration
FMP	Final menstrual period
HERS	Heart and Estrogen/progestin Replacement Study
HRT	Hormone Replacement Therapy
MRS	Menopause Rating Scale
NAMS	The North American Menopause Society
PEPI	Postmenopausal Estrogen/Progestin Interventions
STARW	Stages of Reproductive Aging Workshop
WHI	Women's Health Initiative
WHO	World Health Organization

Introduction & Aim Of The Work

INTRODUCTION AND AIM OF THE WORK

Introduction

The menopause signals the end of a woman's ability to reproduce. It also represents, therefore, the end of her need for contraception. Yet an understanding of the menopause and how it causes change in the woman's body is relevant to the providers of health services for several reasons **(WHO, 1996).**

First, as people live longer, the years after the menopause represent a significant part of a woman's life that she has every right to want to enjoy to the full. A woman's state of health during those years depends a lot on her health before the menopause. So reproductive health services that protect her from unwanted pregnancies, contribute directly to her premenopausal and postmenopausal health. Second, a woman who is approaching the menopause can still become pregnant. Pregnancy at this time is usually neither desired nor desirable. Thus women approaching the menopause need safe and effective contraception **(WHO, 1996).**

Many women may view menopause as a transition from middle age to old age. Although some may look upon this with pleasant anticipation as a time of relative freedom from such worries as undesired pregnancies and the stress of childbearing, many women fear this period because of the anticipated losses; thus the signs of menopausal transition may be ignored as a means of denial **(Hurd et al, 2002).**

The possibility of alleviating menopausal symptoms by hormone replacement therapy (HRT) should be recognized by all physicians, not merely by gynecologists. But which women should be given what therapy, and for how long? Due to the increased risk of endometrial cancer and bleeding problems when u sing e strogen m onotherapy, o nly women who have undergone hysterectomy could use this regimen unless

treatment is aimed at amelioration of urogenital symptomatology only. In all other cases a combination of an estrogen and a progestogen must be used **(Samsioe, 2002)**.

Non-oral, particularly transdermal, therapy is an alternative in women with co-existing morbidity such as migraine, diabetes, malfunction of the gastrointestinal tract and liver disease. Oral therapy is preferred particularly in women with elevated plasma levels of LDL-cholesterol, lipoprotein (a) or homocysteine. Oral therapy induces liver protein synthesis. This could be an advantage in cases with low plasma levels of sex hormone-binding globulin (SHBG) as low levels of SHBG may promote androgenic stigmata such as hirsutism and a lowering of the voice **(Samsioe, 2002)**.

Selective estrogen-receptor modulators (Serums) can help prevent osteoporosis but do not relieve menopausal symptoms. However, some women are unwilling or unable to take HRT, and some decide to discontinue therapy. Patients need to be aware of the potential for drug interactions when these alternative therapies are used concomitantly with prescription drugs **(Gas and Taylor, 2001).**

Many nontraditional alternatives are used to treat the hot flashes and somatic complaints of menopause, for which options such as HRT and other prescription and over-the-counter drugs are also available. To date, no one agent treats all menopausal symptoms as effectively as estrogen **(Grady, 2002).**

Healers have been using herbs as medicine for thousands of years. Many drugs we use today come from plants. Herbal products can help relieve some symptoms of menopause for some women. Although hormone therapy is used most effectively for climacteric complaints, premenstrual syndrome, and dysmenorrhea, herbal medicines (also known as phytopharmaceuticals) are also recognized for their efficacy and safety.

The benefit of C. racemosa in alleviating gynecologic symptoms is cited in several publications on herbal medicines **(Tyler, 1994; Murray, 1996; Laux, 1997).**

Considerable interest in herbal medicine has been a current trend in the North American market that shows no signs of abating. This may be attributed to a renaissance in "natural living." Concerns about contraindications, risk factors, and adverse drug reactions of synthetic pharmaceuticals do not quite motivate compliance. Approximately one third of North Americans older than 18 years of age use herbal remedies for numerous illnesses; 53% are convinced of their therapeutic efficacy and 65% of their safety **(Johnston, 1997).** Women experiencing menopausal symptoms often search for alternatives to hormone-replacement therapy **(Kronenberg, 1994)**; to date, herbal remedies have treated menopausal symptoms in 4% of these patients and premenstrual syndrome in 17% **(Johnston, 1997).**

Phytoestrogens are currently in the focus of interest, since it is known that classical estrogen/progestin replacement therapy (HRT) significantly increases the risk of mammary cancer (**Liehr JG, 2001; Rossouw JE, 2002**)

Recently, the American National Institute of Health stopped a clinical trial with HRT in healthy postmenopausal women due to an increased risk of invasive breast cancer and an increase of cardiovascular risks including venous thrombosis. These risks outweigh any benefits of HRT (**Rossouw JE, 2002**). An estrogen replacement therapy also increases the risk of endometrial cancer (**Southcott BM, 2001**), which is reduced by additional progestin administration (**Feeley KM, 2001**). The strong belief that HRT will reduce the risk for cardiovascular diseases (**Grodstein F, 2000; Mikkola TS, 2002**) has been challenged by the finding of increased fatal heart attacks in women with pre-existing arteriosclerosis

(Hulley S, 1998; Herrington DM, et al, 2000). Experimental and clinical investigations about the effects of phytoestrogens on the cardiovascular system show inconsistent results **(Ariyo and Villablanca, 2002; Clarkson, 2002).** As a consequence, the compliance of classical hormone therapies decreases and many patients look for alternatives.

The use of C. racemosa rootstock (black cohosh), which grows in the eastern United States and Canada, has a long tradition **(Duke, 1985).** The shamans of North American Indian tribes and the colonists used black cohosh extracts for joint pain, myalgia, and neuralgia, as well as for climacteric symptoms, general gynecologic complaints, pain in childbirth, and rheumatism **(Goodenough, 1982).** In traditional Chinese medicine, Cimicifugae rhizoma (rhizome of the Cimicifuga species) has been an anti-inflammatory analgesic, and antipyretic remedy **(Sakurai, 1996).**

Aim Of The Work

To verify the following :

- The effect of phytoestrogens on the menopause related symptoms in postmenopausal women.
- The impact of using phytoestrogens on the endometrium and the breast.

Review Of Literature

REVIEW OF LITERATURE

CHAPTER I

MENOPAUSE

1.1 Definitions and terminology

Menopause is a natural biologic process, not an estrogen deficiency disease. Menopause represents the permanent cessation of menses resulting from loss of ovarian follicular function **(Speroff, 1999)**. Menopause can occur spontaneously (i.e. "naturally") or be induced through the medical intervention (i.e. Surgery, chemotherapy, or pelvic radiation therapy) **(NAMS, 2002).**

Clinicians and researchers involved the field of menopause had long recognized the need for universally accepted menopause terminology as well as a staging system to logically divide the last 10 to 15 years of reproductive aging. In 2001, the Stages of Reproductive Aging Workshop (STRAW) sponsored by The North American Menopause Society (NAMS), the Council of Affiliated Menopause Societies (CAMS), the National Institute of Health, the American Society for Reproductive Medicine, and the National Institute of Child Health and Human Development, addressed nomenclature and a staging system.

The reproductive aging continuum created by STRAW was divided into seven stages, five precede and two follow the final menstrual period (Fig 1). STRAW pointed out that not all healthy women will follow this pattern, some will "seesaw" back and forth between stages or skip a stage altogether.

Figure 1. Stages/nomenclature of normal reproductive aging in women

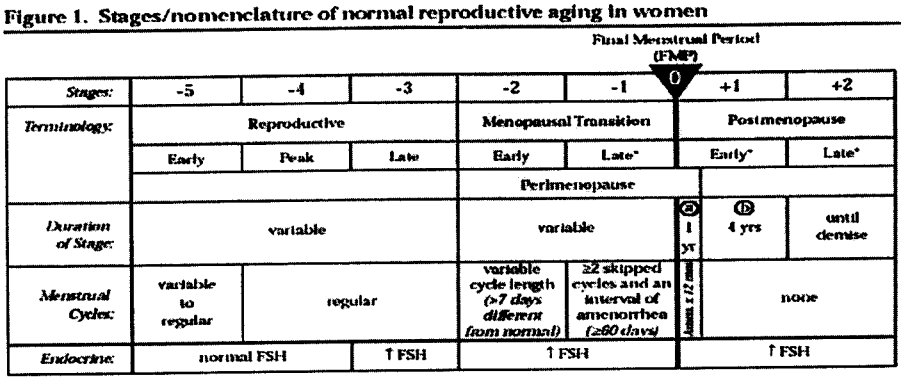

Figure 1: Stages/nomenclature of normal reproductive aging in women

Menopause

Menopause is derived from the Greek words, men (month) and *pausis* (cessation) **(Hargrove and Eisenberg, 1995).** The term menopause as described by STRAW, is the anchor point that is defined after 12 months of amenorrhea following the final menstrual period (FMP) **(NAMS, 2002).**

Premenopause

The term *premenopause*, according to the Council of Affiliated Menopause Societies (CAMS), is often used ambiguously, either to refer to the 1 or 2 years immediately before menopause or to the whole of the reproductive period prior to menopause. CAMS recommended that this term should encompass the entire reproductive period up to the FMP. However CAMS has also indicated that this term can be confusing and, preferably, should be abandoned **(NAMS, 2002).**

Perimenopause

The term *perimenopause,* according to STRAW, is defined as about or around menopause. It begins with stage-2 and ends 12 month after the FMP **(NAMS, 2002).**