Efficacy Comparison of Pueraria mirifica (PM) against Conjugated Equine Estrogen (CEE) with/without Medroxyprogesterone Acetate (MPA) in the Treatment of Climacteric Symptoms in Perimenopausal Women: Phase III Study

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Objective: *To evaluate the efficacy comparison of Pueraria mirifica (PM), name in Thai is Kwao Kruea Khao, against conjugated equine estrogen (CEE) with/without medroxyprogesterone acetate (MPA) in the treatment of perimenopuasal women with climacteric symptoms.*
Material and Method: *Perimenopausal women attending the Menopausal clinic of Hat Yai Regional Hospital were voluntarily recruited. The vasomotor symptoms such as hot flushes and night sweats, as well as other unpleasant symptoms, urogenital and psychological symptoms, were also assessed. Patients were voluntarily enrolled and randomly received daily 50 mg raw material of PM, Group A, or daily 0.625 mg of conjugated equine estrogen (CEE) with/without 2.5 mg of medroxyprogesterone acetate (MPA), Group B, depend on non-hysterectomized/hysterectomized condition.*
Results: *Seventy-one patients were enrolled. Eleven of those were excluded for failing to complete the initial work-up and follow-up. Sixty cases were evaluated, 30 cases in Group A and 30 cases in Group B. After medication, the mean of modified Greene climacteric scale (MGCS) in Group A/Group B had decreased from 29.0/32.26 to 17.86/18.1, 12.56/9.57 and 9.9/8.16 at 1-, 3-, and 6- month respectively. The clinical satisfaction using MGCS was not statistically significant between PM (Group A) and CEE with/without MPA (Group B) in the alleviation of climacteric symptoms (p-value > 0.05,). There were no statistically significant changes of three serum markers: estradiol, follicle-stimulating hormone (FSH), and luteinizing hormone (LH) between both groups.*
Conclusion: *PM, containing phytoestrogens, has estrogenic effect as similar as CEE, and can alleviate the climacteric symptoms in perimenopausal women. PM demonstrates great promise in the treatment of climacteric symptoms. However, optimal doses should be clinically assessed to meet appropriate individual responses.*

Keywords: *Pueraria mirifica, Conjugated equine estrogen, Medroxyprogesterone acetate, Vasomotor symptoms, Perimenopausal women, Phytoestrogen*

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The most common climacteric symptom among perimenopausal women is the occurrence of hot flashes, affecting approximately 80% of women, and requiring 40% of those women to seek medical attention. A hot flush at night is called a night sweat, which may be accompanied by feelings of anxiety or terror[1]. These symptoms may last 1 to 5 years in 64% of women, with a median length of 4 years[2]. Because the occurrence of these symptoms is associated with decreased levels of estrogen, logical treatment approaches have involved replacement of estrogen. Two types of estrogen have been commonly prescribed

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depending on hysterectomized status. The first regimen is conjugated equine estrogen (CEE) and given only to the women who had had a hysterectomy. The second regimen is a combination of CEE with medroxyprogesterone acetate (MPA) for women without hysterectomy. The reason is, estrogen should always be given in combination with a progestin, to prevent the occurrence of endometrial hyperplasia[3].

Hormone therapy (HT), once is the mainstay for managing menopausal symptoms and helping to prevent coronary artery disease and osteoporosis, has recently been reported to increase health risks by the Heart and Estrogen/Progestin Replacement Study II (HERS II) and the Women's Health Initiative (WHI)[3-5]. Although HT may still play a role in the short-term management of hot flushes, many women are concerned about using HT and want to know what other therapeutic options are available[6].

Since 1998, a research question of the Institute of Thai Traditional Medicine (ITTM), Department of Thai Medicine Development and Alternative Medicine (DTMDAM), Ministry of Public Health of Thailand, confined to Pueraria mirifica (PM), namely in Thai is Kwao Kruea Khao which was popularly available for Thai consumers, and foreign users as well. A question was how to conduct the medicinal herb study in the scientific research. Initially, the acute and sub-chronic toxicity in an animal study was carried out by Chivapat S and associates[7]. After a safety study in phase I, then the phase II study was conducted in the daily dosage of raw material of 50 and 100 mg. The result promisingly affirmed that PM, containing phytoestrogens, has alleviated the climacteric symptoms in perimenopausal women[8]. The phase III study aimed to compare the efficacy of PM with that of conventional hormone therapy.

Material and Method

This was a randomized, non-blind trial, conducted in Hat Yai Regional Hospital. Patients were recruited from the menopause clinic, beginning on March 8, 2005. The last patient completed the intended 24-week follow-up on September 12, 2006. Consenting females over 40 years old, experiencing vasomotor symptoms, including one or more of the following; hot flushes, urogenital or psychological symptoms, night sweats with or without other unpleasant symptoms, were enrolled.

Exclusion criteria included, pregnancy, breastfeeding, unwillingness to avoid pregnancy for the duration of the trial, allergy to estrogens, having taken an estrogen replacement within 1 week prior to admission, unwillingness to continuously take the trial product for 6 months of the study, and those with chronic illnesses. The National Ethical Committee, and Institutional Review Board of the trial center, approved the protocol and informed consent.

The climacteric scale used in the present study was modified from Greene climacteric scale[9]. The primary assessment of the present study was the effect of the study product, based on the modified Greene climacteric scale (MGCS) over admission and 1-, 2-, 3-, 4-, 5-, and 6- month follow-up.

The secondary end points were hormonal assays; serum estradiol, serum follicle-stimulating hormone (FSH) and serum luteinizing hormone (LH), at admission and 3- and 6- month visit.

The safety of laboratory monitoring was evaluated monthly, and included complete blood counts, lipoprotein analyses; cholesterol, very low-density lipoprotein (VLDL) + low-density lipoprotein (LDL), high-density lipoprotein (HDL), triglycerides (TG), serum glutamic-oxaloacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT), bilirubin, alkaline phosphatase, blood urea nitrogen, creatinine, and uric acid.

The pulses rate, blood pressure and physical examination, were performed monthly, and no abnormal findings were detectable. The pelvic examination, Papanicolaou smear, breast examination, and electrocardiography were performed at admission, 3-, and 6-month follow-up.

The subjects were randomized for dosages of 50 mg of PM (group A) and 0.625 mg of CEE in hysterectomized women, or CEE with 2.5 mg of MPA in non-hysterectomized women (Group B).

Statistical analysis

Mean $\pm$ Standard deviation (SD), range and frequency (%) were used to describe characteristics. Chi-square test or Fishers' exact test of the exact values were less than 5 were used to compare categorical variables. Student's test was preformed to assess difference between two means. ANOVA with repeated measurement was used to compare between mean at baseline or admission and 1-, 2-, 3-, 4-, 5-, and 6-month respectively. Data management and analysis were performed using EpiInfo version 6. A p-value of less than 0.05 was considered significant difference.

Results

Of the 71 enrolled patients, 11 cases were

excluded for failing to complete the initial work-up and follow-up more than 3 months. Subjects of up to six-month follow-up were analyzed among 60 cases: 30 in Group A and 30 in Group B. The mean age of the Group A/Group B was 48.16/48.53 years with standard deviation of 4.06/5.89, and the range of 40-56/40-59 years old. The majority of the women, 40 in 60 (66.7%) were married, and 7 in 60 (11.7%) were single, 10 in 60 (16.7%) were divorced and 3 in 60 (5%) were widowed. None of them were in the habit of drinking alcohol, and only one case in Group A was a cigarette smoker. The mean of admission characteristics, showed no statistical significance difference between the two groups (p-value > 0.05).

The mean of the modified Greene climacteric scale (MGCS), assessing climacteric symptoms, included 20 indicators, as shown in Table 1. Each indicator was weighted by the subjects; 0 = none, 1 = mild, 2 = moderate, 3=severe. After medication, the mean of MGCS in Group A/Group B had decreased from 29.0/32.26 to 17.86/18.1, 12.56/9.57 and 9.9/8.16 at 1-, 3-, and 6-month respectively. The clinical satisfaction using MGCS was not statistically significant, p-value > 0.05, between Pueraria and CEE with/without MPA in alleviate the nearly overall of climacteric symptoms, except joint pain, dry skin, loss of interest in sex, and dysuria. CEE with/without MPA had significantly improved of joint pain (p-value < 0.05), dry skin (p-value < 0.001), loss of interest in sex (p-value < 0.05) more than Pueraria, while Pueraria had significantly improved of dysuria (p-value < 0.05) more than CEE with/without MPA.

The mean serum estradiol in Group A/Group B had increased from the baseline of 82.67/73.88 to 96.97/143.91, 102.53/137.23, 125.29/202.13, 80.6/99.06, 122.43/133.37 and 110.78/144.56 pg/mL at 1-, 2-, 3-, 4-, 5- and 6-month respectively. The increasing of estradiol in Group A had got along with Group B, with no statistical significance (p-value > 0.5). Whereas, the mean serum follicle-stimulating hormone (FSH)/luteinizing hormone (LH) of Group A were 41.13/17.31, 35.66/18.96 and 35.53/16.35; and Group B were 42.26/19.81, 24.74/12.08 and 32.81/14.06 mIU/mL at baseline, 3- and 6-month respectively. Non of the three markers had

Table 1. Comparison of Modified Greene Climacteric Scale at admission and follow-up visit

Indicators	Admission		1- Month		3- Month		6- Month	
	Gr A n = 30	Gr B n = 30	Gr A	Gr B	Gr A	Gr B	Gr A	Gr B
Hot flushes	2.1	2.1	1.13	0.8	0.55	0.35	0.53	0.3
Night sweats	1.5	1.83	0.93	0.6	0.26	0.39	0.53	0.3
Headaches	2.03	2.1	0.9	1.13	0.83	0.71	0.6	0.66
Mood instability	2.23	2.06	1.46	1.13	0.86	0.5	0.5	0.5
Nervous	2.16	2.03	1.36	1.3	1.03	0.67	0.86	0.6
Feeling neglected	1.2	1.2	0.76	0.5	0.53	0.21	0.33	0.2
Excitable	1.73	1.9	1.16	0.96	0.9	0.6	0.53	0.56
Insomnia	1.53	2.16	0.6	0.66	0.53	0.28	0.26	0.4
Feeling tired	2.16	1.8	1.33	1.06	0.73	0.53	0.8	0.46
Back pain	1.93	2.23	1.26	1.36	1.1	0.82	0.96	0.8
Joint pain	1.86*	2.1	1.36	1.33	0.9	0.82	0.53	0.53
Muscle pain	1.53	1.9	1.0	1.16	0.76	0.71	0.56	0.63
Dry skin	1.0**	1.8	0.93**	1.43	0.86	0.82	0.7	0.6
Dryvagina	0.9	1.3	0.56	0.63	0.4	0.17	0.2	0.23
Dyspareunia	0.6	0.96	0.13	0.4	0.13	0.03	0.1	0
Loss of sex satisfaction	0.63	0.96	0.26	0.66	0.2	0.21	0.23	0.2
Loss of interest in sex	0.83	1.16	0.53	1.1	0.23*	0.64	0.4	0.43
Dysuria	0.53	0.56	0.16	0.06**	0.1	0.1	0.16	0
Urinary frequency	1.33	1.43	1.06	1.06	0.7	0.57	0.5	0.4
Urinary incontinence	1.13	0.9	0.9	0.76	0.93	0.67	0.56	0.33
Total mean scale	29.0	32.26	17.86	18.1	12.56	9.57	9.9	8.16

* p-value < 0.05, ** p-value < 0.01

any statistically significant differences i.e., p-value > 0.05, between Pueraria and CEE with/without MPA.

The mean cholesterol level of Group A/ Group B (normal range of 110-250 mg/dL) was slightly altered from the baseline of 228.13/225.73 to 212.76/ 222.93, 219.48/206.96, and 225.65/224.36 mg/dL at 1-, 3- and 6-month; corresponding with the mean HDL level of Group A/Group B (normal range of 35-55 mg/dL), from 47.13/49.33 at baseline to 50.1/51.17, 53.17/50.25, and 57.0/58.43 mg/dL.

Whereas, the mean VLDL + LDL level of Group A/Group B was slightly changed from baseline of 181.0/176.4 to 162.66/171.75, 166.31/156.7, and 168.65/ 165.93 mg/dL. The mean triglyceride level of Group A/ Group B (normal range of 30-200 mg/dL) were 120.96/ 105.66 at the baseline and increased to 179.13/133.93, 159.6/137.96, 187.96/120.22, 201.27/145.51, 198.13/138.27, and 194.20/124.53 mg/dL at 1-, 2-, 3-, 4-, 5-, and 6-month. There were statistically significant increases in triglyceride levels in subjects of group A more than those in Group B, at 3-, 4-, 5-, and 6-month respectively. During the follow-up visit, there were 5/1 cases of Group A/ Group B having markedly increased triglyceride level more than 400 mg/dL.

Except for one case in Group A with transient hypertension, no other laboratory abnormalities nor physical examination were reported, such as pelvic examination, Papanicolaou smear, breast examination, and electrocardiography.

Serum blood urea nitrogen/creatinine (normal range of 5-25/0.6-1.8 mg%) and uric acid level (normal ranges of 2.5-7.8 mg%) were within normal limits in both groups. Total bilirubin levels in all cases were within the normal range of 0.2-1.5 mg%, except two cases of Group A where the total bilirubin level was more than 1.5 mg%.

Serum SGOT and SGPT had a transient rise, slightly more than 100 IU/L, in one case of Group A. Alkaline phosphatase was within normal limits. However, transient hemoglobin below 10 gm/dL was seen in one case of Group A.

Distribution of adverse drug events, comparison between PM and CEE with/without MPA, are shown in Table 2.

Discussion

Risk of cardiovascular disease, breast cancer, stroke, and thromboembolic disease can be reduced by lower doses of CEE plus MPA, contrary to the higher doses used the study of WHI[3] when compared with

Table 2. Distribution of adverse drug events, comparison between CEE with/without MPA and PM

Adverse events	CEE with/without MPA n = 30	PM n = 30
Abdominal bloating	1 (3.3%)	1 (3.3%)
Abdominal discomfort	1 (3.3%)	-
Anemia	-	1 (3.3%)
Body itching	2 (6.6%)	-
Chest discomfort	3 (10%)	2 (6.6%)
Constipation	2 (6.6%)	-
Dizziness	2 (6.6%)	6 (20%)
Hand itching	-	1 (3.3%)
Hand sweating	2 (6.6%)	-
Increased weight	3 (10%)	-
Insomnia	-	1 (3.3%)
Mastodynia	5 (16.6%)	4 (13.3%)
Myalgia	-	1 (3.3%)
Nausea	1 (3.3%)	3 (10%)
Nausea/vomiting	-	1 (3.3%)
Nocturia	1 (3.3%)	-
Numpness at sole and palm	1 (3.3%)	-
Palpitation	1 (3.3%)	2 (6.6%)
Pelvic discomfort	-	2 (6.6%)
Spotting	9 (30%)	5 (16.6%)
Tired	-	1 (3.3%)

placebo. Furthermore, they are effective in preventing bone loss and reducing hot flushes in post menopausal women, even those in the early menopause[10-12]. These data suggest that lowering the dose of CEE plus MPA may reduce menopausal symptoms and enhance bone health without increasing adverse effects as seen in WHI. Given the positive effects of lower dose estrogen, it is plausible and logical to look for substances that have less affinity for the estrogen receptor than estradiol in the hope of identifying herbs or nutritional supplements that reduce menopausal symptoms and, perhaps, benefit bone without the adverse effects associated with HRT.

Could PM be finalized and demonstrate its comparable clinico-bioactivity with estrogen? The answer is strongly promising. Firstly, the biochemical assays of revealed substances are miroestrol[13-16], deoxy-miroestrol[17], and others. Miroestrol, the main component, has pharmacological effects in animals comparable to an estrogen effects[14,18-22], and reproductive effects such as abortion[18,23], contraception[24-26], embryo interception[18], sperm inhibition[25], inhibition of lactation[27], and spermicidal effect[24].

Secondly, phase II of the PM study clinically demonstrated that PM, both daily dosage of raw material of 50 and 100 mg, alleviates the climacteric symptoms in perimenopausal women, using MGCS[8]. Thirdly, the present study showed that PM 50 mg daily was efficacious in relieving climacteric symptoms, comparable with CEE with/without MPA.

Fourthly, the mean serum estradiol in Group A/Group B had increased from the baseline of 82.67/73.88 to 96.97/143.91, 102.53/137.23, 125.29/202.13, 80.6/99.06, 122.43/133.37, and 110.78/144.56 pg/mL at 1-, 2-, 3-, 4-, 5-, and 6-month respectively. The increasing of estradiol in the PM group was similar to the CEE group with/without MPA, without statistical significance. Finally, the estrogenic effects of the PM group mimic those of the CEE group with/without MPA, such as spotting, mastodynia, dizziness, and so on.

PM, containing phytoestrogens, has an estrogenic effect similar to CEE, and can alleviate the climacteric symptoms in perimenopausal women. PM demonstrates great promise in the treatment of climacteric symptoms. However, optimal doses should be clinically assessed to meet appropriate individual responses.

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ประสิทธิผลเปรียบเทียบระหว่าง *Pueraria mirifica (PM)* กับ *conjugated equine estrogen (CEE)* ร่วม หรือ ไม่ร่วมกับ *medroxyprogesterone acetate (MPA)* ในการรักษาอาการวัยเพศถอยในสตรีก่อนและหลังวัยหมดระดู: การศึกษาระยะที่ 3

วีระพล จันทร์ดียิ่ง, มาลินี แสงถวัลย์

วัตถุประสงค์: *เพื่อประเมินเปรียบเทียบระหว่าง Pueraria mirifica ชื่อไทยว่า กวาวเครือขาวกับ conjugated equine estrogen (CEE) ร่วมหรือไม่ร่วมกับ medroxyprogesterone acetate (MPA) ในการรักษาอาการวัยเพศถอยในสตรีก่อนและหลังวัยหมดระดู*

วัสดุและวิธีการ: *รวบรวมอาสาสมัครจากสตรีวัยก่อนและหลังวัยหมดระดูที่มาตรวจ ณ คลินิกวัยหมดระดู โรงพยาบาลศูนย์หาดใหญ่ ประเมินอาการ vasomotor เช่น ร้อนวูบวาบตามเนื้อตามตัว เหงื่อออกกลางคืน รวมถึงอาการอื่นเช่น อาการของระบบอวัยวะสืบพันธุ์และทางเดินปัสสาวะ อาการทางด้านจิตใจ ผู้สมัครใจเข้าร่วมการศึกษาได้รับการสุ่มอิสระเพื่อได้รับกวาวเครือขาว ขนาด 50 มิลลิกรัมต่อวัน (กลุ่ม เอ) หรือได้รับ CEE ขนาด 0.625 มิลลิกรัมต่อวัน ร่วมหรือไม่ร่วมกับ MPA ขนาด 2.5 มิลลิกรัมต่อวัน (กลุ่ม บี) โดยขึ้นกับว่ายังไม่ตัดมดลูกหรือตัดมดลูกแล้ว*

ผลการศึกษา: *ในจำนวนผู้เข้าร่วมการศึกษา 71 ราย มี 11 ราย ได้รับการคัดออกจากการศึกษาเนื่องจากไม่ผ่านการคัดกรองอย่างครบถ้วนหรือติดตามไม่ครบถ้วน เหลือผู้ป่วยจำนวน 60 รายได้รับการประเมินอย่างครบถ้วน แบ่งเป็น 30 ราย ในกลุ่ม เอ และ 30 ราย ในกลุ่ม บี หลังการรักษา ค่าเฉลี่ยของ modified Greene climacteric scale (MGCS) ในกลุ่มเอ/บี ลดลงจาก 29.0/32.26 เป็น 17.86/18.1, 12.56/9.57 และ 9.9/8.16 ในเดือนที่ 1, 3 และ 6 ตามลำดับ ความพึงพอใจทางคลินิกประเมินจาก MGSC ไม่มีความแตกต่างกันอย่างมีนัยสำคัญทางสถิติ (ค่า p-value > 0.05) ทั้งกลุ่ม CEE ร่วมหรือไม่ร่วมกับ MPA กับกลุ่มกวาวเครือขาวในการบรรเทาอาการวัยเพศถอย สำหรับตัวชี้วัดสามตัวชี้วัดในเลือด estradiol, follicle-stimulating hormone (FSH) และ luteinizing hormone (LH) ไม่มีการเปลี่ยนแปลงที่แตกต่างอย่างมีนัยสำคัญระหว่างทั้งสองกลุ่ม*

สรุป: *กวาวเครือขาวประกอบด้วยฮอร์โมนจากพืช มีการออกฤทธิ์คล้ายกับฮอร์โมนเอสโตรเจนเช่นเดียวกับ CEE และร่วมสามารถลดหรือบรรเทาอาการวัยเพศถอยในสตรีก่อนและหลังวัยหมดระดู กวาวเครือขาวแสดงถึงสัญญาณที่ดีในการรักษาอาการวัยเพศถอย อย่างไรก็ตาม ขนาดที่เหมาะสมควรได้รับการประเมินควบคู่กันไปกับอาการทางคลินิกตามการตอบสนองของผู้ป่วยแต่ละคนอย่างเหมาะสม*