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Effectiveness of Compounded Bioidentical Hormone Replacement Therapy (BHRT) Cream for Menopausal Women: A Clinical Study

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Abstract: ***Hormone replacement therapy with bio-identical hormones (BHRT) has been widely employed to improve menopause syndromes though not yet widely supported with landmark trial as to their efficacy in improving menopause syndromes. Based on this hypothesis, this trial explores the efficacy of compounded BHRT in increasing the serum level as well as the menopause syndromes. The objective of this study is to evaluate the effectiveness of compounded BHRT cream which contain Progesterone 10 % and Bi estrogen 0.25 % for menopausal women. The experimental trial conducted with Pretest-Post test Control Group on 28 menopausal women aged 45-65 years, divided in two groups given with test (containing Progesterone 10 % and Bi estrogen 0.25 %) and placebo cream (cream base without actives). Patient symptom severity was compared at baseline and to 2 months follow-up using the Greene climacteric scale and complete a new patient evaluation form and a laboratory hormone panel (progesterone and estradiol) prior to their initial visit. Results show that the serum levels as well as the Greene climacteric scale between the test and placebo group before the trial did not show difference (independent t test) However, the post test did show difference between the two groups in terms of serum levels as well as the Greene climacteric scale. (p<0.05) The study has proven that trans dermal application of compounded progesterone and bi estrogen cream can increase the serum levels of progesterone and estradiol while at the same time improves the menopause syndromes. Based on this study, further studies can be organized to further conclude the efficacy of BHRT.***

Keywords: menopause, progesterone, estrogen, hormone replacement therapy, bio-identical, trans dermal, BHRT

1. Objective

The objective of this study is to evaluate the effectiveness of compounded BHRT cream which contain Progesterone 10% and Biestrogens 0.25% for menopausal women.

2. Methods

This was a clinical study of 30 women between the ages of 45-65 who received a compounded BHRT cream freshly prepared by compounding pharmacy that is a member of *PCCA (Professional Compounding Centre of America)* (Biundo, 2008). Patient symptom severity was compared at baseline and to 2 months follow-up using the*Mann-Whitney* test.Patients are referred to the *Rafa Health and Beauty Lifestyle clinic* through physicians, family members, and friends. BHRT consultation services consist of an extensive initial evaluation, hormone replacement education, and follow-up visits (Trifena, 2010). Patients complete a new patient evaluation form and a laboratory hormone panel prior to their initial visit. This hormone panel, determined through blood serum, aids in identification of sex hormone deficiency: progesterone and estradiol(Wepfer, 2001). During initial evaluation and follow-up visits, physician use a standardized form to monitor symptom resolution and adverse effects. This form lists several symptoms associated with menopause. Patients are asked to indicate whether their symptoms are "absent," "mild," "moderate," or "severe."

3. Data Collection

A customized, data collection instrument was developed using Microsoft Access 2007® software. The instrument was designed to mimic the appearance of the initial patient intake and follow-up forms used during physician consultations at *Rafa Health and Beauty Lifestyle clinic* (Trifena, 2010). The dependent variables utilized in this study were vasomotor symptoms, mood symptoms and physical changes. A decrease in symptom intensity was defined as a decrease in symptom ratings from baseline to follow-up (two months). Baseline and follow-up symptom ratings were also compared at each time point using the percentage of patients reporting either "moderate" or "severe." Reduction in symptom severity was also evaluated in a subgroup analysis of women between the ages of 45 and 65 years.

4. Data and Statistical Analysis

All statistical comparative analyses were performed using *independent – t.* Statistical significance was defined as an alpha less than 0.05(p> 0,05). Descriptive statistics (e.g., means, medians, and frequencies) were used to characterize the patient demographics, BHRT use, symptom resolution, and adverse effects. Patient conditions, baseline characteristics, conditions, baseline menopausal symptoms, dosing regimens, symptom improvement, and adverse effects were compared between groups. Categorical variables were compared using chi-square and *F test (Levene's test)*. Continuous variables were tested for normality using the *Shapiro Wilk* Test. Normally distributed variables were reported as means (standard deviations), while non-normally distributed variables were reported as medians (25th and 75th percentiles). Paired data were compared using the *Wilcoxon signed-rank tes*t. All tests were two-sided.

5. Results and Discussions

Women initiated on compounded BHRT experienced significant increasing blood level within 2 months (Figure 1

.1 and Figure 1.2). It can be seen that the deficiency of Progesterone before the therapy was more evident than that of Estrogen. This confirms the theory that compared to other hormones, Progesterone level dropped most significantly in women. The improvement of the serum level again is more clear cut in the case of Progesterone. However the fact that both Estrogen and Progesterone level rise drastically after the 2 months of topical application of the compounded cream proves the efficacy of the cream. In other words, the hormones actives do get penetrated through the skin into the blood system to give the desired effects which can be seen in Figure 1.3.

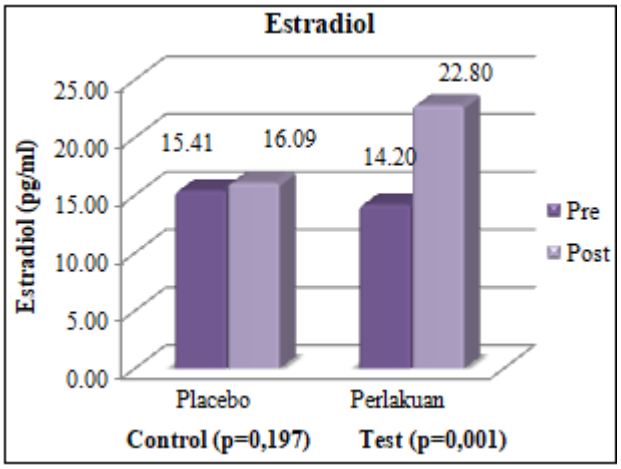

Figure 1.1: Serum Level of Estradiol Before and after the Topical Application of Compounded Progesteron 10% Biestrogen 0.25% cream

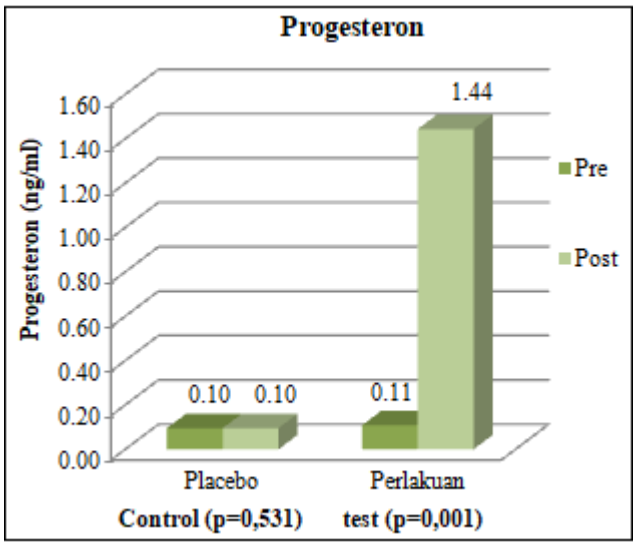

Figure 1.2: Serum Level of Progesterone Before and after the Topical Application of Compounded Progesteron 10% Biestrogen 0.25% cream

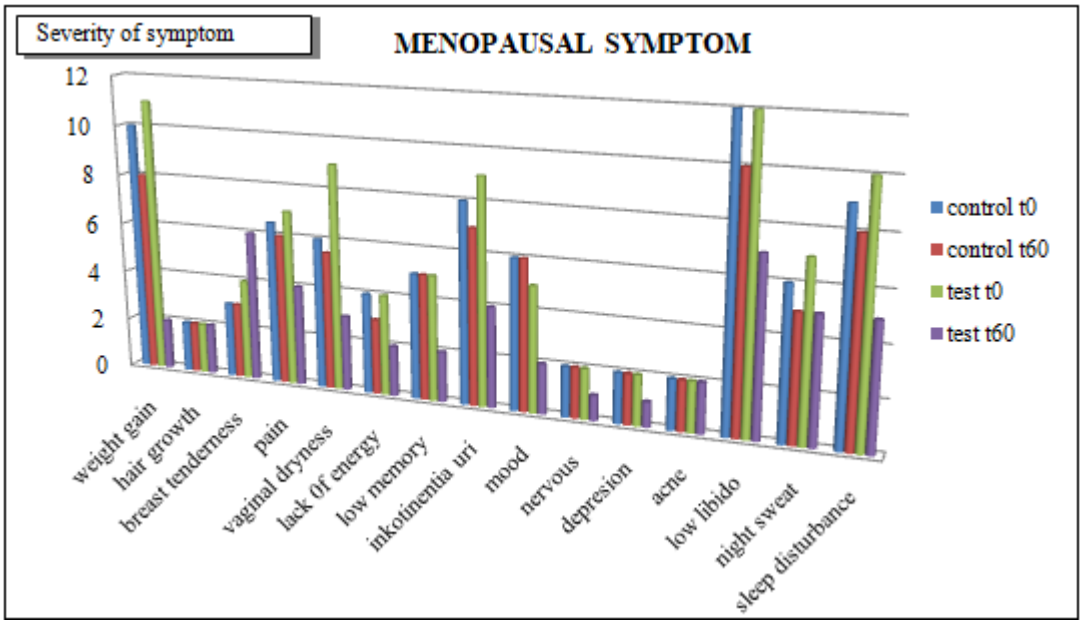

Figure 1.3: Effectiveness of compounded BHRT to Alleviate Moderate to Severe Menopausal Symptoms

The subgroup analysis to determine the effectiveness of compounded BHRT cream (test group) compared to placebo (control group)in women between the ages of 45 and 65 years is illustrated in Figure 1.3) Women initiated on compounded BHRT cream experienced significant reductions in moderate to severe mood symptoms within 2 months.This age group more closely represents those women who are more likely to be affected by menopausal symptoms. The results seen were similar to those in the primary analysis.

This is the first time in Indonesia compounded BHRT therapy for menopausal women has been evaluated, but there are several studies that confirm the effectiveness of "manufactured" BHRT (Holtorf, 2009; Lorentzen, 2001). This study use Randomized controlled trials (RCTs)

confirms that compounded BHRT cream is effective for reducing menopausal symptoms.

6. Conclusions

Our study is the first Indonesian clinical study to provide clinical evidence for the effectiveness of compounded BHRT cream. Given the harmful effects of synthetic hormones observed in the WHI and HERS trials (Holtorf, 2009), these efficacy data provided by the bioidentical hormones are of great value (Klentze, M. 2012; Lorentzen, 2001). Our study provides clear evidence that the compounded BHRT cream used hereis effective for reducing menopausal mood symptoms. Larger studies are needed to examine the impact of compounded BHRT on vasomotor symptoms, myocardial infarction, and breast cancer.

References

[1] Biundo, B. 2008. Personal Communication. Professional Compounding Centers of America. San Antonio.
[2] Holtorf, K.2009. The Bioidentical Hormone Debate: are Bioidentical Hormones (Estradiol, Estriol and Progesterone) Safer or More Efficacious than Commonly Used Synthetic Versions in Hormone Replacement Therapy? Postgrad Med.;121:73–85.
[3] Lorentzen, J. 2001. Hormone Replacement Therapy: The Evolution of Hormone Treatment. Int J Pharmaceut Compounding; 5:336.
[4] Wepfer, S. 2001 The Science Behind Bioidentical Hormone Replacement Therapy. Int J Pharmaceut Compounding;5:10.
[5] Klentze, M. 2012. Safety and Efficacy of Bioidentical Hormone Replacement Therapy for Menopausal Women, Personal email.
[6] Trifena. 2010. Population of Indonesian Menopausal Women, Data in file.