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Opinion

Current Hormone Treatments to Improve Sleep Problems in Menopause

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Menopause marks the cessation of menstruation due to the loss of follicular function [1,2]. Some women in this stage report several symptoms that prevent them from reaching deep sleep, reducing their quality of life, and triggering a depressive state, lousy mood, and memory loss [3-5]. It has been previously reported that such sleep disorders worsen with age; 9.2% of women between 40 - 49 years, 21.1% between 50 - 59 years, and 25.7% > of 60 years suffer from them [2,5].

During the late menopausal transition in women, annual hormone testing indicates a decrease in estradiol and an increase in follicle-stimulating hormone (FSH) [1]. The rise in FSH levels has been positively associated with sleeplessness, measured by polysomnography. The polysomnography [6] process has been useful in determining and defining the arousals in perimenopausal women after sleep onset [7]. Lowering FSH levels with estrogen and progesterone treatment (EPT) may be an option to decrease the arousals after sleep onset and the number of awakenings in women who report this sleep problem [8]. It has been demonstrated that estrogen therapy improves sleeping problems in postmenopausal women [2,8]. Moreover, Plamberger., *et al*. showed, in women, that both progestogen treatment and the luteal phase of the menstrual cycle increase fast sleep spindle density.

Plamberger., *et al*. [9] thus, suggesting that sex hormones play a role in sleep. However, studies that support the participation of 17β-estradiol (E2) and progesterone (P) in the fragmented sleep of these women are inconsistent because primarily male animals, not humans, have been used to conduct sleep studies [2].

The existence of X-001HR [BijuvaTM] on the market provides perimenopausal women with an alternative to combination hormone therapy (EPT). X-001HR (1 mg E_2/100 mg P) brand Bijuva is the first FDA-approved combination EP formulation designed for postmenopausal women [10].

The effect of TX-001HR on awakings in postmenopausal women with vasomotor symptoms (VMS) has been previously described [11]. This formulation improved sleep parameters from week 12 to month 12, according to the determinations by the MOS-Sleep parameter [12,13]. Studies on the relationship between improvement in VMS, quality of life, and sleep have shown that treatment with TX-001HR decreases the frequency and severity of VMS. This results in a recovery of quality of life and sleep [14].

The North American Menopause Society has declared that hormone therapy (HT) is the best treatment to control VMS and genitourinary syndrome of menopause (GSM). It also prevents bone loss and fractures. The risks of this therapy depend on the dose, duration

of use, route of administration, time of initiation, and whether a progestogen is used. Therefore, treatment should be designed for each patient, seeking periodic reassessment [15].

However, the risks of the treatment are increased for women who start HT more than 10 to 20 years after menopause or who are 60 years or older due to threats of coronary heart disease, stroke, venous thromboembolism, and dementia. For these reasons, the prescription should be based on this case, for indications such as persistent VMS or bone loss, with shared decision-making and periodic reassessment [15].

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