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A New Pharmacologic Treatment for Nausea and Vomiting of Pregnancy

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Nausea and vomiting of pregnancy (NVP) is a common condition that can affect up to 80 percent of all pregnant women. Symptoms can range from mild nausea alone to nausea with vomiting that is unrelenting (Lacroix, Eason, & Melzack, 2000). The most severe form, hyperemesis gravadarum, affects a smaller proportion of women and can lead to serious complications including dehydration, weight loss and electrolyte imbalance that can require hospitalization (Davis, 2004). Women with NVP report higher levels of discomfort, lower quality of life and lost time from work (Kramer, Bowen, Stewart, & Muhajarine, 2013; Munch, Korst, Hernandez, Romero, & Goodwin, 2011).

Abstract Nausea and vomiting of pregnancy (NVP) affects up to 80 percent of pregnant women. This condition is usually self-limiting, but the symptoms can be distressing and interfere with work, social activities and sleep. Symptoms can often be managed by diet and lifestyle changes, but these interventions may not be successful for everyone. In April 2013, the U.S. Food and Drug Administration approved doxylamine succinate 10 mg/pyridoxine hydrochloride 10 mg (Diclegis®) as the first medication to specifically treat NVP in more than 30 years. This article reviews the indications, dosage and nursing interventions associated with using doxylamine succinate/pyridoxine to treat NVP. DOI: 10.1111/1751-486X.12096

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Etiology of NVP

The exact etiology of NVP is unknown, although rising levels of human chorionic gonadotropin and other endocrine factors, such as fluctuating levels of estrogen, progesterone and thyroid-stimulating hormone, have been implicated in the development of NVP (Lee & Saha, 2011; Niebyl, 2010). Other possible contributing factors include slowed peristalsis of the gastrointestinal tract from mechanical and hormonal factors and changes in carbohydrate metabolism (Cibulka & Barron, 2013).

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Controlling NVP

Women with NVP are educated about the typical course of symptoms and strategies to alleviate these symptoms, and are encouraged to avoid potential triggers such as odors, foods and situations that may increase the likelihood of nausea and/or vomiting. Women's and health care providers' concerns about possible teratogenic effects of medications during pregnancy, especially during the first trimester, has led to many health care providers being cautious about prescribing pharmacologic treatments for NVP (Davis, 2004; Matthews, Dowswell, Haas, Doyle, & O'Mathuna, 2010). Therefore, medications that are safe and effective are often underutilized, and women who may benefit from treatment are not able to fully explore this option.

A New Option

In April 2013, the U.S. Food and Drug Administration (FDA) approved doxylamine succinate 10 mg and pyridoxine hydrochloride 10 mg (brand name Diclegis®) for the treatment of NVP. This is the first drug approved specifically for NVP in more than 30 years (FDA, 2013). The drug is a new version of Bendectin®, which was originally manufactured by Merrill Dow but was voluntarily removed from the market by the manufacturer in the early 1980s because of concerns over birth defects and costs associated with malpractice litigation (Brent, 2002). Subsequent evidence-based reviews and meta-analyses did not demonstrate an increased risk of birth defects (Magee, Mazzotta, & Koren, 2002; McKeigue, Lamm, Linn, & Kutcher, 1994), and the FDA concluded that there were no reproductive risks to the developing fetus associated with the use of doxylamine succinate/pyridoxine hydrochloride in pregnancy (Brent, 2002).

Medication Overview

Doxylamine succinate 10 mg and pyridoxine hydrochloride 10 mg is a combination drug consisting of an antihistamine (doxylamine) and a vitamin B_6 analog (pyridoxine) (Duchesnay, Inc., 2013). This delayed-release oral medication is indicated for NVP that has not responded to other treatment modalities, such as dietary modification and lifestyle management.

Mechanism of Action

The specific mechanism of action for how the combination of doxylamine succinate/pyridoxine hydrochloride works to alleviate NVP is not entirely known. The vomiting center in the medulla of the brain receives signals from the cerebral cortex, the inner ear and the sensory organs through multiple neurotransmitters, including histamine. When the pathway of the neurotransmitters is interrupted, the vomiting reflex is decreased or eliminated. Doxylamine, an antihistamine, may interrupt the histamine pathway and reduce vomiting (Davis, 2004). Vitamin B_6 alone and combined with other medications (such as doxylamine) has shown to be effective in some clinical trials to reduce nausea, although the therapeutic mechanism is unclear (Matthews et al., 2010). Although the mechanism of action is not clear, the combination of doxylamine and pyridoxine has been shown to be effective over placebo in clinical trials (Koren et al., 2010).

Dosage and Administration

The dose amount and schedule are determined by response to the medication. The initial starting dose is two tablets at bedtime. If symptoms are relieved, the next day this dosing schedule can be maintained. If symptoms persist, the dose can be increased to one tablet in the morning and two tablets at bedtime. If adequate relief still isn't obtained, the dose can

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