

Severe morning sickness patients get relief from anti-seizure drug, professor has found

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(Medical Xpress)—Good news may be on the horizon for Kate Middleton, Duchess of Cambridge, and other women stricken with severe nausea and vomiting during pregnancy, thanks to the work of a University at Buffalo professor who is conducting research on a drug that is showing success treating pregnant women with this condition.

Thomas Guttuso Jr., MD, assistant professor of neurology in the UB School of Medicine and Biomedical Sciences, has been studying the drug gabapentin, an anti-seizure and anti-pain drug that he previously had studied in cancer patients receiving chemotherapy.

"I became interested in this drug for hyperemesis gravidarum (an extreme form of morning sickness) because I saw how effective it appeared to be in treating chemotherapy-induced nausea and vomiting in patients who had failed treatment with conventional anti-emetics," says Guttuso. Anti-emetics are drugs currently approved for treating nausea and vomiting.

In 2010, he published in the journal *Early Human Development* the results of an open-label pilot study that enrolled seven women from Western New York examining the drug's safety, tolerability and effectiveness in treating hyperemesis gravidarum.

"It was really exciting to see how quickly the women responded," says Guttuso.



None of the women had seen any improvement on any other anti-emetic medications they had tried.

"But when they started with gabapentin, all of them showed a dramatic improvement," he says. "Within two hours of taking the first pill, most of the patients were feeling much better and several were able to start eating and drinking again. It was a pretty amazing thing to see.

"The study showed that after two weeks of gabapentin therapy, the seven women experienced an average 80 percent reduction in their nausea and a 94 percent reduction in their vomiting and near normal levels of eating and drinking," Guttuso says. After this study was published, Guttuso knows of five more women with hyperemesis gravidarum that tried gabapentin and all experienced excellent relief.

The women needed to take gabapentin on average until about half way through their pregnancies before they could stop it without recurrent nausea and vomiting.

One of the potential concerns with gabapentin was that two of the babies born to patients in the UB study were found to have congenital defects. As a result, the Food and Drug Administration placed the study on clinical hold in April 2011 until further safety data was available on the use of gabapentin during pregnancy.

By May 2012 several pregnancy registries and other studies had reported that the rate of congenital defects among a total of 258 infants born to women taking gabapentin early in their pregnancies was about the same as the rate of congenital defects in the general population. After reviewing these findings, the FDA removed the clinical hold allowing Guttuso to resume his research on the effects of gabapentin on hyperemesis gravidarum.



Although the results of the small pilot study were very encouraging, Guttuso emphasizes that a placebo-controlled study among many more patients needs to be conducted in order to know if gabapentin truly is effective for hyperemesis gravidarum. "The evidence right now is still very preliminary," he states.

Early next year, Guttuso plans to submit a new grant proposal to the National Institutes of Health in order to support such a study with enrolling sites both at UB and at the University of Rochester. Guttuso is hopeful that the study will be funded.

"This is a study that really needs to be done because currently there are no effective treatments for hyperemesis gravidarum," Guttuso says. "Women end up having to keep going back to the hospital for intravenous fluids because of dehydration from their persistent nausea and vomiting."

Guttuso is a Western New York neurologist and UB professor whose practice focuses primarily on patients with movement disorders such as Parkinson's disease. He originally became interested in gabapentin when he accidentally discovered that it appeared to be effective in treating hot flashes in postmenopausal women. Soon thereafter, another patient with breast cancer undergoing chemotherapy informed him that gabapentin appeared to fully resolve her chemotherapy-induced nausea and vomiting.

After observing the marked improvements in nausea and vomiting that many <u>cancer patients</u> experienced from gabapentin, he thought that it should be tried with <u>patients</u> suffering from hyperemesis gravidarum. He then teamed up with several Buffalo obstetricians to do the pilot study on pregnant women.

"I think a lot of people don't appreciate just how sick and disabled these



women can be," Guttuso says. He notes that 15 percent of women with this condition end up having abortions even though they really want to have children.

"Some of the most severely affected end up having abortions because they have no hope of getting better," he says. "Ending the pregnancy is currently the only effective treatment for hyperemesis gravidarum. These women are so sick. They often retch every 15 to 30 minutes and it can go on all day and often at night as well."

Two of the women in Guttuso's small <u>pilot study</u> were planning to have abortions. One of them was scheduled for one the next day out of desperation. Once she went on gabapentin, her symptoms abated and she was able to continue with her pregnancy to term. Since then, she has had a second healthy child while taking gabapentin throughout her pregnancy, during which she had only mild and rare <u>nausea and vomiting</u>

"I think this research has great potential to provide relief to many women suffering with hyperemesis.gravidarum," says Guttuso.

Provided by University at Buffalo

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