## Poor Outcomes Seen in Pregnancy-Tied Breast Ca

BY BRUCE JANCIN Denver Bureau

SAN ANTONIO — Survival outcomes in women with pregnancy-associated breast cancer were significantly worse than in nonpregnant controls matched for age and tumor stage in a relatively large single-center study.

This finding is at odds with most prior series, which have found no difference in 5-year survival depending upon whether a breast cancer patient was pregnant, study investigator Dr. Rajesh Sehgal said at the San Antonio Breast Cancer Symposium.

## Vulvar, Vaginal Pain Is Common In Pregnancy

CHICAGO — Many women report vulvar and vaginal symptoms during pregnancy, but little is known about the frequency, severity, and timing of complaints such as vulvar pain, burning, itching, and dyspareunia, said Dr. Colleen M. Kennedy of the University of Iowa, Iowa City, in a poster presentation at the annual meeting of the Central Association of Obstetricians and Gynecologists.

Vulvar and vaginal symptoms account for more than 10 million office visits annually and represent the most common gynecologic complaint.

To identify the prevalence rates of burning, itching, pain, and dyspareunia during pregnancy and in the 3 months post partum, and to determine how rates of vulvar and vaginal symptoms compare in pregnant and nonpregnant women, Dr. Kennedy and her colleagues evaluated 103 pregnant women recruited from the University of Iowa obstetrics clinics. Sixty-three of these participants completed the final postpartum survey. The study also included 122 nonpregnant women in a control group.

The participants had a mean age of 28 years and were mostly white (92%) and married or living with a partner (81%); most had completed some education beyond high school (86%).

The results showed that both vulvar and vaginal symptoms commonly occur in pregnancy. Pregnant women reported vulvar pain more frequently in their second and third trimesters than in the first trimester, but pregnant women and their nonpregnant controls reported the same level of severity. Vaginal discharge increased in frequency and severity in the second and third trimesters. Dyspareunia was less common in the first trimester than in subsequent trimesters, but reached its peak in the postpartum period, particularly in those women who gave birth vaginally. All other symptoms decreased during the postpartum period.

'Symptoms are dynamic and change [during pregnancy]," said Dr. Kennedy. Compared with nonpregnant controls, the pregnant women in the study did not have higher rates of vulvar pruritus and burning.

—Sarah Pressman Lovinger

"We don't know why our results were different. We could not explain it on any basis," he said in an interview.

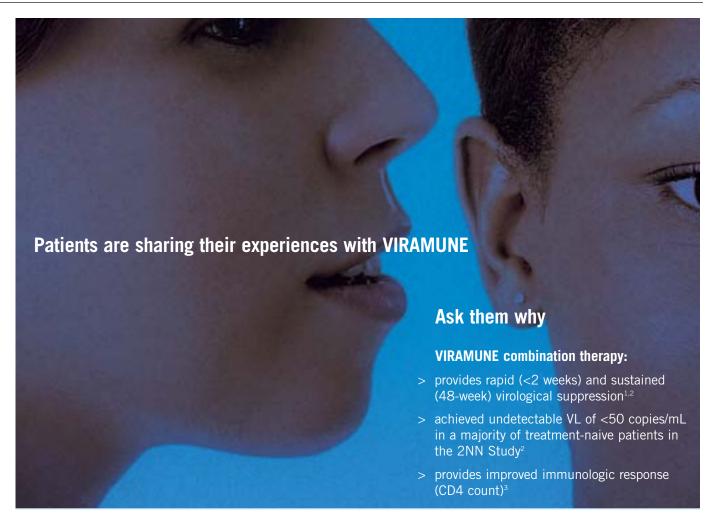
Breast cancer is the most frequently diagnosed malignancy in pregnancy, with an incidence of roughly three cases per 10,000 live births.

Dr. Sehgal presented a retrospective study involving 40 women with pregnancy-associated breast cancer (defined as breast cancer diagnosed during pregnancy, within 1 year of delivery, or at any time during lactation) and 40 matched nonpregnant controls, all treated at University of Pittsburgh Medical Center.

Median overall survival was 4.9 years in the pregnancy-associated breast cancer group, significantly less than the 6.0 years in controls. Median disease-free survival was 2.7 years in women with pregnancyassociated breast cancer, compared with 5.1 years in controls. The most common site of relapse in the pregnancy-associated breast cancer group was bone. In controls, recurrences were most commonly local.

Pregnancy remained an independent predictor of worse outcomes in breast cancer patients after adjusting for key variables including hormone receptor status, family history, tumor stage, human epidermal growth factor receptor 2 (HER2) status, and the use of radiotherapy and/or chemotherapy.

None of the studies reported to date is large enough to be definitive, and a national registry is warranted, Dr. Sehgal said.



## INDICATION AND IMPORTANT SAFETY INFORMATION

VIRAMUNE is indicated for use in combination with other antiretroviral agents for the treatment of HIV-1 infection. This indication is based on one ncipal clinical trial that demonstrated prolonged suppression of HIV-RNA and two smaller supportive studies.

Life-threatening and fatal hepatotoxicity has occurred in patients receiving VIRAMUNE. Any patient can experience hepatic events; however, female gender and higher CD4 counts at initiation of therapy place patients at greater risk. Women, including pregnant women, with CD4+ cell counts >250 cells/mm³ are at the greatest risk. VIRAMUNE should not be initiated in adult females with CD4+ cell counts greater than 250 cells/mm³ or in adult males with CD4+ cell counts greater than 400 cells/mm³ unless the benefit outweighs the risk. Hepatic events are often associated with rash.

Life-threatening and fatal skin reactions have also occurred, including Stevens-Johnson Syndrome, toxic epidermal necrolysis and hypersensitivity reactions characterized by rash, constitutional findings, and organ

Patients should be intensively monitored for hepatic and skin reactions for the first 18 weeks of therapy with extra vigilance during the first 6 weeks, which is the period of greatest risk. Frequent monitoring should be performed throughout therapy with VIRAMUNE.

**References: 1.** van Leth F, Kappelhof B, Hall DB, Beijnen J, Lange JMA; for the 2NN Study Group. Regional differences in treatment failure in the 2NN study. Presented at the 7<sup>th</sup> International Congress on Drug Therapy in HIV Infection. Glasgow, Scotland. November 14-18, 2004. Poster. **2.** van Leth F, Phanuphak P, Ruxrungtham K, et al; for the 2NN Study Team. Comparison of first-line antiretroviral therapy with regimens including nevirapine, efavirenz, or both drugs, plus stavudine and lamivudine: a randomised open-label trial, the 2NN Study. *Lancet.* 2004;363:1253-1263. **3.** Viramune® (nevirapine) Prescribing Information. Boehringer Ingelheim Pharmaceuticals, Inc. June 2007.

VIRAMUNE should be discontinued and not restarted in patients who develop signs or symptoms of hepatitis, hypersensitivity or severe skin reactions. In some cases, hepatic injury has progressed despite discontinuation of treatment.

Other common side effects include nausea, fatigue, fever, headache, vomiting, diarrhea, abdominal pain, and myalgia. Immune reconstitution syndrome has been reported in patients treated with combination ARV therapy.

Please see Brief Summary of Prescribing Information for VIRAMUNE on following pages, including boxed WARNING.

The dose of VIRAMUNE for adults is one 200-mg tablet daily for the first 14 days (this has been shown to reduce the frequency of rash), followed by one 200-mg tablet twice daily.

## REDISCOVER



