

Young Breast Ca Patients at Higher Risk of Distress

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BOSTON — The psychosocial needs of young breast cancer patients should be viewed in a different context than those of older women, said Lidia Schapira, M.D.

“Premenopausal women with breast cancer are at greater risk of psychological distress at diagnosis and during treatment, especially when it coincides with child-bearing years or with years spent in active

parenting roles,” Dr. Schapira said at a breast cancer meeting sponsored by Harvard Medical School.

Because younger women face such concerns as premature death and the impact that treatment will have on fertility, child rearing, career, finances, and appearance, clinicians must broaden their traditional vertical focus on managing the medical aspects of the disease “and look at the horizontal axis of patients’ social functioning as they deal with their diagnosis and treat-

ment,” said Dr. Schapira of Massachusetts General Hospital, Boston.

The nature and extent of a breast cancer patient’s psychological distress will vary depending on both the individual and the phase of the disease. The concerns at diagnosis might be different from those experienced during primary treatment or at treatment completion, Dr. Schapira said.

At all points along the disease trajectory, clinicians should address “normal” levels of psychosocial distress and be alert for

signs of persistent distress that would benefit from specific mental health intervention. Toward this end, according to guidelines in a 2004 Institute of Medicine report on the psychosocial needs of women with breast cancer, clinicians should:

- ▶ Clarify and ensure understanding of diagnosis and treatment options and side effects.
- ▶ Advise that distress is normal and expected and can increase at transition points.
- ▶ Build trust.
- ▶ Mobilize resources and direct patients to educational materials and local resources.
- ▶ Consider medication for symptoms.
- ▶ Ensure continuity of care.
- ▶ Monitor and reevaluate for referral to more specialized services if needed.

Additionally, a variety of interventions have been shown to favorably impact psychological status and quality of life, Dr. Schapira said. “Notably, there is strong evidence for the benefit of relaxation, hypnosis, and imagery in early-stage breast cancer, for group interventions in both early and metastatic disease, and for indi-

vidual interventions primarily in the early setting,” she said.

Finally, clinicians need to be acutely aware of the special issues facing women who are diagnosed during their parenting years. “Being a parent affects preference for adju-

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vant chemotherapy in women with breast cancer, yet the impact that the side effects of treatment will have on the parenting experience are rarely discussed in the context of a medical encounter,” Dr. Schapira said. “Studies have shown that parents want to know how to talk about the illness with their kids in a developmentally appropriate way,” she said, and that parents need guidance in understanding and dealing with the impact of maternal disease on children’s behavior and level of distress.

One example of how such issues might be addressed is a program developed by Paula Rauch, M.D., at Massachusetts General called Parenting at a Challenging Time (PACT). Through PACT, child psychiatrists and psychologists provide free consultations to adult cancer patients or their partners to help them address the needs of their children during treatment, Dr. Schapira said. “The program recommends that clinicians ask patients if they have children, and follow up with questions about the children and discuss the resources that are available to them,” she said.

Clearly, clinicians cannot be the only source of psychosocial support for their younger breast cancer patients; they should be cognizant of the potential for significant distress and be prepared to help these women get the support they need, Dr. Schapira concluded. ■

ZOVIRAX® (acyclovir) Ointment 5% Begins to Comfort on Contact to Heal Herpes Fast

Symptoms With Primary First Episode of Genital Herpes*

Duration vs Placebo*

Itching	4.4 days shorter (P<0.01)
Pain	1.8 days shorter (P<0.05)
Lesion duration	4.6 days shorter (P<0.05)
Viral shedding from lesions	3.3 days shorter (P<0.001)

*Duration of itching: ZOVIRAX® Ointment (3.6 days) vs placebo (8.0 days) at primary first episode of genital herpes.

Duration of pain: ZOVIRAX® Ointment (5.2 days) vs placebo (7.0 days) at primary first episode of genital herpes.

Duration of lesion: ZOVIRAX® Ointment (11.2 days) vs placebo (15.8 days) at primary first episode of genital herpes.

Duration of viral shedding: ZOVIRAX® Ointment (2.3 days) vs placebo (5.6 days) at primary first episode of genital herpes.

Reference: 1. Corey L, Benedetti JK, Critchlow CW, et al. Double-blind controlled trial of topical acyclovir in genital herpes simplex virus infections. *Am J Med.* 1982;73:326-334.

ZOVIRAX® (acyclovir) Ointment 5%

INDICATIONS AND USAGE

ZOVIRAX (acyclovir) Ointment 5% is indicated in the management of initial genital herpes and in limited non-life-threatening mucocutaneous Herpes simplex virus infections in immunocompromised patients.

CONTRAINDICATIONS

ZOVIRAX Ointment 5% is contraindicated in patients who develop hypersensitivity to the components of the formulation.

WARNINGS

ZOVIRAX Ointment 5% is intended for cutaneous use only and should not be used in the eye.

PRECAUTIONS

General: The recommended dosage, frequency of applications, and length of treatment should not be exceeded (see DOSAGE AND ADMINISTRATION). There are no data to support the use of ZOVIRAX Ointment 5% to prevent transmission of infection to other persons or prevent recurrent infections when applied in the absence of signs and symptoms. ZOVIRAX Ointment 5% should not be used for the prevention of recurrent HSV infections. Although clinically significant viral resistance associated with the use of ZOVIRAX Ointment 5% has not been observed, this possibility exists.

Drug Interactions: Clinical experience has identified no interactions resulting from topical or systemic administration of other drugs concomitantly with ZOVIRAX Ointment 5%.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Systemic exposure following topical administration of acyclovir is minimal. Dermal carcinogenicity studies were not conducted. Results from the studies of carcinogenesis, mutagenesis, and fertility are not included in the full prescribing information for ZOVIRAX Ointment 5% due to the minimal exposures of acyclovir that result from dermal application. Information on these studies is available in the full prescribing information for ZOVIRAX Capsules, Tablets, and Suspension and ZOVIRAX for Injection.

Pregnancy: Teratogenic Effects: Pregnancy Category B. Acyclovir was not teratogenic in the mouse, rabbit, or rat at exposures greatly in excess of human exposure. There are no adequate and well-controlled studies of systemic acyclovir in pregnant women. A prospective epidemiologic registry of acyclovir use during pregnancy was established in 1984 and completed in April 1999. There

were 749 pregnancies followed in women exposed to systemic acyclovir during the first trimester of pregnancy resulting in 756 outcomes. The occurrence rate of birth defects approximates that found in the general population. However, the small size of the registry is insufficient to evaluate the risk for less common defects or to permit reliable or definitive conclusions regarding the safety of acyclovir in pregnant women and their developing fetuses. Systemic acyclovir should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: It is not known whether topically applied acyclovir is excreted in breast milk. Systemic exposure following topical administration is minimal. After oral administration of ZOVIRAX, acyclovir concentrations have been documented in breast milk in 2 women and ranged from 0.6 to 4.1 times the corresponding plasma levels. These concentrations would potentially expose the nursing infant to a dose of acyclovir up to 0.3 mg/kg per day. Nursing mothers who have active herpetic lesions near or on the breast should avoid nursing.

Geriatric Use: Clinical studies of ZOVIRAX Ointment did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. Systemic absorption of acyclovir after topical administration is minimal (see CLINICAL PHARMACOLOGY).

Pediatric Use: Safety and effectiveness in pediatric patients have not been established.

ADVERSE REACTIONS

In the controlled clinical trials, mild pain (including transient burning and stinging) was reported by about 30% of patients in both the active and placebo arms; treatment was discontinued in 2 of these patients. Local pruritus occurred in 4% of these patients. In all studies, there was no significant difference between the drug and placebo group in the rate or type of reported adverse reactions nor were there any differences in abnormal clinical laboratory findings.

Observed During Clinical Practice: Based on clinical practice experience in patients treated with ZOVIRAX Ointment in the US, spontaneously reported adverse events are uncommon. Data are insufficient to support an estimate to their incidence or to establish causation. These events may also occur as part of the underlying disease process. Voluntary reports of adverse events that have been received since market introduction include:

General: Edema and/or pain at the application site.

Skin: Pruritus, rash.

OVERDOSAGE

Overdosage by topical application of ZOVIRAX Ointment 5% is unlikely because of limited transcutaneous absorption (see CLINICAL PHARMACOLOGY).

DOSAGE AND ADMINISTRATION

Apply sufficient quantity to adequately cover all lesions every 3 hours, 6 times per day for 7 days. The dose size per application will vary depending upon the total lesion area but should approximate a one-half inch ribbon of ointment per 4 square inches of surface area. A finger cot or rubber glove should be used when applying ZOVIRAX to prevent autoinoculation of other body sites and transmission of infection to other persons. **Therapy should be initiated as early as possible following onset of signs and symptoms.**

HOW SUPPLIED

Each gram of ZOVIRAX Ointment 5% contains 50 mg acyclovir in a polyethylene glycol base.

It is supplied as follows:

15-g tubes (NDC 64455-993-94)

3-g tubes (NDC 64455-993-41).

Store at 15° to 25°C (59° to 77°F) in a dry place.

Manufactured by
GlaxoSmithKline
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