Peripartum Depression, Abuse Underdiagnosed

BY BETSY BATES Los Angeles Bureau

SAN DIEGO — Rare is the pregnant patient whose obstetrician fails to ask whether she cleans her cat's litter, yet few are asked about conditions that pose far greater risks to them and their babies than toxoplasmosis: depression and partner abuse.

The risk of peripartum depression is 1 in 10, with consequences for mother and fetus that can be profound.

Domestic violence kills more pregnant women than any single medical complication of pregnancy.

Yet both conditions are underdiagnosed and undertreated, according to speakers at the annual meeting of the American College of Obstetricians and Gynecologists.

"As ob.gyns., we need to look at the bigger picture and understand that good prenatal and postpartum care involve a focus not just on our patients' physical health but also on their emotional and psychological health," said Dr. Stanley Zinberg, deputy executive vice president of ACOG and vice president for practice activities.

Dr. Sharon T. Phelan, professor of obstetrics and gynecology at the University of New Mexico, Albuquerque, said she believes priorities may need to be restructured.

"It's interesting that we have laws in effect that we have to offer all women



ORozerem.

Brief Summary of Prescribing Information ROZEREM™ (ramelteon) Tablets

INDICATIONS AND USAGE

the treatment of insomnia characterized by

CONTRAINDICATIONS ROZEREM is contraindicated in patients with a hypersensitivity to ramelteon or any components of the ROZEREM formulation. WARNINGS

WARNINGS Since sleep disturbances may be the presenting manifestation of a physical and/or psychiatric disorder, symptomatic treatment of insomnia should be initiated only after a careful evaluation of the patient. The failure of insomnia to remit after a reasonable period of treatment may indicate the presence of a primary psychiatric and/or medical illness that should be evaluated. Worsening of insomnia, or the emergence of new cognitive or behavioral abnormalities, may be the result of an unrecognized underlying psychiatric or physical disorder and requires further evaluation of the patient. As with other hypototics exacerbation of insomnia and emergence of cognitive and behavioral abnor-malities were seen with ROZEREM during the clinical development program. ROZEREM should not be used by patients with severe hepatic impairment. ROZEREM should not be used in combination with fluvoxamine (see **PRECAUTIONS: Drug Interactions**).

PRECAUTIONS: Drug Interactions). A variety of cognitive and behavior changes have been reported to occur in association with the use of hypnotics. In primarily depressed patients, worsening of depression, including suicidal ideation, has been reported in association with the use of hypnotics. Patients should avoid engaging in hazardous activities that require concentration (such as operating a motor vehicle or heavy machinery) after taking ROZEREM.

After taking ROZEREM, patients should confine their activities to those necessary to prepare for bed.

PRECAUTIONS

General ROZEREM has not been studied in subjects with severe sleep apnea or severe COPD and is not recommended for use in those populations.

Severe Corb and is not recommended for use in mose populations. Patients should be advised to exercise caution if they consume alcohol in combination with ROZEREM. Use in Adolescents and Children ROZEREM has been associated with an effect on reproductive hormones in adults, e.g., decreased testosterone levels and increased prolactin levels. It is not known what effect chronic or even chronic intermittent use of ROZEREM may have on the reproductive axis in developing humans (see **Pediatric Use**).

Information for Patients Patients should be advised to take ROZEREM within 30 minutes prior to going to bed and should confine their activities to those necessary to prepare for bed

Patients should be advised to avoid engaging in hazardous activities (such as operating a motor vehicle or heavy machinery) after taking ROZEREM. Patients should be advised that they should not take ROZEREM with or immediately after a high-fat meal.

Patients should be advised to consult their health care provider if they experience worsening of insomnia or any new behavioral signs or symptoms of concern.

Patients should consult their health care provider if they experience one of the following: cessation of menses or galactorrhea in temales, decreased libido, or problems with fertility.

Laboratory Tests No standard monitoring is required.

For patients presenting with unexplained amenorrhea, galactorrhea, decreased libido, or problems with fertility, assessment of prolactin levels and testosterone levels should be considered as appropriate.

Drug Interactions ROZEREM has a highly variable intersubject pharmacokinetic profile (approxi-mately 100% coefficient of variation in C_{max} and AUC). As noted above, CYP1A2 is the major isozyme involved in the metabolism of ROZEREM, the CYP2C subfamily and CYP3A4 isozymes are also involved to a minor degree

CYP2C subfamily and CYP3A4 isozymes are also involved to a minor degree. Effects of Other Drugs on ROZEREM Metabolism Fluvoxamine (strong CYP1A2 inhibitor): When fluvoxamine 100 mg twice daily was administered for 3 days prior to single-dose co-administration of ROZEREM 16 mg and fluvoxamine, the AUCo₂ for ramelteon increased approximately 190-fold, and the C_{max} increased approximately 70-fold, compared to ROZEREM Administered alone. ROZEREM should not be used in combination with fluvoxamine (see WARNINGS). Other less potent CYP1A2 inhibitors have not been adequately studied. ROZEREM should be admin-istered with caution to patients taking less strong CYP1A2 inhibitors.

Interest with caution to patients taking less strong CYP1A2 inhibitors. *Rifarmini (strong CYP enzyme inducer):* Administration of rifampin 600 mg once daily for 11 days resulted in a mean decrease of approximately 80% (40% to 90%) in total exposure to ramelteon and metabolite M-II, (both AUC_{0-m} and C_{mg}) after a single 32 mg dose of ROZEREM. Efficacy may be reduced when ROZEREM is used in combination with strong CYP enzyme inducers such as rifampin.

Inducers such as rifampin. *Ketoconazole (strong CYP3A4 inhibitor):* The AUC_{0, leff} and C_{max} of ramelteon increased by approximately 84% and 36%, respectively, when a single 16 mg dose of ROZEREM was administered on the fourth day of ketoconazole 200 mg twice daily administration, compared to administration of ROZEREM alone. Similar increases were seen in M-I pharmacokinetic variables. ROZEREM Should be administrated with caution in subjects taking strong CYP3A4 inhibitors such as ketoconazole. *Fluconazole (Strong CYP2C9 inhibitor):* The total and peak systemic exposure (AUC₀)_{iff} and C_{max}) of ramelteon after a single 16 mg dose of ROZEREM was increased by approximately 150% when administered with fluconazole. Similar increases were also seen in M-I exposure. ROZEREM should be administered with caution in subjects taking strong CYP2C9 inhibitors such as fluconazole.

as incontazole: Interaction studies of concomitant administration of ROZEREM with fluoxetine (CYP2D6 inhibitor), omeprazole (CYP1A2 inducer/CYP2C19 inhibitor), theophylline (CYP1A2 substrate), and dextromethorphan (CYP2D6 substrate) did not produce clinically meaningful changes in either peak or total exposures to ramelteon or the M-II metabolite.

did not produce cilinically meaningfui changes in either peak or total exposures to ramelteon or the M-I metabolite. Effects of ROZEREM on Metabolism of Other Drugs Concomitant administration of ROZEREM with orneprazole (CYP2C19 substrate), dextromethorphan (CYP2D6 substrate), midazolam (CYP3A4 substrate), theotyphilme (CYP1A2 substrate), diogxin (p-glycoprotein substrate), and warfarin (CYP2OS [S)/CYP1A2 [R] substrate), diogxin (p-glycoprotein substrate), theotyphilme (CYP1A2 substrate), diogxin (p-glycoprotein substrate), and warfarin (CYP2OS [S)/CYP1A2 [R] substrate), diogxin (p-glycoprotein substrate), theotyphilme (CYP2AS [R]) substrate), diogxin (p-glycoprotein substrate), *Effect of Alcohol on Rozerem* Alcohol: With single-dose, daytime co-administration of ROZEREM 32 mg and alcohol (0.6 g/kg), there were no clinically meaningful or statistically significant effects on peak or total exposure to ROZEREM. However, an additive effect was seen on some measures of psychomotor performance (i.e., the Digit Symbol Substitution Test, the Psychomotor Vigilance Task. Test, and a Visual Analog Scale of Sedation) at some post-dose time points. No additive effect was seen on the Delayed Word Recognition Test. Because alcohol by itself impairs performance, and the intended effect of ROZEREM is to promote sleep, patients should be cautioned not to consume alcohol when using ROZEREM.

Drug/Laboratory Test Interactions ROZEREM is not known to interfere with commonly used clinical laboratory tests. In addition, *in vitro* data indicate that ramelteon does not cause false-positive results for benzodiazepines, opiates, barbiturates, cocaine, cannabinolids, or amphetamines in two standard urine drug screening methods *in vitro*.

Carcinogenesis, Mutagenesis, and Impairment of Fertility

Carcinogenesis Carcinogenesis In a two-year carcinogenicity study, B6C3F, mice were administered ramelteon at doess of 0, 30, 100, 300, or 1000 mg/kg/day by oral gavage. Male mice exhibited a dose-related increase in the incidence of hepatic tumors at dose levels ≥ 100 mg/kg/day including hepatic adenoma, hepatic carcinoma, and hepatoblastoma. Female mice developed a dose-related increase in the incidence of hepatic adenomas at dose levels ≥ 300 mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day index level. The no-effect level for hepatic tumors in male mice was 30 mg/kg/day (151-times and 3-times the therapeutic exposure to ramelteon and the active metabolite M-II, respectively, at the maximum recommended human dose (IMRHD) based on an area under the concentration-time curve (AUC) comparison). The no-effect level for hepatic tumors in female mice was 100 mg/kg/day (827-times and 12-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

the MRHD based on AUC). In a two-year carcinogenicity study conducted in the Sprague-Dawley rat, male and female rats were administered ramelteon at doses of 0, 15, 60, 250 or 1000 mg/kg/day by oral gavage. Male rats exhibited a dose-related increase in the incidence of hepatic adenoma and benign Leydig cell tumors of the testis at dose levels ≥ 250 m/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. Female rats exhibited a dose-related increase in the incidence of hepatic adenoma toose levels ≥ 60 mg/kg/day and hepatic carcinoma at the 1000 mg/kg/day dose level. The no-effect level for hepatic tumors and benign Leydig cell tumors in male rats was 60 mg/kg/day (1 429-times and 12-times the therapeutic exposure to ramelteon and M-II, respectively, at the MHHD based on AUC). The no-effect level for hepatic tumors in temale rats was 15 mg/kg/day (4/72-times and 16-times the therapeutic exposure to ramelteon and M-II, respectively, at the MRHD based on AUC).

the MRHD based on AUC). The development of hepatic tumors in rodents following chronic treatment with non-genotoxic compounds may be secondary to microsomal enzyme induction, a mechanism for tumor generation not thought to occur in humans. Levdig cell tumor development following treatment with non-genotoxic compounds in rodents has been linked to reductions in circulating testosterone levels with compensatory increases in luteinizing hormone release, which is a known proliferative stimulus to Levdig cells in the rat testis. Rat Leydig cells are more sensitive to the stimulatory effects of luteinizing hormone than human Leydig cells. In mechanistic studies conducted in the rat, daily ramelteon administration at 250 and 1000 mg/kg/day for 4 weeks was associated with a reduction in plasma testosterone levels. In the same study, luteinizing hormone levels were elevated over a 24-hour period after the last ramelteon treatment, however, the durability of this luteinizing hormone finding and its support for the proposed mechanistic explanation was not clearly established.

though the ordent tumors observed following ramelteon treatment curred at plasma levels of ramelteon and M-II in excess of mean clinical sama concentrations at the MRHD, the relevance of both rodent hepati mors and benign rat Leydig cell tumors to humans is not known.

Mutagenesis Ramelteon was not genotoxic in the following: *in vitro* bacterial reverse mutation (*mess*) assay: *in vitro* mammalian cell gene mutation assay using the mouse lymphoma TK^{+/-} cell line; *in vivo/in vitro* unscheduler DNA synthesis assay in rat hepatocytes; and in *in vivo* micronucleus assays conducted in mouse and rat. Ramelteon was positive in the chromosomal aberration assay in Chinese hamster lung cells in the presence of S9 metabolic activation.

Separate studies indicated that the concentration of the M-II metabolite formed by the rat liver S9 fraction used in the *in vitro* genetic toxicology studies described above, exceeded the concentration of ramelteon; therefore, the genotoxic potential of the M-II metabolite was also assessed in these studies.

Interferote, the groups of the theorem in the above was also assessed in these studies. Impairment of Fertility Ramelteon was administered to male and female Sprague-Dawley rats in an initial fertility and early embryonic development study at dose levels of 6, 60, or 600 mg/kg/day. No effects on male or female mating or fertility were observed with a ramelteon dose up to 600 mg/kg/day (786-times higher than the MRHD on a mg/m² basis). Irregular estris cycles, reduction in the number of implants, and reduction in the number of live embryos were noted with dosing females at \geq 60 mg/kg/day (79-times higher than the MRHD on a mg/m² basis). A reduction in the number of corpora lute a occurred at the 600 mg/kg/day dose level. Administration of ramelteon up and/m² basis) on of 000 mg/kg/day to maile rats for 7 weeks had no effect on sperm quality and when the treated male rats were mated with untreated female rats there was no effect on implants or embryos. In a repeat of this study using oral administ-tration of ramelteon at 20, 60 or 200 mg/kg/day for the same study duration, females demonstrated irregular estrus cycles with doses \geq 60 mg/kg/day, but no effects were seen on implants or or embryo viability. The no-effect dose for fertility endopints was 20 mg/kg/day in females (786-times higher than the MRHD on a mg/m² basis), when considering all studies. **Pregnancy: Pregnancy Category C**

Pregnancy: Pregnancy Category C Rametteon has been shown to be a developmental teratogen in the rat when given in doses 197 times higher than the maximum recommended human dose [MRHD] on a mg/m² basis. There are no adequate and well-controlled studies in pregnant women. Rametteon should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. controlled studies in pregnant women. Ramelteon should be used during pregnancy only if the poletnial benefit justifies the potential risk to the fetus. The effects of ramelteon on embryo-fetal development were assessed in both the rat and rabbit. Pregnant rats were administered ramelteon by oral gavage at doses of 0, 10, 40, 150, or 600 mg/kg/day during gestation days 6 -17, which is the period of organogenesis in this species. Evidence of maternal toxicity and fetal teratogenicity was observed at doses greater than or equal to 150 mg/kg/day. Maternal toxicity was chiefly characterized by decreased body weight and, at 600 mg/kg/day ataxia and decreased spontaneous movement. At maternally toxic doses (150 mg/kg/day or greater), the fetuses demonstrated visceral malformations consisting of diaphragmatic hernia and minor anatomical variations of the skeleton (irregularly shaped scapula). At 600 mg/kg/day. Letter the skeleton (irregularly shaped scapula). At 600 mg/kg/day. Letter additionally observed. The no-effect level for teratogenicity in this study was 40 mg/kg/day (1.892-times and 45-times higher than the therapeutic exposure to ramelteon and the active metabolite M-II. respectively at the MMHD based on an area under the concentration-time curve [AUC] comparison). Pregnant rabbits were administered ramelteon by oral gavage at doses of 0, 12, 60, or 300 mg/kg/day during gestation days 6 -18, which is the period of organogenesis in this species. Although maternal toxicity was apparent with a rameleon dose of 300 mg/kg/day, no evidence of fetal effects or teratogenicity was associated with any dose level. The no-effect level for teratogenicity was associated with any dose level. The no-effect level for teratogenicity was associated with any dose level. The no-effect level for teratogenicity was associated with any dose level. The no-effect level for teratogenicity was associated with any dose level. The no-effect level for teratogenicity was therefore, 300 mg/kg/day, no evidence of

The effects of ramelteon on pre- and post-natal development in the rat were L-RAM-00029

studied by administration of ramelteon to the pregnant rat by oral gavage at doses of 0, 30, 100, or 300 mg/kg/day from day 6 of gestation through parturition to postnatal (lactation) day 21, at which time offspring were weaned. Maternal toxicity was noted at doses of 100 mg/kg/day or greater and consisted of reduced body weight gain and increased adrenal gland weight. Reduced body weight during the post-weaning period was also noticed in the offspring of the groups given 100 mg/kg/day and higher. Offspring in the 300 mg/kg/day eruption of the lower incisors, a delayed acquisition of the righting reflex, and an alteration of emotional response. These delays are often observed in the presence of reduced offspring body weight but may still be indicative of developmental delay at this dose level. Offspring of the 300 mg/kg/day group was likely due to altered maternal behavior and function observed evidence of diaphragmatic hernia, a finding observed in the embryo-fetal development study previously described. There were no effects on the reproductive capacity of offspring and the resulting progeny were not different from those of vehicle-treated offspring. The no-effect level for pre- and post-natal development in this study was 30 mg/kg/day (39-times higher than the MRHD on a mg/m² basis).

Labor and Delivery The potential effects of ROZEREM on the duration of labor and/or delivery, for either the mother or the fetus, have not been studied. ROZEREM has no established use in labor and delivery.

Nursing Mothers Nursing Mothers Ramelteon is secreted into the milk of lactating rats. It is not known whether this drug is excreted in human milk. No clinical studies in nursing mothers have been performed. The use of ROZEREM in nursing mothers is not recommended.

Bindt recommendence of ROZEREM in pediatric patients have not been safety and effectiveness of ROZEREM in pediatric patients have not been established. Further study is needed prior to determining that this product may be used safely in pre-public and public scheme patients.

Geriatric Use A total of 654 subjects in double-blind, placebo-controlled, efficacy trials who received ROZEREM were at least 65 years of age; of these, 199 were 75 years of age or older. No overall differences in safety or efficacy were observed between elderly and younger adult subjects.

ADVERSE REACTIONS Overview

Overview The data described in this section reflect exposure to ROZEREM in 4251 subjects, including 346 exposed for 6 months or longer, and 473 subjects for one year. Adverse Reactions Resulting in Discontinuation of Treatment Sk percent of the 3594 individual subjects exposed to ROZEREM in clinical studies discontinued treatment owing to an adverse event, compared with 2% of the 1370 subjects receiving placebo. The most frequent adverse events leading to discontinuation in subjects receiving ROZEREM were somnolence (0.8%), diztanes (0.5%), nausea (0.3%), fatigue (0.3%), headache (0.3%), and insomnia (0.3%).

headache (0.3%), and insommia (0.3%). **ROZEREM Most Commonly Observed Adverse Events in Phase 1-3 trials** The incidence of adverse events during the Phase 1 through 3 trials (% placebo, n=1370; % ramelteon [8 mg], n=1250) were: headache NOS (%, %), somolence (3%, 5%), latigue (%, 4%), dizziness (3%, 5%), nausea (2%, 3%), insomnia exacerbated (2%, 3%), upper respiratory tract infection NOS (2%, 3%), diarrhea NOS (2%, 2%), arthralgia (1%, 2%), depression (1%, 2%), dysquesuia (1%, 2%), arthralgia (1%, 2%), influenza (0, 1%), blood cortisol decreased (0, 1%).

(0, 1%), blood cortisol decreased (0, 1%). Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in clinical trials of other drugs, and may not reflect the rates observed in practice. The adverse reaction information from clinical trials does, however, provide a basis for identifying the adverse events that appear to be related to drug use and for approximating rates. **DRUG ABUSE AND DEPENDENCE** ROZEREM is not a controlled substance.

Human Data: See the CLINICAL TRIALS section, Studies Pertinent to Safety Concerns for Sleep-Promoting Agents, in the Complete Prescribing Information.

Prescribing Information. Animal Data: Rametteon did not produce any signals from animal behavioral studies indicating that the drug produces rewarding effects. Monkeys did not self-administer rametteon and the drug did not induce a conditioned place preference in rats. There was no generalization between rametteon and midazolam. Rametteon did not affect rotorod performance, an indicator of disruption of motor function, and it did not potentiate the ability of diazepam to interfere with rotorod performance. Discontinuation of rametteon in animals or in humans after chronic administration did not produce withdrawal signs. Rametteon does not appear to produce physical dependence. **VVFRIDSAGF**

OVERDOSAGE

Signs and Symptoms No cases of ROZEREM overdose have been reported during clinical development ROZEREM was administered in single doses up to 160 mg in an abuse liability trial. No safety or tolerability concerns were seen.

Recommended Treatment General symptomatic and supportive measures should be used, along with immediate gastric lavage where appropriate. Intravenous fluids should be administered as needed. As in all cases of drug overdose, respiration, pulse, blood pressure, and other appropriate vital signs should be monitored, and general supportive measures employed.

Hemodialysis does not effectively reduce exposure to ROZEREM. Therefore, the use of dialysis in the treatment of overdosage is not appropriate.

Poison Control Center Poison Control Center As with the management of all overdosage, the possibility of multiple drug ingestion should be considered. The physician may contact a poison control center for current information on the management of overdosage.

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screening for certain birth defects that have a rate far lower than 10%. Yet 10% is the rate of peripartum depression," she said.

For Dr. Paul Gluck, the need to screen for depression in perinatal visits became clear when he conducted a pilot survey of 50 obstetricians in the Miami area where he practices and found that just 2 of the respondents asked any questions about patients' mental well-being.

The potential impact of such screening struck home when he gave a longtime patient a depression screening tool as part of a research project and learned she was severely depressed.

"I'd been seeing her for years. It never dawned on me she was depressed," he said during an ACOG press briefing.

Six weeks after he prescribed the patient an antidepressant, he received "the most beautiful letter" that he said changed his practice.

"I didn't realize how depressed I really was," the patient wrote. "I didn't realize how much life I was missing. ... The sun shines brighter.'

"I did as much good for this woman as for the woman I take to surgery to perform a hysterectomy," Dr. Gluck said. "This is something we can be diagnosing and treating within the scope of an ob.gyn. practice."

Dr. Zinberg said maternal depression seems to get little attention, "except when tragedies occur such as Andrea Yates [the Texas mother with postpartum depression who drowned her children] or when celebrities are involved."

Postpartum psychosis, suicide, and homocide are only the most visible consequences of maternal depression, emphasized Dr. Phelan.

Depressed women self-medicate with cigarettes, alcohol, and other drugs. Their depression often prevents them from seeking prenatal care or following advice for a healthy pregnancy. They are more prone than are other women to preterm labor, delivery of small-for-gestational-age infants, and even fetal death. As mothers, they may be inattentive and have trouble bonding with their infants, while struggling to find energy and focus to care for their older children.

Screening tools are often helpful in spotting these patients, since many symptoms of depression overlap with normal occurrences in pregnancy and new parenthood, including fatigue, sleep problems, changes in appetite, and mood swings.

Dr. Gluck said that he has implemented a multipronged approach to screening.

His general intake questionnaire now includes two mental health questions: "Do you feel down or depressed?" and "Do you not enjoy doing things you used to enjoy?"

He has trained his nurses to weave several questions about psychological well-being into the conversation while patients are being weighed and having their blood pressure taken. For example, they will say, "How are things going in your life? Are you feeling down at all?"

If either the intake form or the nurse in-Continued on following page

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Continued from previous page

dicates there might be reason to suspect a patient has depression, he uses a validated, 20-question screening tool. Patients found to have suicidal ideation are handled as "a medical emergency as much as a ruptured appendix." He refers to a trusted network of mental health professionals.

He refers other patients for psychotherapy and/or prescribes antidepressants himself, although he is fully supportive of colleagues who refer all patients with depression to mental health professionals. Not all ob.gyns. feel comfortable managing psychotropic medications, but all should make the effort to find out if their patients are depressed, he said.

"I think it's very important that we're the ones doing the screening. We're the ones who have contact with women throughout their pregnancies and ... throughout their whole lifetimes," he said.

Screening for intimate partner violence was also highlighted at the meeting, including an award-winning paper by Dr. Jennifer Ballard Dwan, a maternal-fetal medicine fellow at Brown University, Providence, R.I..

Dr. Dwan compared screening for toxoplasmosis, which has an estimated incidence of 0.001%, with intimate partner violence, which occurs in approximately 4%-8% of pregnancies.

Among 324 randomly selected pregnant women seen at private and public clinics, 68% were asked about cat exposure and 16% were screened for intimate partner violence. Of note, 15% of women screened positive for domestic violence when asked, she said.

Women attending public clinics were far more likely to be screened for domestic violence than were privately insured women, while the reverse was true for screening about cat exposure.

During the press briefing, Dr. Phelan said she "almost ... worries more" about

middle- to higher-income women being missed during depression screening as well. When it's a 16-year-old who's in a crisis pregnancy, people are more likely to accept that she might be depressed, she said.

Old myths die hard when it comes to a married, economically stable woman with a "very planned pregnancy" who becomes depressed. "There's an idea that if she were strong, she could overcome it," certainly without taking a medication that has a remote chance of harming her baby.

"I don't see us hesitating to tell the overweight, type 2 diabetic patient [to take her diabetes medication]," said Dr. Phelan.

Two Questions Can Often Detect Abusive Relations

SAN DIEGO — A formal, two-question screening tool identified significantly more pregnant women in abusive relationships than did questions formulated by physicians to conform to guidelines of the American College of Obstetricians and Gynecologists, a study has found.

The two questions from the Women's Abuse Screening Tool (short form) are: ► In general, how would you describe your relationship? (A lot of tension, some tension, or no tension?)

► Do you and your partner work out arguments with a lot of difficulty, some difficulty, or no difficulty?

Dr. Tiffany A. Moore Simas and associates at the University of Massachusetts, Worcester, screened 136 prenatal patients with both the formal questions and informal physician prompts. (Guidelines from ACOG recommend asking about violence and trauma during prenatal visits; however, no formal questions are specified.)

Results were presented in poster form at the ACOG's annual meeting. Six patients (4.4%) who were experiencing intimate partner violence in their current relationships were identified by both screening methods. An additional 10 patients (7.4%) were detected only by the two questions from the Women's Abuse Screening Tool.

Six patients refused to participate in domestic violence screening. Of the total 16 patients in violent relationships, 5 separated from their partners during pregnancy.

Dr. Moore Simas and colleagues concluded that the two-question screen is "valid, reliable, easy, and unobtrusive."

The other six questions in the long form of the Women's Abuse Screening Tool that may be used to make a more comprehensive assessment (answers for each are Occasionally, Sometimes, Never) are:

► Do arguments ever result in your feeling down or bad about yourself?

► Do arguments ever result in hitting, kicking, or pushing?

► Do you ever feel frightened by what your partner says or does?

► Has your partner ever abused you physically?

► Has your partner ever abused you emotionally?

► Has your partner ever abused you sexually?

-Betsy Bates



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[†]Compared to original formulas.

*This statement has not been evaluated by the Food and Drug Administration. These products are not intended to diagnose, treat, cure or prevent any disease.

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