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# Pouch Procedure Tied to Impaired Sexual Function

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PHILADELPHIA — Women who underwent an ileal pouch/anal anastomosis procedure for ulcerative colitis reported impaired sexual function, compared with historic, normal controls, Laura H. Goetz, M.D., said at the annual meeting of the American Society of Colon and Rectal Surgeons.

The etiology of worsened sexual func-

tion, found in a survey of 92 patients, is unclear. It might be caused by nerve damage during proctectomy, inadequate pouch function, or aging, said Dr. Goetz, a colon and rectal surgeon at the University of California, San Francisco.

A questionnaire was used to assess sexual function in women who had undergone the ileal pouch/anal anastomosis procedure. The questionnaire included the modified Female Sexual Functioning Index (FSFI), the Fecal Incontinence Severity Index, and additional questions about pouch function. The questionnaire was sent to 167 women who had surgery for ulcerative colitis during 1990-2004 at UCSF. Of those, 92 women returned completed surveys. Their mean age was 39.5 years, with a range of 19-61 years. The questions were answered a mean of 6 years after surgery, with a range of 1-14

The average score on the modified FSFI was 23.9. The highest score possible on this index is 36.0, which would indicate no impairment. The previously published average score of healthy women

The average score of women in the current study was higher than that reported in prior studies of women with sex-

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ual arousal disorders, whose average score was 19.2. In the surveyed group, 26% of the women had scores greater than 30, and 26% had scores

The FSFI score also varied by age, with w o m e n younger than

age 50 having an average score of 25, and

The FSFI scores of the surveyed women did not correlate with their Fecal Incontinence Severity Index scores. There was also no correlation with fecal frequency, urgency, or fear of leakage, although women who experienced actual leakage during sex did have lower sexual function

less than 20.

## women older than age 50 having an average score of 18. When scores were compared before and after surgery, 24% of the women had their scores improve after surgery and 43% had their scores worsen; the rest had no change.

## Screen High-Risk Women For Gonorrhea

linicians should perform routine screening of all sexually active women at increased risk for gonorrhea, because of the high risk for pelvic inflammatory disease, ectopic pregnancy, and chronic pelvic pain associated with asymptomatic gonorrhea infection, according to the U.S. Preventive Services Task Force.

Those at risk include sexually active women under age 25 years, those with previous gonorrhea or other sexually transmitted infections, those with new or multiple sex partners, those who don't consistently use condoms, sex workers, and drug users. Pregnant women with these risk factors should be screened at the first prenatal visit, and those with ongoing or new risk factors should also be screened during the third trimester because gonorrhea increases the risk of preterm rupture of membranes, chorioamnionitis, and preterm labor (Ann. Fam. Med. 2005;3:263-7).

The task force recommended against routine screening in women and men at low risk for gonorrhea, and it found insufficient evidence to recommend for or against routine screening in men at high

-Sharon Worcester

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## **BRIEF SUMMARY**

INDICATIONS AND USAGE

upidem tartrate) is indicated for the short-term treatment of insomnia, seen shown to decrease sleep latency and increase the duration of to 35 days in controlled clinical studies. s should generally be limited to 7 to 10 days of use, and reevaluation nt is recommended if they are to be taken for more than 2 to 3 weeks, suld not be prescribed in quantities exceeding a 1-month supply (see

CONTRAINDICATIONS

None known.

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 7 to 10 days of treatment may indicate the presence of a primary psychiatric and/or medical filness which should be evaluated. Worsening of insomnia or the emergence of new thinking or behavior abnormalities may be the consequence of an unrecognized psychiatric or physical disorder. Such findings have emerged during the course of treatment with sedative/hypotic drugs, induling Ambien. Because some of the important adverse effects of Ambien appear to be dose related (see Precautions and Dosage and Administration), it is important to use the smallest possible effective dose, especially in the elderly.

A variety of abnormal thinking and behavior changes have been reported to occur in association with the use of sedative/hypnotics. Some of these changes may be characterized by decreased inhibition (e.g. aggressiveness and extroversion that seemed out of character), similar to effects produced by alcohol and other CNS depressants. Other reported behavioral changes have included by alcohol and other CNS depressants. Other reported behavioral changes have included by alcohol and other neuropsychiatric symptoms may occur unpredictably. In primarily depressed patients, worsening of depression, including suicidal thinking, has been reported in association with the use of sedative/hypnotics.

R can rarefy be determined with certainty whether a particular instance of the abnormal behaviors listed above is drug induced, spontaneous in origin, or a result of an underlying psychiatric or physical disorder. Nonetheless, the emergence of any new behavioral sign or symptom of concern requires careful an immediate evaluation.

Following the rapid dose decrease or abrupt discontinuation of sedative/hyprotics, there have been reports of signs and sy

ated with withdrawal from other CNS-depressant drugs (see *Drug Abuse and Dependence*).

Amblien, like other sedative/hypnotic drugs, has CNS-depressant effects. Due to the rapid onset of action, Ambien should only be ingested immediately prior to going to bed. Patients should be cautioned against engaging in hazardous occupations requiring complete mental alertness or motor coordination such as operating machinery or driving a motor vehicle after ingesting the drug, including potential impairment of the performance of such activities that may occur the day following ingestion of Ambien. Ambien showed additive effects when combined with alcohal and should not be taken with alcohal, Patients should also be cautioned about possible combined effects with other CNS-depressant drugs. Dosage adjustments may be necessary when Ambien is administered with such agents because of the potentially additive effects.

PRECAUTIONS

General

Was in the elderly and/or debilitated patients: Impaired motor and/or cognitive performance after repeated exposure or unusual sensitivity to sedative/hypnotic drugs is a concern in the treatment of elderly and/or debilitated patients. Therefore, the recommended Ambien dosage is 5 mg in such patients (see Dosage and Administration) to decrease the possibility of side effects. These patients should be closely monitored.

Use in patients with concomitant illness: Clinical experience with Ambien in patients with concomitant illness: Clinical experience with Ambien in patients with concomitant illness: Is limited. Caution is advisable in using Ambien in patients with diseases or conditions that could affect metaborism or hemodynamic responses. Although studies did not reveal respiratory depressant effects at hypnotic doses of Ambien in normals or in patients with mild to moderate chronic obstructive pulmonary disease (COPD), a reduction in the Total Arousal Index together with a reduction in lowest oxygen saturation and increase in the times of oxygen desaturation below 80% and 90% was observed in patients with mild-to-moderate sleep apnea when treated with Ambien (10 mg) when compared to placeboe. However, precautions should be observed if Ambien is prescribed to patients with compromised respiratory furice. Post-marketing reports of respiratory insufficiency, most of which involved patients with pre-existing respiratory insufficiency, most of which involved attents with pre-existing respiratory insufficiency, most of which involved attents with pre-existing respiratory insufficiency, most of which involved attents with pre-existing respiratory furiament have been received. Date in end-stage renal failure patients repeatedly treated with Ambien (in ot demonstrate drug accumulation or alterations in pharmacokinetics). A study in subjects with heaptic impairment of level perforaced elimination in this group; therefore, treatment should be initiated with 5 mg interests with heaptic comprehers, and they shoul

mise, and they should be closely monitored.

Wes in depression: As with other sedative/hypnotic drugs, Ambien should be administered with caution to patients exhibiting signs or symptoms of depression. Suicidal tendencies may be present in such patients and protective measures may be required. Intentional overdosage is more common in this group of patients; therefore, the least amount of drug that is feasible should be prescribed for the patient at any one time.

Information for patients: Patient information is printed in the complete prescribing information.

Laboratory tests: There are no specific laboratory tests recommended.

Drug interactions

CNS-active drugs: Ambien was evaluated in healthy volunteers in single-dose interaction studies for several CNS drugs. A study involving haloperidol and zolpidem revealed no effect of haloperidol on the planmacokinetics or pharmacokynamics of zolpidem. Impiramine in combination with zolpidem produced no pharmacokinetic interaction other than a 20% decrease in peak levels of mipramine, but there was an additive effect of decreased alertness. Similarly, chlorpromazine in combination with zolpidem produced no pharmacokinetic interaction, but there was an additive effect of decreased alertness and psychomotor performance. The lack of a drug interaction following single-dose administration does not predict a lack following chronic administration.

An additive effect on psychomotor performance between alcohol and zolpidem was demonstrated.

A single-dose interaction study with zolpidem 10 mg and fluoxetine at stacy-state levels in male volunteers did not demonstrate any clinically significant pharmacokinetic or pharmacodynamic interactions. When multiple doses of zolpidem and fluoxetine at steady-state concentrations were evaluated in healthy females, the only significant change was a 17% increase in the zolpidem half-life. There was no evidence of an additive effect in psychomotor performance. Following five consecutive nightly doses of zolpidem 10 mg in the presence of certraline 50 mg (17 consecutive daily doses at 7:00 m, in healthy females volunteers), zolpidem C<sub>max</sub> was significantly higher (43%) and T<sub>max</sub> was significantly decreased (53%). Pharmacokinetics of sertraline and N-desmethylsertraline were unaffected by zolpidem.

Since the systematic evaluations of Ambien in combination with other CNS-depressant effects could potentially enhance the CNS-depressant effects of zolpidem.

Pregnancy
Teratogenic effects: Category B. Studies to assess the effects of zolpidem on human reproduction and development have not been conducted.

Teratology studies were conducted in rats and rabbits.

In rats, adverse maternal and fetal effects occurred at 20 and 100 mg base/kg and included dose-related maternal lethargy and ataxia and a dose-related trend to incomplete ossification of fetal skull bones.

In rabbits, dose-related maternal sedation and decreased weight gain occurred at all doses tested. At the high dose, 16 mg base/kg, there was an increase in postimplantation fetal loss and underossification of sternebrae in viable fetuses.

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This drug should be used during pregnancy only if clearly needed.

\*\*Nonteratogenic effects: Studies to assess the effects on children whose mothers took zolpidem during pregnancy have not been conducted. However, children born of mothers taking sedative/hypnotic drugs may be at some risk for withdrawal symptoms from the drug during the postnatal period. In addition, neonatal flacidity has been reported in infants born of mothers who received sedative/hypnotic drugs during pregnancy.

Pediatric use: Safety and effectiveness in pediatric patients below the age of 18 have not been established.

have not been established.

Geriatric use: A total of 154 patients in U.S. controlled clinical trials and 897 patients in non-U.S. clinical trials who received zolpidem were ≥60 years of age. For a pool of U.S. patients receiving zolpidem at doses of ≤10 mg or placebo, there were three adverse events occurring at an incidence of at least 3% for zolpidem and for which the zolpidem incidence was at least twice the placebo incidence (ie, they could be considered drug related).

Adverse Event	Zolpidem	Placebo
Dizziness	3%	0%
Drowsiness	5%	2%
Diarrhea	3%	1%

sweating, leg cramps, malaise, meinstrual disoroer, migraine, paior, parestnesia, postural hypotension, purituris, scheritis, sleeping (after daytime dosing), speech disorder, stupor, syncope, tachycardia, taste perversion, thirst, tinnitus, trauma, tremor, urinary incontinence, vaginitis.

Rare: abdominal body sensation, abnormal accommodation, abnormal gait, abnormal thinking, abseess, acne, acute renal failure, aggressive reaction, allergic reaction, allergive reaction, allergive reaction, apetities, and properties, and properties, and proteins, apathy, appetite increased, arrhythmia, arteritis, arthrosis, billirubinemia, breast fibroadenosis, breast neoplasm, breast pain, bronchospasm, bullous eruption, circulatory failure, conjunctivitis, corneal ulceration, decreased fibido, delusion, dementis, depersonalization, dermatistis, epistaxis, eructation, esophagospasm, extrasystoles, face edema, feel gistange, flushing, furunculosis, gastritis, glaucoma, goul, hemorrhoids, herpes simplex, herpes zoster, hot flashes, hyperchoesteremia, hyperhemoglo-linemia, hypoxia, hysteria, impotence, increased alkaline phosphatase, infraesed BUN, increased ESRS, increased salva, increased SCOT, injection-site inflammation, intestinal obstruction, intoxicated feeling, lacrimation abnormal, laryngitis, leukopenia, hymphadenopathy, macrocytic anemia, manic reaction, micturition frequency, muscle weakness, myocardiai infarction, neuralgia, neuris, neuropathy, neurosis, nocturia, otitis externa, otitis media, pain, panicatacks, paresis, parosmia, periorbital edema, personality disorder, phlebitis, neuropathy, neurosis, nocturia, otitis externa, otitis media, pain, panicatacks, paresis, parosmia, periorbital edema, personality disorder, phlebitis, neuropathy, neurosis, somambulisms, sucided attempts, tendinitis, tenesmus, tetany, thrombosis, tolerance increased, tooth caries, urinary retention, uritaria, varicose veins, ventricular tachycardia, weight decrease, yawning.

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