

# HT Considered Unsuitable for Disease Prevention

*Task force says the risks of unopposed estrogen and combined hormone therapy probably exceed benefits.*

BY MICHELE G. SULLIVAN  
Mid-Atlantic Bureau

Postmenopausal women should not receive unopposed estrogen or combination hormone therapy for the prevention of chronic disease, including heart disease, stroke, and osteoporosis, according to a new recommendation by the U.S. Preventive Services Task Force.

The task force also recommended against using unopposed estrogen therapy for disease prevention in postmenopausal women who have undergone hysterectomy.

In 2002, the task force found insufficient evidence to recommend for or against such preventive therapy. The task force noted that HT has beneficial effects on

bone and reduces the risk of colorectal cancer. But after reviewing findings from the Women's Health Initiative study, the task force concluded that the risks of both unopposed estrogen and combined HT probably exceed their benefits.

"These recommendations expand the evidence base physicians depend on to deliver good quality medical care that meets the needs of individual patients," Carolyn M. Clancy, M.D., who is director of the Agency for Healthcare Research and Quality, said in a statement. "The evidence can also help women become better-informed patients

**Evidence can help women be better-informed patients and decide with their clinicians what alternatives are available to prevent chronic disease.**

and decide with their clinicians what alternatives are available to prevent these chronic diseases."

In addition to data from the WHI, the task force based its recommendations on the conclusions of the U.K. Million Women Study and many metaanalyses of other studies. Based on these studies, the force concluded that HT:

- ▶ Doubles the risk of invasive breast cancer.
- ▶ Doubles the risk of endometrial cancer.
- ▶ Doubles the risk of venous thromboembolism.
- ▶ Increases the risk of stroke by up to 41%.
- ▶ Increases the risk of heart disease by 29%.
- ▶ Increases the risk of dementia by about 40%.

The task force acknowledged that the additional risks conferred by HT are small (eight more strokes, eight more pulmonary embolisms, eight more invasive breast cancers, and seven more coronary heart disease events/10,000 women per year), but said patients and physicians should take them into account.

"The balance of benefits and harms for a woman will be influenced by her personal preferences, her risk for specific chronic diseases, and the presence of menopausal symptoms," according to the task force.

"A shared decision-making approach to preventing chronic disease in perimenopausal and postmenopausal women involves consideration of individual risk factors and preferences in selecting effective interventions for reducing the risks for fracture, heart disease, and cancer." ■

The new recommendations are available at [www.preventiveservices.ahrq.gov](http://www.preventiveservices.ahrq.gov).

## Adhesion-Prevention Fluid Works Through Hydroflotation

BY KATE JOHNSON  
Montreal Bureau

LONDON — An adhesion-prevention solution made from 4% icodextrin significantly reduced the incidence of adhesions after gynecologic laparoscopic adhesiolysis, compared with Ringer's lactate solution, according to results of a multicenter, double-blind clinical trial.

The product, called Adept, is made by ML Laboratories PLC of Leicester-shire, England. It has been licensed for use in Europe since 1999; in the United States, it is licensed only as an investigational medical device, said Elizabeth Peers, Ph.D., head of research and development for the company.

The study of postsurgical adhesions after gynecologic laparoscopic adhesiolysis—known as the PAMELA study—will form the basis of the company's submission for Food and Drug Administration approval, she told this newspaper. The company plans to apply for approval this year.

Data from the PAMELA study were presented at the annual congress of the International Society for Gynecologic Endoscopy. The study randomized 449 laparoscopic adhesiolysis patients to intraoperative irrigation and instillation of Adept or Ringer's lactate solution (RLS) during a first surgical procedure. The fluids were irrigated at 100 mL/30 min intraoperatively, and a postoperative instillate of 1 L was left in the pelvic cavity.

Because of its high molecular weight, Adept is absorbed slowly via the lymphatic system and remains in the pelvic cavity, providing hydroflotation for 3-5

days post surgery, the critical time for adhesion formation, said Dr. Peers.

During the initial surgical procedure, the presence of adhesions, their extent (localized, moderate, or extensive) and severity (mild or severe) were assessed at 23 anatomical sites. A reassessment made on second-look laparoscopy 4-8 weeks later analyzed the change in number of sites with adhesions, as well as the number of new adhesions.

**The product, which will be submitted to the FDA later this year, was more effective than Ringer's lactate solution in preventing adhesions.**

Adept performed significantly better than RLS on both measures, with 53% of Adept-treated patients free of new adhesions, compared with 43% of RLS patients.

Additionally, Adept-treated patients had a greater reduction in the mean number of sites with adhesions—from 10.3 to 7.9—compared with a reduction from 10.3 to 8.3 for RLS-treated patients.

Subgroups of 192 and 199 patients contributed to a separate analysis assessing American Fertility Society (AFS) scores for adnexal adhesions. Mean initial AFS scores were 7.4 for the Adept group and 7.3 for the RLS group. At second look, the score dropped to 4.9 for the Adept group and 6.2 for the RLS group—significantly favoring the Adept treatment.

Additionally, among patients whose primary diagnosis was infertility, the AFS score was reduced in significantly more Adept than RLS patients (51% vs. 30%).

The fact that any improvements were noted in patients treated with RLS was unexpected, since RLS is not known to reduce adhesions. This finding may be associated with the large volumes of both fluids as postsurgical instillates. "One liter is considerably more than is generally left in the pelvic cavity," she said. ■

## Factors May Help Predict Urinary Retention After TVT

BY SHERRY BOSCHERT  
San Francisco Bureau

RANCHO MIRAGE, CALIF. — Preoperative characteristics may help identify patients more or less likely to need catheterization for urinary retention immediately after minimally invasive sling surgery, said Abraham Morse, M.D.

Outpatients treated for urinary incontinence with the tension-free vaginal tape (TVT) system were studied retrospectively. Of the 119 cases, those who had a parity of at least three, were very anxious in the preoperative holding area, or had a normal Valsalva leak point pressure were less likely to require postoperative catheterization, Dr. Morse said at the annual meeting of the Society of Gynecologic Surgeons.

Dr. Morse of the University of Massachusetts, Worcester, and his associates hope to use these parameters to develop a scoring system for likelihood of postoperative voiding to better counsel patients before the TVT procedure.

"For [many] patients, the idea of going home on a catheter is a big issue . . . . If we could better predict who will be able to immediately void postoperatively, we [could] more effectively manage patient expectations and concerns, and identify those most likely to benefit from preoperative teaching of self-catheterization," said Dr. Morse, who disclaimed any financial interest in Gynecare, which markets the TVT system.

A review of TVT cases over a 3.5-year period focused on 119 outpatient procedures and excluded outpatients with cystotomies, because they were discharged with Foley catheters in place. Nurses in the preoperative holding area asked patients to rate their anxiety on a 10-point scale, with 1 being the least anxious.

Overall, 39% failed an immediate postoperative voiding trial and needed some kind of catheterization to be discharged. Of the total, 28% were discharged with a Foley catheter, and 11% went home using intermittent self-catheterization. Eventually, two patients (2%) needed mesh sectioning to treat persistent urinary retention lasting longer than 2 weeks. These rates are similar to those in other reports in the literature, Dr. Morse said.

Patients with a parity of at least three were five times more likely to pass the postoperative voiding trial, compared with patients who had a lower parity, a logistic regression analysis showed. A normal Valsalva leak point pressure conferred a sevenfold greater likelihood of not needing catheterization, compared with those with abnormal pressures. Patients with high preoperative anxiety were six times more likely to pass the voiding trial, compared with less anxious patients, he said.

Immediate postoperative urinary retention is common after incontinence surgery. Two previous series of TVT procedures found that 45%-49% of patients required some catheterization at discharge, he said.

Patients in the current study had a mean age of 53 and a median parity of two. A majority of the women were menopausal. Preoperatively, 55% of patients had stress urinary incontinence only, 45% had mixed incontinence, 11% had detrusor instability, and 87% had urethral hypermobility. Six percent had undergone previous surgery for pelvic organ prolapse, and 12% had undergone surgery for incontinence. The procedures lasted a median of 42 minutes each.

The lead investigator in the study was Kim I. Barron, a medical student at the university. ■