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Hormone Therapy and In-Hospital Survival after Myocardial Infarction in Postmenopausal Women

ABSTRACT & COMMENTARY

The present study was performed with 114,724 women aged 55 years or older with confirmed myocardial infarction (MI) who presented between April 1998 and January 2000 to one of 1674 hospitals participating in the National Registry of Myocardial Infarction-3. At the time of hospitalization, 6.4% of the women reported current use of hormone replacement therapy (HRT). Unadjusted mortality was 7.4% in users of HRT and 16.2% in nonusers. The unadjusted odds ratio was 0.41 with a confidence interval (CI) of 0.36-0.43, indicating that the result reached statistical significance. The women who used HRT differed from the rest of the population in several ways. Hormone users were younger, more likely to be white, less likely to have a history of diabetes or prior MI or stroke, more likely to have hypercholesterolemia and family history of premature coronary artery disease, and more likely to smoke tobacco. The proportion of women who experienced hypotension, ventricular arrhythmia, recurrent MI, stroke, and cardiac rupture with hospitalization was similar among users and nonusers. After adjustment for patient characteristics, use of HRT remained statistically significantly associated with a reduced odds ratio of in-hospital mortality of 0.65 (CI, 0.59-0.72). Shlipak and associates thus concluded that use of HRT at the time of MI was associated with approximately a 35% reduction in mortality (Shlipak MG, et al. *Circulation*. 2001;104:2300-2304).

COMMENT BY SARAH L. BERGA, MD

The present study enrolled women at the time of hospitalization for MI. At the time of enrollment, HRT status was recorded as a yes/no variable. The type or regimen of HRT was not elicited. All that is known is whether a given woman reported taking HRT at the time of their MI. The Heart and Estrogen/Progestin Replacement Study (HERS) trial enrolled women who were not taking HRT at the time of a MI and then randomized them to HRT or placebo. The present study found a significant benefit in terms of survival if one was taking HRT at the time of a MI. The HERS found that women who

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INSIDE

started HRT after a MI fared less well in the beginning, but better with increasing duration of HRT use. By year 4, the women randomized in the HERS to HRT had a decreased risk of mortality. The variables most likely to explain what might appear to be discrepant results between the HERS and many other observation trials, including the present one, is the duration of HRT use and whether it was begun before the index event. Taken together, these 2 studies raise the question as to how long it takes for HRT to have a beneficial effect. The HERS trial suggested that it takes about 4 or more years for the benefits to clearly outweigh the risks in terms of cardioprotection in women with established cardiovascular disease (CVD).

The editorial that accompanies the present study provides a balanced review about what is known about the mechanisms by which estrogen use might impart cardioprotection.[1] Of note, Mendelsohn and Karas highlight the abundant molecular data indicating that estrogen imparts a beneficial effect at the vessel wall.

They make the following points:

- HRT should continue to be used for primary cardioprevention;
- Statins should be used in women with dyslipidemias;
- In selecting the HRT regimen, consideration should be given to the lipid profile because different HRT regimens have different effects on various lipoproteins;
- The first-line therapies for women with known CVD include risk factor modifications, aspirin, beta-blockers, statins, and angiotensin-converting-enzyme inhibitors, just as in men. These therapies are underused, especially in women.

These recommendations make abundant sense. The question that looms is which physician will accept responsibility for implementing them? The choices include cardiologists, internists, family physicians, and gynecologists. There is no doubt in my mind that HRT is best given by gynecologists, if only because we know best how to manage the side effects, especially uterine bleeding. It would be extremely helpful, however, if all physicians sang the same song. Optimally, all would recommend HRT and then defer the administration of HRT to gynecologists with an interest in caring for postmenopausal women. That way, patients would hear a chorus and they would feel less ambivalent about taking HRT. As it is, physicians, especially those in different disciplines, tend to make discordant recommendations. Patients are understandably confused and reluctant. Further, I am hoping that gynecologists can do better in terms of learning to tailor the HRT regimen to the clinical circumstances of the patient. We need to have a firm grounding in the pros and cons of various HRT regimens. ❖

Reference

1. Mendelsohn ME, Karas RH. *Circulation*. 2001;104: 2256-2259.

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In order to reveal any potential bias in this publication, and in accordance with Accreditation Council for Continuing Medical Education guidelines, we disclose that Dr. Speroff is involved as a consultant, and does research for Wyeth Ayerst, Pfizer, Ortho, and Novo Nordisk. Dr. Berga is a consultant for Pfizer, Organon, and Women First, Inc., and is involved in research for Berlex and Health Decisions, Inc. Dr. Gershenson is involved in research for Pharmacia-Upjohn, Oncotech, Genetech, SmithKline Beecham, Atairigen, and the National Cancer Institute. Dr. Sakornbut, Dr. Noller, and Dr. Hobbins report no relationships related to this field of study.

Use of Peripheral Bone Density Measurements

ABSTRACT & COMMENTARY

Synopsis: The prevalence of unsuspected low bone density is high enough to warrant detection and treatment. Lower cost measurements of peripheral bone are effective.

Source: Siris ES, et al. *JAMA*. 2001;286:2815-2822.

Siris and colleagues reviewed data from the National Osteoporosis Risk Assessment (NORA)

study to identify the prevalence of low bone density and the efficacy of peripheral bone measurements. This study that began in 1997 is longitudinal in design, following more than 200,000 postmenopausal women in primary care practices. Peripheral bone density was measured with several methods: forearm using pDEXA from Norland (67,566 women), finger using AccuDEXA from Schick (15,011 women), or heel using either Osteoanalyzer from Siemens-Osteon (107,897 women), or Sahara from Hologic (9686 women). Overall, 39.6% of the women had osteopenia and 7.2% had osteoporosis. Native Americans had the same risk of osteoporosis as Caucasians, Asians and Hispanics had higher risks, and African-Americans had a lower risk. However, the likelihood of fracture was lower for Asians and no different for Hispanics compared with Caucasians. The current use of estrogen was associated with 73% reduced risk of osteoporosis (odds ratio, 0.27; confidence interval [CI] = 0.25-0.28). Women with osteopenia had a 1.8-fold higher risk of fracture, and those with osteoporosis had a 4-fold higher risk. The factors associated with an increased risk of low bone density were low body weight, maternal history of osteoporosis or fracture, personal history of fracture, smoking, lack of exercise, use of glucocorticoids, and nonuse of estrogen. A lower percentage of women tested with heel ultrasonography (Sahara) were identified as having osteoporosis (3.4%). Measurement of bone density at the finger yielded the highest percentage (13.5%).

COMMENT BY LEON SPEROFF, MD

I am often asked about the value of office-based bone density machines. There is a good-sized literature establishing the fact that peripheral bone mineral density can be used to assess fracture risk with one exception. The exception is hip fracture risk, which is best assessed with direct measurements of hip density, and this is the reason there has been reluctance to promote the machines that measure peripheral bone density. However, this study indicates that the peripheral machines do a good job, with the method that uses a finger doing the best. This is believed to be due to the ability to immobilize a finger in a standard fashion, minimizing variability.

In this large cohort of postmenopausal women without known bone status, almost half had low bone density measurements and about 7% had osteoporosis. It is reasonable to assume that these percentages underestimate the general prevalence in America because women who had a recent bone density measurement or who were being treated for osteoporosis were excluded from the study. The fracture rates are also an underestimation because nonclinical, asymptomatic spinal fractures could not be detected in this study. Even though the risk of osteoporosis for African-American women was about half that of Caucasian women, they had a 32% prevalence of osteopenia and a 4% incidence of osteoporosis, still high enough to represent significant fracture risk.

Clinical lesions from this study:

- The prevalence of unsuspected low bone density is relatively high;
- A fracture means osteoporosis until ruled otherwise;
- No single bone density measurement will identify all women at risk of fracture;
- Peripheral measurements of bone density have a predictive value very similar to that of central measurements;
- Finding a low bone density by any method indicates a high risk of fracture within the following year.

For these reasons, an inexpensive method to measure bone density in a clinician's office is an effective method to prevent osteoporotic fractures. Identifying these patients and providing preventive therapy with one of the many options available today are important obligations for clinicians who care for postmenopausal women. Measuring bone density in a finger by ultrasound is a method with great potential because it is relatively inexpensive, has a high-detection rate with good correlation with fracture risk, and minimizes individual variability.[1] ❖

Reference

1. Mauloni M, et al. *Menopause.* 2000;7:402-412.

Estrogen Replacement and Improved Nonverbal Memory and Attentional Measures in Postmenopausal Women

ABSTRACT & COMMENTARY

Synopsis: In a cross-sectional analysis of HRT always-users and never-users in their mid-60s, always-users displayed slightly better performance in delayed recall and attention.

Source: Smith YR, et al. *Fertil Steril.* 2001;76: 1101-1107.

This study compared 16 women with a mean age of 65 who had used HRT in the form of conjugated equine estrogens since menopause to 13 women with a

mean age of 67 who had never used HRT using standardized psychometric inventories. No statistically significant differences between the groups were found for general demographic, intellectual, and psychological measures. A total of 10 tests were administered. On 2 tests, there were differences in scores between always-users and never-users. The domains that differed were attention and delayed recall (nonverbal memory).

■ COMMENT BY SARAH L. BERGA, MD

The main strength of this study is the comparison of HRT always-users with never-users. There are also some significant limitations. First, the women were relatively young. The hypothesis being tested was that HRT would retard the age-related decline in cognitive prowess. However, age-related losses of cognitive and psychomotor functioning typically do not appear until after age 70 and do not become pronounced until after age 85. Thus, the groups were too young for major differences in performance to have emerged. Second, psychometric inventories are notoriously insensitive instruments. There is typically large variation in performance due primarily to longstanding interindividual differences in aptitudes and experiences. Even when the same individual takes the same battery of tests twice, however, there is still a lot of performance variation. This lack of sensitivity means that large groups of women would need to be studied for group differences to be detected. In this study, only a total of 29 postmenopausal women were studied. Third, the study was cross-sectional, so, again, to get beyond the expected differences due primarily to pre-existing endowments, one would need to study 2 large cohorts. In a prospective study, one could measure performance in the same individuals before and after a given treatment, but that type of study would take a long time to complete. For a study like this, one would prefer a treatment interval in the range of 20 or 30 years. Obviously, we cannot expect to see data like that being reported anytime soon. If we began such a study today, by the time it was finished, most of us would be too old to remember the question that we were trying to answer.

What advice can one give to patients about this important topic? The best that one can do is offer an educated guess based on available biological data. I emphasize that there is a wealth of biological data demonstrating that the brain is a target tissue for sex steroids. Sex steroids have a panoply of important effects on just about every known neurotransmitter system in the brain, including the cholinergic neurons that mediate memory and learning. Sex steroids increase synaptic density, cause glial to secrete nerve growth factors, promote blood flow, and in general enhance neuronal viability and connectivity. Available data suggest that to achieve full neuroprotection, one needs to take an estrogen that binds to both estrogen receptor subtypes, alpha and beta.

Given the above limitations that describe presently available data, I would be reluctant to discard the hypothesis. At this point, negative results are more likely to be due to limitations in study design rather than a valid negative result. While HRT use may pose some risks for some tissues or bodily systems, no one has yet suggested that HRT use damages the brain. All that is being debated is the type and magnitude of the benefits expected and the age at which the expected benefits will manifest. As always, the decision about HRT rests with a careful delineation of priorities, medical risks, and fears. Like osteoporosis and heart disease, no one is immune from age-related cognitive declines. Since estrogen started after dementia is clinically evident is of no apparent use, it would appear that one should recommend starting HRT at the time of menopause and continuing it indefinitely. ❖

Simultaneously Detected Endometrial and Ovarian Carcinomas: A Prospective Clinicopathologic Study

ABSTRACT & COMMENTARY

Synopsis: The prognosis for women with simultaneously detected carcinomas in the uterus and ovary with gross disease confined to the pelvis is surprisingly good, particularly for those with disease microscopically limited to the uterus and ovary or of low histologic grade.

Source: Zaino R, et al. *Gynecol Oncol.* 2001;83: 355-362.

In this prospective clinicopathologic study of the Gynecologic Oncology Group (GOG) conducted between 1985 and 1991, Zaino and colleagues enrolled 85 patients with apparent simultaneously detected adenocarcinomas in the endometrium and ovary with disease grossly confined to the pelvis. Of these, 74 patients were eligible. All patients were initially treated with total abdominal hysterectomy, bilateral salpingo-oophorectomy, and staging laparotomy, with radiation and chemotherapy left to the discretion of the treating physician and patient. Fifteen pathologic variables were

examined to identify differences in tumor behavior. Of the 74 patients, 23 (31%) had microscopic spread of tumor in the pelvis or abdomen. Sixty-four (86%) patients had endometrioid carcinomas in both the endometrium and the ovary, and endometriosis was found in the ovary of 23 (31%) patients. There was concordance between the histologic grade of the tumor in the ovary and the uterus in 51 (69%) patients. The estimated probability of recurrence 5 years following staging surgery is 15.1%. The presence of metastasis discriminated 2 groups of patients that experienced different probabilities of recurrence within 5 years: 10.0% for those with tumors confined to the uterus and ovary, and 27.1% for those with metastasis. The histologic grades of ovarian and uterine tumors also distinguished groups of patients with different probabilities of recurrence at 5 years: 8.0% for those patients with no more than grade 1 disease at either site and 22.4% for those with a higher grade in either the ovary or the endometrium. The estimated overall probability of surviving 5 years is 85.9% and that of surviving 10 years is 80.3%. Zaino et al concluded that the prognosis for women with simultaneously detected carcinomas in the uterus and ovary with gross disease confined to the pelvis is surprisingly good, particularly for those with disease microscopically limited to the uterus and ovary or of low histologic grade.

COMMENT BY DAVID M. GERSHENSON, MD

This study is a simple yet important step toward understanding the pathogenesis and biologic behavior of synchronous tumors of the endometrium and ovary. The coexistence of these 2 tumors is uncommon and occurs in approximately 5% of women with endometrial cancer and 10% of women with ovarian cancer. Prior to publication of this study, the literature has consisted of small, usually retrospective series. In addition, although histologic criteria have been proposed for distinguishing this entity of synchronous tumors, they have not been validated in any large study. Furthermore, several investigators have attempted to define the molecular signatures of synchronous tumors of the endometrium and ovary through molecular analysis in order to distinguish them from tumors metastatic from endometrium to ovary or vice versa. However, such reports have been hampered by disagreements in methodology and interpretation of results. Ultimately, this entity will be defined by its molecular profile. In my view, this report elucidates the excellent clinical course of patients with synchronous endometrioid tumors of the uterus and ovary. Importantly, the obstetrician-gynecologist should be aware of the existence of this uncommon entity and understand that prognosis is not worsened but actually improved by having 2 cancers rather than 1. ❖

The Aspirin Story in Reducing the Incidence of Preeclampsia

ABSTRACT & COMMENTARY

Synopsis: This study evaluates the ability of aspirin to lessen the incidence of preeclampsia in patients who had abnormal uterine artery Dopplers in the second trimester.

Source: Coomarasamy A, et al. *Obstet Gynecol*. 2001; 98:861-866.

Coomarasamy and colleagues recently published a meta-analysis evaluating the ability of aspirin (ASA) to lessen the incidence of preeclampsia in patients who had abnormal uterine artery (UtA) Dopplers in the second trimester. The group applied stringent criteria to articles in the literature surfacing after 1990 that were met by 5 randomized clinical trials (RCTs). Each study involved patients with at least 1 abnormal UtA waveform at 18-24 weeks of gestation who were then randomized to having 50-100 mg of aspirin, no treatment, or a placebo. Coomarasamy et al were interested in 2 main outcomes: the presence or absence of preeclampsia and the birthweight.

The pooled data showed a significant benefit of ASA in preventing preeclampsia (OR, 0.55, 95% CI, 0.32-0.95). Although infants born to mothers on ASA were on average 84 g larger, this difference did not attain statistical significance.

COMMENT BY JOHN C. HOBBINS, MD

Original work by Brosens and, later, others indicates that the spiral arteries, the end tributaries of the UtAs, are invaded in 2 phases by the adjacent trophoblast in the first and second trimester. This creates open conduits for maternal blood to freely enter the intravillous space. In preeclampsia, this trophoblastic invasion simply does not occur.

Years ago, Campbell postulated that this critical event could be monitored with UtA Dopplers since the opening of the spiral arteries would create a decrease in resistance that would be reflected upstream. The original work from the King's College Hospital group, showing a strong relationship between abnormal UtA waveform

and preeclampsia has been confirmed by many recent investigations, the last of which involving 8300 patients, emerged in November. The strongest correlation with abnormal UtA waveform occurs in patients with severe preeclampsia requiring delivery prior to 33 weeks of gestation. Here the sensitivity of abnormal UtA waveforms exceeds 90%.

Unfortunately, there are 2 facets of this type of screening that have generated confusion. First, some patients who have abnormal UtA waveform at 18 weeks will convert to a normal waveform by 24 weeks and these patients will have normal outcomes. These "late bloomers" confused the interpretation of the original investigations that were aimed at screening only at 18 weeks. However, if screening were to be accomplished at 24 weeks, the sensitivity and positive predictive values are enhanced appreciably.

The second problem has to do with the definition of abnormality. When increased resistance (impedence) is encountered downstream, the UtA will reflect this in 1 of 2 ways: 1) a low-end diastolic flow (S/D ratio of > 2.9); or 2) a notch in the diastolic component of the waveform. Many of the studies in the literature have defined any of the above in either UtA as being abnormal. However, it is clear that patients with bilateral notches and low-end diastolic flows have a far higher risk of preeclampsia and/or intrauterine growth retardation (IUGR) than a patient who, for example, has only low-end diastolic flow in 1 artery.

Boiling down the literature to numbers that can be used clinically, at 24 weeks the chance of a patient developing some form of preeclampsia and/or IUGR with a unilateral UtA abnormality is about 20%, while bilateral abnormalities increase the chance to about 70%.

Now to this, many might legitimately say "So what! What can one do preemptively, except to watch these patients carefully for signs of preeclampsia?"

This is where the above meta-analysis comes in. In preeclampsia, there is an imbalance between thromboxane (higher) and prostacyclin (lower). Low-dose ASA can restore this critical balance by selectively diminishing thromboxane levels.

Interestingly, 2 NICHD perinatal network RCTs did not yield results that generated much excitement about the preventative value of ASA. The first study involved relatively low-risk patients for preeclampsia (nulliparous), and the second involved "high-risk" patients. Neither showed a significant decrease in preeclampsia in those taking aspirin. However, most importantly, these studies did not include assessment of UtA waveform.

Sifting through the data generated over the last 15 years (including our own investigation), it seems that screening everyone in the second trimester with UtA Dopplers is not worthwhile. However, in patients who are at-risk for preeclampsia and/or IUGR, this type of Doppler investigation makes sense. These would include patients with a previous history of hypertension in pregnancy, a strong family history of hypertension, a history of IUGR, and elevated second trimester human chorionic gonadotropin (HCG) or maternal alpha-fetoprotein (MSAFP), or a strong suspicion by reproductive history of antiphospholipid antibody syndrome without laboratory confirmation of such.

Coomarasamy et al found that for every case of preeclampsia prevented with ASA, 16 patients would have to be treated. This may be well worth the effort, since low-dose ASA has a negligible risk of complications.

The questions that remain are "when to screen and when to treat?" By screening and treating at 18 weeks, one would be unnecessarily treating the late convertors who are destined to have normal pregnancies. However, although there are no studies available that address this, it would seem that the earlier the opportunity to get ASA on board, the better the chance of preventing a problem whose genesis starts long before the 24th week of gestation. Repeating the Doppler evaluation at 24 weeks in those with abnormal results at 18 weeks would allow the discontinuation of ASA in the later convertors, comprising about half of the treated population. In this way, only those who needed the ASA would get it throughout the remainder of pregnancy and these patients might benefit from an early start. ❖

Suggested Reading

1. Caritis S, et al. *N Engl J Med*. 1998;338(11):701-705.
2. Campbell S, et al. *Lancet*. 1983;1(8326 Pt 1):675-677.
3. Bower S, et al. *Obstet Gynecol.* 1993;82(1):78-83.
4. Papageorghiou AT, et al. *Ultrasound Obstet Gynecol*. 2001;18:441-449.

Special Feature

Maintaining Board Certification

By Kenneth L. Noller, MD

The process of achieving certification by the American Board of Obstetrics and Gynecology (ABOG) is well known. All of us who are certified have successfully completed a residency program that is fully approved and have passed 2 examinations: a writ-

ten test that focused on recall of information, and an oral examination that was designed to review our methods of practice.

Several boards began to offer, and later require, recertification after a variable number of years in practice. In most cases, this involved achieving a passing grade on a written test. The shortcoming of this process is that it only tests recall, not method of practice. A physician might know many facts, but not have applied them to his/her daily practice. For example, an OB/GYN might be able to answer any number of questions about the role of HPV in the etiology of cervical cancer, but still be performing hysterectomies for CIN3/carcinoma in situ.

ABOG was the first board to develop an annual recertification process, known as Annual Board Certification (ABC). The program has been extremely successful. Many OB/GYNs who do not need to recertify because of "grandfathering" have registered to receive the test materials. In this program, the physician who has entered the process receives regular mailings of several recent articles from the literature that have been chosen because of their quality and importance to the field. After reviewing the articles, he/she takes a test on the content. This has been seen by many boards as a major improvement in the process now known as "maintenance of certification."

However, even the new ABOG process will not satisfy the requirements that will be in place in a few years. All of the boards will be required to develop a system that can judge "competency." Exactly what this term means is the subject of great debate at the highest levels. At one end of the spectrum would be actual observation of practice. Of course, that is not possible. The other end is the continuation of the present system in which passing a test every few years is considered to be evidence of maintenance of skills—an easy process to implement, but hardly a measure of performance.

While I am on dangerous ground trying to predict the future of this movement, it does seem clear that all of us (yes, even those of us who have been "grandfathered") will need to be tested and reviewed on a regular basis. In many ways, this seems to be redundant, as our hospitals are currently required to evaluate our practice and skills on a regular basis. Unfortunately, far too few hospitals make much of a genuine attempt at true evaluation. Indeed, there is a built-in conflict for the hospital to do so since the loss of a busy practitioner adversely affects the bottom line. Nonetheless, it is likely that our hospital practice will be judged in some way that is similar to the current "QA" processes with which we are familiar.

A new element will be the need to provide information about our office practices. Since an ever-increasing proportion of medical care occurs in the office rather than in the hospital, this makes great sense. However, it will add yet another layer of paperwork on top of the already huge pile, resulting in increased costs. It is unlikely that it will be possible to use data that are already collected for another purpose to satisfy the needs of the "competency-based" maintenance of certification process.

There will be other requirements such as proving that we hold an unrestricted license to practice medicine, that our list of malpractice claims is "reasonable," and that we have had no "adverse actions" taken against us. In short, we will need to satisfy the "impartial observer" that we are up to date and safe to practice obstetrics and gynecology.

By now, you are probably wondering where I'm going with this editorial. My sole purpose was to inform you that there will be big changes in the requirements for maintaining your status as a board-certified practitioner in the not-too-distant future. Many have felt comforted knowing that they would "never" be required to recertify or to take another test. It now appears that might have been too optimistic. You can be assured, though, that ABOG will try to minimize any bad effects of the new requirements when they are published. Unfortunately, ABOG will have little to say about the general requirements, as they are being developed at a level above any individual Board. We can only hope that the process does improve the quality of health care in the United States. ❖

CME Questions

4. Which of the following therapies is *not* recommended for use in a postmenopausal woman with a strong family history of cardiovascular disease and a personal history of an elevated LDL-cholesterol and mild hypertension?

a. Angiotensin-converting-enzyme inhibitors
b. Thiazide diuretics
c. Statins
d. Aspirin
e. Transdermal estradiol with cyclic progestin use

5. For the majority of patients who have simultaneously detected endometrial and ovarian cancers, the histologic type of both tumors is:

a. serous.
b. endometrioid.
c. clear cell.
d. mucinous.
e. undifferentiated.

6. **The following statements are true regarding the association of bone density and osteoporosis *except*:**
   a. Bone density measurements detect most, although not all, postmenopausal women at risk for fractures due to osteoporosis.
   b. Many women at risk for fractures can be identified by historical factors.
   c. Osteopenia is not associated with an increased risk of fracture.
   d. African-American women have a clinically significant increased prevalence of fracture due to osteoporosis.

7. **Which of the following is *not* a limitation of the current estrogen replacement study by Smith et al?**
   a. Small sample size
   b. Insensitivity of psychometric inventories for assessing cognitive performance
   c. Short duration of follow-up
   d. Comparison of always-users with never-users
   e. Cross-sectional design

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In Future Issues:

Melatonin Treatment for Age-Related Insomnia