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Menopause: & Hormone Therapy Other Options

Remember July 2002? Some think of it as the summer that changed women's health care forever. That's when researchers abruptly halted part of the Women's Health Initiative (WHI), a major federally funded clinical study to assess the effect of long-term use of hormone therapy (HT). Early results indicated that postmenopausal women using a combination estrogen/progestin medication called Prempro faced a slightly increased risk of breast cancer, heart disease, stroke and blood clots, results that were deemed too risky to ethically allow women to continue on the drug.[1]

Almost overnight, it seemed, women were ditching their hormone therapy like a bad stock.[2] Doctors around the country counseled patients to stop taking hormones, and even the U.S. Food and Drug Administration (FDA) jumped into the fray, requiring that a so-called "black box," the agency's strongest warning label, be added to all estrogen products warning women of the potential risks.[3]

What a difference two years can make.

When investigators announced in March 2004 that they were ending the other major part of the WHI study early—the one involving the estrogen-only product, Premarin—because results showed participants had a slightly increased risk of stroke, the world took the news relatively calmly, with little of the hysteria and media frenzy that ensued in 2002.

Back then, Joan Flynn, 66, of Hilton Head, SC, who had been taking Premarin for nearly 20 years, quit cold turkey, even though the study's findings were for Prempro, an entirely different medication.

But after trying non-hormonal options such as black cohosh and vitamin E and enduring three months of hot flash misery, she returned to Premarin, albeit at a lower dose. Even after the March announcement, she had no intention of changing her mind.

"Every day you hear or read about something that will cause 'something,'" she says. "But while I'm living, I need to be comfortable."

It's an attitude more and more women have taken as the fallout from the 2002 WHI study settles and new research and thinking emerges. Even 50 percent of female ob-gyns surveyed by the American College of Obstetricians and Gynecologists in December 2003 said they used hormone therapy to treat their own menopausal symptoms.[4]

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MENOPAUSE: HORMONE THERAPY & OTHER OPTIONS continued from page 1

And when researchers surveyed 377 women who regularly used hormone therapy for at least one year before July 1, 2002 and tried to stop taking it between July 2002 and March 2003, they found that about one in four resumed hormone therapy, most because of troublesome symptoms such as hot flashes.[5]

It may be now that women are realizing they shouldn't have thrown the baby out with the bathwater, says Carol Landau, PhD, a clinical professor of psychiatry and human behavior at Brown Medical School in Providence, RI, whose clinical practice focuses on menopausal women. Just as the original findings of the WHI were oversimplified, she says, so, too, was the message of what women should do about them.

"I think the message here is that hormone therapy is still appropriate for recently menopausal women with significant symptoms," says JoAnn E. Manson, MD, DrPH, the Elizabeth F. Brigham Professor of Women's Health at Harvard Medical School, Boston, MA.

The key is tailoring hormone therapy to an individual woman's needs. And, with more than 20 varieties of hormone therapy on the market today, ranging from creams and gels, to patches, rings and pills, that's easier to do than ever before.

Questions About the WHI

Here's the reality behind the WHI: Basically, in 2002 the WHI found that women taking the hormone therapy Prempro, composed of progestin (a synthetic progestogen known as medroxyprogesterone acetate or MPA) and conjugated equine estrogen, had a 26 percent increased risk of invasive breast cancer, a 29 percent increased risk of heart attack, a 41 percent higher rate of stroke and more than a 100 percent increase in blood clots in the lung.[6] Later results also found women taking Prempro had twice the risk of dementia compared to those not using any hormones.[7]

That sounds scary. But when examined in terms of individual risk, the results paint a far less frightening picture. Of 10,000 women taking HT, over the course of one year 23 additional women would develop dementia, eight more would have blood clots in the lung, strokes, or breast cancer, and seven more would have heart attacks or other coronary events, than women not taking Prempro. But don't forget the study's good news: Over the course of a year, those 10,000 women taking Prempro would have five fewer hip fractures and six fewer incidences of colon cancer.

Since July 2002, researchers and health care professionals have raised significant questions about the WHI. For instance, many experts note that with an average participant age of 63, the women in the study started taking hormone therapy 10 to 15 years later than most women do, a delay that could have significantly affected the outcome, says Phillip Sarrel, MD, emeritus professor of obstetrics/gynecology and psychiatry at Yale Medical School in New Haven, CT.

Plus, the North American Menopause Society, in its most recent statement on the WHI released in September 2003, cautions that the effects of hormone therapy on the risk for breast cancer and osteoporotic fractures on perimenopausal women—the ones most likely to need hormone therapy for symptom relief—have not been established.[8]

All of which leaves the ball, so to speak, squarely in the court of individual women. "What I think happened is that women were getting this very strong message for the past 10 years to take hormone therapy long-term to prevent heart disease and other chronic health conditions," says Dr. Landau, "and then they got this other message, to stop immediately. Finally, they've had enough."

To try and help women understand their choices, she and Michele G. Cyr, MD, internist and Associate Dean for Women in Medicine at Brown Medical School, wrote, *The New Truth About Menopause* (St. Martin's Press, 2003). As they point out in their book: Even though the WHI study was stopped and it is probably wise to take the smallest dose of hormone therapy for the shortest amount of time, "that's an individual decision. While there were very small increases in risk in WHI, certainly enough to stop the study and certainly enough to make you think, they weren't enough to make you say 'never,'" says Dr. Landau.

Stopping Hormone Therapy

Still, for some women, the only answer to the hormone therapy question is to stop taking it. Before quitting, however, talk to your health care professional. Many women just went "cold turkey" after the 2002 WHI report, notes Dr. Landau, causing unnecessary discomfort that might have been reduced had they gradually tapered off the medication.

Unfortunately, no one really knows the best way to discontinue hormone therapy. In fact, a study published in the December 2003 issue of the journal *Obstetrics and Gynecology* found that women who abruptly stopped taking hormone therapy experienced fewer withdrawal symptoms than those who tapered off.[5] That could be because the women didn't taper off slowly enough, the authors suggest.

The researchers also found that women who had undergone a hysterectomy and who started hormone therapy for menopausal symptoms and had used hormones for more than 10 years were most likely to return to hormones once they stopped than other women. Plus, women who reported troublesome symptoms after stopping were nearly nine times more likely to resume using hormone therapy than women without such symptoms.[5]

The good news, though, is that the study found just one-third of women who stopped using hormone therapy—either abruptly or gradually—experienced severe symptoms.[5]

Evaluating Your Own Risk

Whether you stop hormone therapy or continue it, you need to consider your own health risks and where you are in the menopausal process. "Women who are recently menopausal have a very low baseline risk of heart disease," says Dr. Manson. "Even the 20 to 30 percent increase in the risk of heart disease the WHI study found translates into a very small risk for the individual woman."

And while the research is pretty clear about the fact that starting hormone therapy 10 to 20 years after menopause is not advisable, especially for the purpose of preventing chronic disease, Dr. Manson says, "there are very few women in that age group who experience the primary symptom that drives most women to hormone therapy in the first place: hot flashes. As far as its use for moderate to severe hot flashes, I think it still has a role in clinical practice for short-term treatment and is the most effective treatment out there."

Indeed, the WHI study found that 77 percent of the 2,000 women in the study who complained of hot flashes said their flashes diminished while on Prempro.[9] Of course, keep in mind that women with severe hot flashes were not included in the study to begin with, since they would have known immediately whether they were taking the drug or a placebo. The results of the medication's effectiveness in reducing hot flashes have not been released yet.

And while there are other options for hot flashes (see page 6), none are as effective as hormone therapy and none are FDA-approved for the purpose.

Exploring the Options

When the WHI results on Prempro were announced in 2002, none of Dr. Sarrel's patients stopped taking the drug. That's because he's only ever prescribed natural progesterone,

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Whether you stop hormone therapy or continue it, you need to consider your own health risks and where you are in the menopausal process.

NWHRC Menopausal Hormone Therapy Survey Reveals Concerns, Interest in Options

In the Fall of 2003, the National Women's Health Resource Center conducted an online survey to learn more about women's views on menopausal hormone therapy. Six hundred and forty-eight visitors completed the survey, and about 60 percent had experienced either natural or surgical menopause. Among the results:

- Nearly 70 percent of respondents said they were very or somewhat confused about the safety of menopausal hormone therapy.
- One out of five (22 percent) said they stopped taking hormone therapy after news reports questioning its safety were published, and only 20 percent of those women said they discussed their decision with their health care professional.
- Eight percent of those who stopped hormone therapy said they were considering taking it again, while 15 percent said they were investigating alternative options.
- More than 70 percent of women said that they would consider an alternative natural hormone therapy if it was approved by the FDA.[11]

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The key then, is tailoring hormone therapy to an individual woman's needs. And, with more than 20 varieties of hormone therapy on the market today. . .that's easier to do than ever before.

such as Prometrium, and the form of estrogen called estradiol, for his patients.

According to Dr. Sarrel, the estrogen used in Prempro bears little resemblance to the estrogen produced by a woman's body, and it contains MPA, one of the strongest progestins available. MPA, he says, interferes with estrogen's action on various tissues throughout the body and actually negates or even reverses some of estrogen's beneficial effects.

Indeed, it is looking possible that the culprit in the Prempro trials may be MPA, in conjunction with estrogen, since the estrogen-only arm found no increase in breast cancer or heart disease, notes Dr. Manson.

But before you switch to a different type of progestogen (the class of medications that includes natural progesterone as well as synthetic progestin), it's important to realize that other types may have the same risks. Same with estradiol, says Dr. Manson, who says some studies suggest similar increased risks of heart disease and breast cancer with 17-beta estradiol, the type found in most estradiol therapy preparations. In general, she says, lower doses of any hormone therapy should be safer in terms of health risks, even though no studies yet prove that.

It's important that women don't ignore their symptoms and be aware that they still have hormonal options in the post-WHI world, suggests Dr. Landau. "If you're having bad hot flashes and you've tried other things, like black cohosh and vitamin E, and you're still having hot flashes, my view is there is no need to suffer or 'tough it out,'" she says. Plus, cautions Dr. Landau, untreated hot flashes can lead to depression due to lack of sleep.

Thus, she and other experts recommend that women who feel they still need hormone therapy for symptom relief talk to their health care professionals about starting on the lowest possible dose, then gradually increasing it until they're comfortable.

They might also consider using transdermal hormonal options, such patches or gels, instead of taking oral hormones, says Dr. Manson. Because transdermal estrogens are metabolized by the liver in much lower concentrations than estrogens taken orally, estrogens from transdermal formulations are less likely to increase clotting factors, triglycerides and inflammatory markers such as CRP, all of which can play a role in heart disease and stroke. Plus, notes Dr. Sarrel, today's transdermal options provide exceptionally accurate delivery of hormones.

For problems with vaginal dryness and sexual dysfunction, which can interfere with intimate relationships, consider a topical estrogen formulation, such as an estrogen ring or estrogen cream, suggests Dr. Manson. These formulations work locally on the areas to which they are applied and only small amounts are absorbed by the body as compared with oral formulations. "So, there is strong reason to believe that you will not have the same risks that you would have with oral or patch estrogens," she says.

New Hormone Therapy Available

Beginning in mid-2004, women will have a brand-new option. EstroGel, approved by the FDA in February 2004, is a clear, odorless, fast-drying gel that's applied once a day on one arm from the shoulder to the wrist. It is approved for hot flashes and night sweats, and for vulvar and vaginal atrophy.[10] EstroGel has been used for more than 25 years in Europe, according to Dr. Sarrel. It should be available throughout the U.S. by this summer.

Other hormone therapy options, oral and non-oral alike, likely will appear in the next few years.

Resources

American Menopause Foundation
350 Fifth Avenue, Suite 2822
New York, NY 10118
212-714-2398
http://www.americanmenopause.org
Offers support, information and resources on menopause-related issues.

Hormone Foundation
4350 East West Highway, Suite 500
Bethesda, MD 20814-4410
1-800-467-6663
http://www.hormone.org
Provides information and resources on hormone-related disorders.

Landau, C. and Cyr, MG.
The New Truth About Menopause
New York: St. Martin's Press, 2003

National Institutes of Health
Postmenopausal Hormone Therapy Information
http://www.nih.gov/PHTindex.htm
Provides details on WHI and resources and links to hormone therapy, women's health and menopause information.

North American Menopause Society
5900 Landerbrook Drive, Suite 195
Mayfield Heights, OH 44124
440-442-7550
http://www.menopause.org
Offers consumer and professional information on menopause-related topics and research.

Women's Health Initiative Home Page
National Heart, Lung and Blood Institute
http://www.nhlbi.nih.gov/whi
Provides information on the WHI study and menopause and women's health.

Overview: A Woman's Guide To Hormone Therapy[22]

Hormone therapy (HT) is used to relieve one or more menopausal symptoms caused by declining estrogen levels. These symptoms may include hot flashes, night sweats and vaginal and urinary tract changes. HT can be either estrogen alone or include a progestogen (either progestin or progesterone). Progestogen is added to estrogen therapy to decrease the risk of uterine cancer associated with estrogen-alone therapy for women who have not had a hysterectomy. If you have had a hysterectomy, estrogen-only therapy may be prescribed. Ask your health care professional for details about potential side effects and risks associated with any hormone therapy products you may consider using.

HORMONE THERAPY DELIVERY METHOD*

	ESTROGEN ONLY	ESTROGEN/PROGESTIN COMBINATION	ESTROGEN/ TESTOSTERONE	PROGESTOGENS	CYCLICAL PROGESTOGEN ADDED TO ESTROGEN
Gel: Transdermal (applied to one arm daily)	**EstroGel** *(estradiol bioidentical estrogen)*				
Cream: Vaginal (applied with applicator into vagina)	**Estrace** *(micronized estradiol)* **Ogen** *(estropipate cream)* **Premarin** *(conjugated estrogen cream)*				
Lotion (applied to both legs daily)	**Estrasorb** *(estradiol topical emulsion)*				
Injection (typically injected into the upper buttock area every 4 weeks)	**Delestrogen** *(estradiol valerate)* **Estrone**				
Patch (typically applied to lower abdomen, buttocks or outer hip; replaced every 4-7 days, depending on product)	**Alora** *(estradiol)* **Climara** *(estradiol)* **Esclim** *(estradiol)* **Estraderm** *(estradiol)* **FemPatch** *(estradiol)* **Vivelle Dot** *(estradiol)*	**Combipatch** *(estradiol/norethindrone acetate)*			
Vaginal Ring (inserted into and retained in the vagina; replaced every 90 days)	**Estring** *(estradiol)* **FemRing** *(estradiol)*				
Capsule (taken orally)				**Prometrium** *(micronized progesterone)*	
Pill (taken orally)	**Premarin** *(conjugated equine estrogen)* **Estrace** *(micronized estradiol)* **Menest** *(esterfied estrogen)* **Estinyl** *(ethinyl estradiol)* **Ogen** *(estropipate)* **Cenestin** *(conjugated soy/yam plant-derived estrogen)*	**Activella** *(estradiol/ norethindrone)* **Prempro** *(conjugated estrogen/medroxy-progesterone acetate)* **Prefest** *(beta-estradiol/ norgestimate)* **FemHRT** *(norethindrone acetate/ethinyl)*	**Estratest***(esterfied estrogen/methyl-testosterone)*	**Provera** *(medroxy-progesterone acetate)*	**Premphase** *(conjugated estrogen and conjugated estrogen/medroxy-progesterone acetate)*
Vaginal Tablets *(tablets are inserted into the vagina twice weekly)*	**Vagifem** *(estradiol)*				

**As of March 2004. Products come in varying dosages. Not all menopause-related hormone therapy products are included here.* 4/04

Other Treatment Options For Menopausal Symptoms

Nearly one-third of all women who responded to a Fall 2003 online survey at the NWHRC's Web site, www.healthywomen.org, said they were taking vitamins, over-the-counter medications and/or herbal remedies to manage their menopausal-related symptoms mostly because they felt they would be safer than hormonal therapies.[11]

They're not alone.

After the Women's Health Initiative results were announced in 2002, thousands of women stopped taking hormones and began looking for other options, many for the most troublesome of their menopausal symptoms: hot flashes. Among the alternatives:

- **Prescription medications.** Studies on the antidepressants fluoxetine (Prozac), paroxetine (Paxil) and venlafaxine (Effexor); the anti-seizure medication gabapentin (Neurontin); and the anti-hypertensives clonidine (Catapres) and methyldopa (Aldoril), find these medications significantly reduce the frequency and severity of hot flashes in postmenopausal women.[12,13] However, antidepressants have well-established side effects affecting sexual response, which is often a problem for menopausal women to begin with, notes Philip Sarrel, MD, an emeritus professor at Yale Medical School.
- **Oral contraceptives.** Women approaching menopause are often prescribed oral contraceptives to help with heavy bleeding and other menstrual irregularities. One three-year study of a triphasic oral contraceptive in 200 perimenopausal women found it significantly reduced women's hot flashes when compared to placebo. It also reduced bone-mass loss, helped with vaginal dryness and sexual responsiveness, and prevented or improved mood, concentration, insomnia and loss of concentration, among other menopause-related symptoms.[14] Oral contraceptives contain higher doses of estrogen and progesterone than most hormone therapies on the market.
- **Herbal and alternative remedies.** Leading the pack of herbal remedies touted for hot flash relief is black cohosh, with some randomized, controlled studies showing improvement in mild hot flashes. But there are no long-term data on the safety of black cohosh, a plant estrogen, in postmenopausal women, and some researchers worry it could increase the risk of certain reproductive cancers.[19] Furthermore, since it is thought to act similarly to estrogen in some ways in the body, it is usually not recommended for women for whom estrogen is not recommended.

Other herbal remedies, including isoflavones, red clover, evening primrose oil, ginseng, licorice, or dong quai, show little effect on menopausal symptoms.[15] Though a handful of controlled studies conducted on acupuncture for menopausal symptoms also found no effect, one study did.[15,21] There is also some evidence that hypnosis may help reduce the frequency, duration and severity of hot flashes.[16]

If you're considering herbal remedies or other supplements, keep in mind that the U.S. Food and Drug Administration doesn't oversee the production of supplements, nor require manufacturers to prove their products are effective, as they do with prescription or even over-the-counter drugs.

- **Vitamins.** The first well-controlled trial of vitamin E, conducted in 1953, found it was no more effective than a placebo in relieving menopausal symptoms, but a trial in women with breast cancer conducted in 1998 found it did relieve hot flashes. Plus, vitamin E is believed to have healthful benefits for your heart, and at doses of 800 IU, presents no danger.[17,18]
- **Progesterone cream.** Whether or not this product works on hot flashes isn't certain. With only two randomized clinical trials conducted on the use of progesterone cream on hot flashes, one showed a small improvement at 20 mg/day, but the other trial, which used 32 mg/day, showed no improvement over placebo. According to a position statement by the North American Menopause Society in the March/April 2003 journal *Menopause*, progesterone cream or gel preparations available by prescription or over-the-counter may not protect the uterine lining from the effects of unopposed estrogen. These products should not be used for this purpose until more is known from long-term clinical trials about ideal therapeutic doses.[20]

Common Questions About Hormone Therapy

Q Are there any definite rules at this point for who should and shouldn't use hormone therapy?

A Hormone therapy is not a 'one-size-fits-all' solution. It is important for women and their health care providers to determine whether hormone therapy is an appropriate treatment option. This decision should be based on a woman's menopausal symptoms and her medical history.

There is, however, one very clear rule at this point: Hormone therapy should not be started or continued for the express purpose of preventing cardiovascular disease, a common clinical practice in the past.

Based on the research to date, there is no apparent benefit to hormone therapy for cardiovascular disease, and there is even an increased risk for stroke with either estrogen alone or with estrogen and progestin. Generally, beginning hormone therapy at age 60, 70 or even later is not advisable. And, women at high risk for cardiovascular disease should also avoid it. Hormone therapy still has a role in the short-term treatment of menopausal symptoms, but the lowest effective dose should be used for the shortest duration necessary.

Q **I know that hormone therapy has often been prescribed to prevent osteoporosis. How does it compare with other osteoporosis medications?**

A So far, results from the Women's Health Initiative find that estrogen, either alone or with progestin, helps decrease the risk of hip fracture and other osteoporotic fractures in women. As more women stop taking hormone therapy, however, they are looking for alternatives to protect their bones. Today, several medications are available for the prevention or treatment of osteoporosis, such as Evista (raloxifene), a selective estrogen receptor modulator, or SERM, which is protective against vertebral fractures. However, studies find that estrogen, either alone or combined with progestin, is about twice as powerful in preventing osteoporosis as Evista. Bisphosphonates, a class of drugs including Fosamax (alendronate) and Actonel (risedronate) that is used in the treatment of osteoporosis, are at least as effective as hormone therapy for this purpose.

Q **When are hot flashes at their worst?**

A Generally, hot flashes are at their worst within the first two years of menopause. They gradually taper off after menopause in most women. A small percentage of women will have long-term, severe hot flashes that can be controlled with only hormone therapy. The wide variety of options now available can help relieve discomfort and minimize the negative impact hot flashes can have on women's lives, such as disrupting sleep.

–JoAnn E. Manson, MD, DrPH
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A principal investigator of the Women's Health Initiative

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Looking for Relief? Change Your Lifestyle

Soon after the Women's Health Initiative results were announced in July 2002, several of my patients came to me anxious for some kind of non-hormonal therapy to help with their hot flashes. And I had just the answer: change your lifestyle.

For while hormones may work best for moderate-to-severe hot flashes, a growing body of research finds that making some simple changes in your life can make a big difference when it comes to reducing the severity and number of milder hot flashes. My favorite options:

- **Exercise.** Rack up another reason to take that walk! Compelling evidence suggests that regular exercise may reduce the number and severity of hot flashes. In one study, for instance, Swedish researchers evaluated 793 postmenopausal women on their exercise habits and the prevalence of hot flashes. Only five percent of highly physically active women said they experienced severe hot flashes, compared to 14 to 16 percent of women who had little or no weekly exercise. One possible reason, researchers theorized, is that regular physical exercise may have some effect on the brain chemicals that regulate body temperature.
- **Quit smoking.** It makes intuitive sense that since smoking is so bad for you in so many ways, it probably doesn't help with hot flashes. Now research bears this out. A study published in the February 2003 issue of the journal *Obstetrics and Gynecology* found that smokers were nearly twice as likely to have moderate or severe hot flashes as those who never smoked, and more than twice as likely to have daily hot flashes. The more they smoked, the more they flashed.
- **Lose weight.** It's no secret that overweight people suffer from the heat more, regardless of whether or not they're having hot flashes. But studies find that women with a body mass index (BMI) greater than 30, which is considered obese, were more likely to have frequent and severe hot flashes than women with a BMI under 25, considered a healthy weight.
- **Add soy to your diet.** While studies show little effect from the soy component isoflavones on hot flashes, they do suggest that adding soy to your diet can make a difference. Plus, the U.S. Food and Drug Administration has already noted the heart benefits of 25 grams of soy protein a day. So while the evidence is far from conclusive as to the daily benefits of soy, it certainly won't hurt to drink an eight-ounce glass of soy milk (11 grams of soy protein), microwave a couple of soy sausages for breakfast (12 grams of soy protein) or down a soy protein bar for a late-afternoon snack (14 grams of soy protein). ✖

By Pamela Peeke, MD, MPH
NWHRC Medical Advisor

Dr. Peeke is a Pew Foundation Scholar in Nutrition and Metabolism, and Assistant Clinical Professor of Medicine at the University of Maryland in Baltimore. She writes about health and lifestyle issues important to all women.

Talking to Your Health Care Professional About Menopause

It's important to find a health care professional with whom you feel comfortable discussing menopause-related concerns. To help you determine if your health care professional is the one, ask him or her some or all of the following questions:

1. How many women in my age group do you treat? What percentage does this number represent of your total practice?
2. Do you consider yourself up-to-date on menopausal treatment options including hormone and other therapies?
3. I'm experiencing several different types of symptoms. Could they be caused by menopause?
4. How will we determine what's causing my symptoms and if I am menopausal?
5. If I am interested in alternative therapies, will you work with me to help identify those that might be helpful?
6. How do the benefits and risks of HT apply to my personal health needs?
7. If I start the treatment that you recommend, how soon will you be able to see me again to monitor the treatment for effectiveness and side effects?

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