

Cold caps tested to prevent hair loss during chemo

July 22 2013, by Lauran Neergaard

(AP)—The first time Miriam Lipton had breast cancer, her thick hair fell out two weeks after starting chemotherapy. The second time breast cancer struck, Lipton gave her scalp a deep chill and kept much of her hair—making her fight for survival seem a bit easier.

Hair loss is one of chemotherapy's most despised side effects, not because of vanity but because it fuels stigma, revealing to the world an illness that many would rather keep private.

"I didn't necessarily want to walk around the grocery store answering questions about my cancer," recalled Lipton, 45. "If you look OK on the outside, it can help you feel, 'OK, this is manageable, I can get through this.'"

Now U.S. researchers are about to put an experimental hair-preserving treatment to a rigorous test: To see if strapping on a cap so cold it numbs the scalp during chemo, like Lipton did, works well enough to be used widely, as it is in Europe and Canada.

Near-freezing temperatures are supposed to reduce blood flow in the scalp, making it harder for cancer-fighting drugs to reach and harm hair follicles. But while several types of cold caps are sold around the world, the Food and Drug Administration hasn't approved their use.

Scalping cooling is an idea that's been around for decades, but it never became popular in the U.S. in part because of a concern: Could the cold

prevent chemotherapy from reaching any stray [cancer cells](#) lurking in the scalp?

To Dr. Hope Rugo of the University of California, San Francisco, the impact of [hair loss](#) has been overlooked by health providers. She's had patients delay crucial treatment to avoid it, and others whose businesses suffered when clients saw they were sick and shied away.

"Quite frankly, it's the first or second question out of most patients' mouths when I tell them I recommend [chemotherapy](#). It's not, 'Is this going to cure me? It's, 'Am I going to lose my hair?'" said Dr. Susan Melin of Wake Forest Baptist Medical Center.

Later this summer, Rugo and Melin, along with researchers at a few other hospitals in New York and California, will begin enrolling 110 early stage [breast cancer](#) patients in a study of the DigniCap brand of scalp cooling. The tight-fitting, insulated cap is attached to a cooling machine as patients undergo chemo. Participants' hair will be photographed for experts to assess, and they'll be compared with a small group of similarly ill patients who get chemo alone.

Lipton was among 20 U.S. patients who pilot-tested the DigniCap in 2011, most of whom kept more than half of their hair. Lipton's thinned quite a bit at the crown, where the cap didn't fit snugly. But because her bangs and surrounding hair remained, she covered the thinning with a headband, not a wig. The side effect: Pain and a headache as the cold set in.

"It wasn't perfect, but it was easier," said Lipton, who's healthy today. "I felt normal much more quickly."

If the larger study is successful, Sweden's Dignitana AB plans to seek FDA approval to market the medical device in the U.S. The move could

open the way for other brands and insurance coverage.

Clearly there's demand: Despite the lack of FDA approval, a growing number of U.S. patients are renting a similar product, called Penguin Cold Caps, from a British company for \$455 a month. Patients haul a collection of caps to chemo sessions on dry ice, or store them in special freezers provided by about 50 hospitals.

The FDA declined comment on the Penguin caps.

What's the evidence behind scalp cooling? A recent review by oncologists in the Netherlands found numerous overseas studies conclude scalp cooling can work—but it's far from clear which patients are most likely to benefit, even how cold the scalp should be. That's because most of the research so far has been from observational studies that can't provide proof. But it seems harder to save hair with higher doses and certain types of [chemo](#).

Researchers at New York's Weill Cornell Breast Center reported at a recent meeting of the American Society for Clinical Oncology that among just over a dozen Penguin cap users tracked so far, one lost enough [hair](#) to use a wig.

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