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UCSF tests promising solutions for cancer hair loss

UCSF physicians are combating a devastating side effect of chemotherapy with an innovative new program -- "Hair to Stay" -- to evaluate devices that could reduce scalp hair loss in breast cancer patients.

One feasibility study on a scalp cooling system, the first significant inquiry of its kind in the United States, will test the safety and effectiveness of a device already widely used overseas called the "DigniCap." The FDA recently approved a pilot study of the Swedish cool cap, which continuously cools a patient's scalp during treatment using a circulating coolant inside a gel cap. The first patients are being enrolled at the UCSF Helen Diller Family Comprehensive Cancer Center and at Wake Forest University Medical Center.

"Devices that prevent hair loss have the potential to make a huge difference to our patients," said Laura Esserman, MD, MBA, co-leader of the Breast Oncology Program at the center and director of the UCSF Carol Franc Buck Breast Care Center. "If we can avoid hair loss, then our patients can avoid one of the most emotionally difficult and dreaded side effects of chemotherapy."

The cool cap process is a relatively simple and low-cost solution. By cooling the scalp, blood vessels surrounding the hair roots contract, resulting in a significant reduction of cytotoxins to the follicle. With reduced blood flow, less chemotherapy is available for cell uptake, while at the same time the lower temperature results in less absorption of the chemicals.

UCSF breast cancer patients ineligible for the FDA DigniCap trial have other scalp-cooling options. As part of another study evaluating patient experience, the university has purchased a freezer for cold caps, allowing patients to bring in their own caps and keep them cooled during chemotherapy. Currently, patients who provide caps go through as many as a dozen during a treatment session -- the caps heat up in as little as 20 minutes.

Chemotherapy-caused hair loss takes a profound physical and psychological toll on cancer patients and is considered one of the most feared and traumatic side effects of cancer treatment.

"Almost all standard chemotherapy treatments for early stage breast cancer cause hair loss," said Hope S. Rugo, MD, principal investigator for the study and director of Breast Oncology and Clinical Trials Education at the UCSF Helen Diller Family Comprehensive Cancer Center.

"Every day, I sit across from women with a breast cancer diagnosis for whom the inevitability of losing their hair is a painful and emotionally distressing prospect. By helping to identify devices that can reduce hair loss, we have the potential to impact patients' quality of life."

Historically, Rugo said, cooling systems and cold caps have not been used in the United States because of concerns that the scalp cooling could allow cancer cells to hide in the scalp. But, Rugo said, "the incidence of scalp metastases in breast cancer is extremely low and we are carefully following patients using these systems."

The goal of the new feasibility study -- the first step toward FDA product approval -- is to test how well patients tolerate the device, invented in the 1990s by a Swedish oncology nurse.

In the study, a tight-fitting silicone cap is placed directly on the head; an outer neoprene cap is placed on top to insulate and secure the inner cap. Both are connected to a cooling and control unit with touch screen controls. A coolant circulates throughout the inner silicone layer, delivering consistent cooling to the entire scalp.

Following the feasibility study of 20 patients, a larger study of 100 patients is planned, an example of UCSF's commitment toward accelerating the translation of cutting-edge research into advances in patient care.

According to research by Dignitana, makers of the DigniCap system, 8 out of 10 women in Europe and Asia who used the company's cap cooling system during chemotherapy retained their hair.

"The DigniCap system has been extremely well received in clinical trials at leading medical centers around the world," said Chief Executive Officer Martin Waleij. "We are very pleased that UCSF is conducting this test so that cancer patients in the United States might benefit as well."

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"Hair to Stay" is being funded by the Laszlo N. Tauber Family Foundation with a goal of mitigating trauma, maintaining dignity and restoring self-esteem to cancer patients.

Dignitana AB is a Swedish company focusing on developing and marketing medical cooling devices. For more information on the company visit <http://www.dignitana.com>.

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