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Diagnosis, Tibetan Style, Underlies Small Herbal Study of Advanced Breast Cancer

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Faced with metastatic breast cancer, hundreds of women from around the world have flocked for treatment to Yeshe Dhonden, a traditional Tibetan practitioner who was the Dalai Lama's personal physician for 20 years, and who is based in Dharamsala, India, but regularly visits the United States. About 5 years ago, [Helene Smith, Ph.D.](#), a cytogeneticist, then head of the Geraldine Brush Cancer Research Institute at the California Pacific Medical Center in San Francisco, became one of them.

Diagnosis Tibetan style is low-tech, relying entirely on such methods as extensive pulse readings, a careful examination of the tongue and an assessment of the odor, appearance and behavior (when stirred) of an early morning urine specimen. In skilled hands like Dhonden's, these ancient techniques may detect subtle underlying differences between patients having the same disorder that modern Western diagnostic techniques miss. For breast cancer patients, these differences are the decisive factor that determines for him which of a variety of combinations of herbs is best.

Smith found the system intriguing and thought it potentially valid because of something she knew from her own work to be true: that the cancers of any two breast cancer patients are virtually never genetically identical. For that reason, too, she thought it plausible that finely tuned herbal therapy based on a Tibetan diagnosis might have something to offer patients that its one-size-fits all counterparts in Western medicine lack.

Still, she was also a scientist and one who had to her credit a long list of publications in peer-reviewed journals. She was, therefore, eager to have Dhonden's formulations assessed by the rigorous standards and systematic methodology that Western medicine respects. Although she did not live to see that happen — she died of her breast cancer in 1997 — a team of people with whom she had networked has made her wish their command.

The team's principal investigator is [Debu Tripathy, M.D.](#), director of clinical research at the Carol Franc Buck Breast Care Center at the University of California, San Francisco. An oncologist who is a graduate of Duke University School of Medicine, Tripathy claims no more in-depth knowledge of Tibetan medicine than would any other Western-trained physician. But he is keenly aware of the genetic heterogeneity of breast cancer and so shares Smith's educated guess that the Tibetan system of medicine may have some validity for oncology.

Tripathy's hunch that there may well be something worth pursuing led to a \$50,000 grant from the state of California that has been used as seed money to develop a study that — now that it has the requisite approvals from UCSF's institutional review board and the U.S. Food and Drug Administration — is expected to start accruing patients soon.

Participants will be 30 advanced breast cancer patients ineligible for other measures for metastatic disease, or willing to forego them. They will be seen three times in the course of the 1-year study by Dhonden who will prescribe an herbal formulation for them based on what he finds. The combination of herbs in the formulation will thus differ from patient to patient and, in some cases, in the same patients over time. However, all patients will be regularly monitored with strictly Western techniques of physical examination and with such other medical mainstream tools as computerized tomography scans and blood and liver function tests.

Tumor Size

“This will be a phase I-phase II study with a straightforward outcome measure,” said Tripathy. “Our objective is simple: to look for changes in tumor size. Evaluating that will be a little tricky because the investigational therapy here will be variable instead of pretty much uniform as it is conventional clinical trials. Our challenge in designing the trial has been to compensate for that inconsistency while retaining the principles of the Tibetan approach.”

To be sure, some compromises have had to be made. The trial will be restricted to only seven of the many different herbal formulations that Dhonden customarily uses in his breast cancer practice. Without that limitation, according to Tripathy, the study could not — at a reasonable size and cost — achieve the requisite statistical power.

Also a consideration for Tripathy and for UCSF was that, just as no truly novel drug can be formally tested in a clinical trial without the FDA issuing an “investigational new drug” permit, the clinical testing of herbal formulations — no matter how ancient — requires an IND, too.

Much of the credit for getting the FDA's crucial nod, according to Tripathy, goes to two of Smith's old friends who have worked closely with Michael Patterson, the study's UCSF project manager.

They are Fredi Kronenberg, Ph.D., a physiologist at the Columbia University College of Physicians and Surgeons in New York City who first met Smith when they were both on the advisory panel (Smith was its chairman) of the Department of Defense Breast Cancer Research Program, and Marsha Woolf of Alternative Resources Unlimited, a non-profit organization with offices in New York City and Seekonk, Mass., that Dhonden uses as his headquarters when he is in the United States. Both women knew Helene Smith and greatly admired her.

Kronenberg had the advantage of having earlier obtained an IND for a Chinese herbal formula that she wanted to study for the management of menopausal hot flashes. “FDA has done quite a lot to educate itself about herbals in the 4 years since then,” she said. “For example, it now understands that allowances in trial design can sometimes be made for traditional medicines even though most of them are

mixtures, rather than the single molecular entities FDA has been accustomed to dealing with.”

Meticulous Records

As for Marsha Woolf, she works so closely with Dhonden, that the records of his patients in the United States — including breast cancer patients — have been kept by her and are in her care. She has, in addition, made it her business to learn which herbs are in which of his herbal mixtures, what is done to ensure the uniform quality of these mixtures, and the extent to which some of them have ingredients in common.

All that information was made available to the FDA where it appears to have been key to UCSF's getting the requisite IND. For example, the agency might well have insisted on more in vitro and animal data, had not the patient records kept by Woolf strongly suggested that little toxicity has been associated with the herbal mixtures at issue.

Woolf confessed to “a little disappointment” that the FDA had been skeptical about reports in her registry that the tumors of some of Dhonden's patients had shrunk or even disappeared. “But then I remembered what I learned from Helene [Smith] about the scientific method and its requirements,” she said, “ to have those reports taken on faith.”

So what will be next for the Tibetan approach if the forthcoming UCSF trial indeed shows it to be less toxic than the conventional alternatives and equally or more effective? “At this point, I can't be sure,” said Tripathy, “but it's surely safe to predict that further studies would then be justified and that they, likely, would include a phase III trial for stage IV disease.”

Dr. Helene Smith

Dr. Debu Tripathy

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