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Mystery cure for prostate cancer?

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At first, it didn't sound like the way a modern cancer treatment would be created. As the story went, it was an elixir extracted from the root of a mysterious plant found deep in the Amazon forest in Ecuador, used there for decades against everything from lupus to AIDS.

It was brought to Miami by a Quito businessman who was being treated here for prostate cancer, which eventually killed him.

The Ecuadoran doctor who developed the elixir was trying to patent it, so he was being evasive about the plant and the process by which the extract is made.

So what made Dr. Mark Soloway, chairman of urologic oncology at the University of Miami School of Medicine and a member of the UM/Sylvester Cancer Center, take it seriously enough to ask UM researchers to look into it?

JAMES ALTLAND / OREGON STATE UNIVERSITY EXTENSION

The Solanum dulcamara plant for years was believed to be the source of the anti-prostate cancer elixer from Ecuador. But when plant scientists investigated, it turned out the elixer is not from this plant but from a closely related species.

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"He [the businessman] was a very bright fellow," Soloway says. ``I had done surgery on him. We'd become friends. He brought a bottle of it with him, and put me in touch with the doctor in Ecuador.

'I said, `Well, shoot. Let's see if this really works.' "

Between that beginning and today -- when the liquid has passed its first scientific tests and been found worthy of a $1.2 million grant for further research from the National Institutes of Health's Center for Complementary and Alternative Medicine -- lies a fascinating tale.

It's an *Indiana Jones* adventure, with researchers scouring the globe from Quito to Germany to Africa in search of botanists who could identify the plant and experts in plant science and even nuclear magnetic resonance trying to crack its chemical makeup.

Soloway isn't expecting a cure for cancer. But this might become a valuable addition to more traditional ways of treating men whose cancers have defeated all other means.

"A lot of our remedies come from things like herbal medicines," Soloway says. ``They're not all out of test tubes."

In 2001, the Ecuadoran patient confided in Soloway that he had been taking an local remedy in addition to the treatment he was getting in Miami. It was an extract made by boiling the root of an Amazonian plant. In Ecuador, Colombia and other Andes nations, it was said to fight cancer, lupus, maybe even AIDS.

It had been developed in the 1970s, he said, by a respected local cancer and immunology specialist, Dr. Edwin Sevallos, director of the Tumor Institute of Ecuador in Quito. Sevallos had impressive credentials -- a degree in medical surgery from the Central University of Ecuador, post-graduate work in oncology and radiotherapy at the Autonomous University of Mexico.

On Cevallos' website, the medicine sounds exotic: ``One of the primary ingredients is the extract of a plant in the Solanaceae family. It grows deep in the Ecuadoran forest giving the plant its unique qualities -- the properties of the mineral rich, volcanic soil of the Amazon."

Locals called the plant dulcamara, Latin for "bittersweet." The name Cevallos gave the elixir extracted from it was less exotic -- "BIRM," for Biological Immune Response Modifier."

Intrigued, Solomon turned to two UM associate professors in the Sylvester Comprehensive Cancer Center, Dr. Bal Lokeshwar, a researcher in prostate cancer, and Dr. Vinata Lokeshwar, his wife, a researcher in bladder cancer.

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Their charge: investigate BIRM "in vitro," meaning in laboratory Petrie dishes, and "in vivo," meaning, in this case, in rats.

For the in vitro part, they put a few ounces of cells from a cancerous human prostate in a Petrie dish, then added BIRM, at doses from 1 part per million to 100 parts per million. The goal was to see what concentration of BIRM was needed to kill 50 percent of the cancer cells. The answer turned out surprisingly low -- only eight parts per million.

That was encouraging, says Bal Lokeshwar. If it worked well at low doses, it was more likely to do its job without being toxic to humans.

Then they sought the mechanism by which BIRM was arresting the cancer. It turned out that, at low doses, it arrested the cancer's growth. At higher doses it killed the cancer cells, by de-fragmenting the DNA in them, causing them to almost literally explode.

For the in vivo part, the researchers used a dozen gray rats and injected cancerous cells from other rats' prostates just beneath their skin.

To the now-cancerous rats, they then applied BIRM -- one milliliter per rat, injected directly into the stomach -- the equivalent of about half a cup taken by mouth if it were a human patient.

The results were stunning: Half the injected rats never developed a tumor. In the rest, fewer tumors appeared than in the untreated rats in the study, and those that did appear grew more slowly.

And none of the rats showed any toxic effects.

In 2003 came a satisfying step for the researchers: publishing their work in the medical journal *Cancer Chemotherapy and Pharmacologoy,* and offering the conclusion that the treatment appears to work.

Still, the researchers didn't break out the champagne. "It's a routine thing," Bal Lokeshwar says.

Then came drudgery: Applying for federal grants to continue their research. It was easy to demonstrate its importance. More American men contract prostate cancer than any other form of the disease, except skin cancer. The American Cancer Society says 218,890 new cases will be diagnosed in 2007, and 27,050 men will die of it.

And once prostate cancer has metastasized to other organs, chemotherapy struggles to slow it -- driving many patients to try alternative medicines.

Doctors know that developing effective, modern drugs from plants and even folk remedies is not unusual -- although perhaps pursued with more enthusiasm in Japan and China than in the United States.

The NIH liked the study, says Bal Lokeshwar. ``But they had a million questions. What is BIRM? What plant is it based on? Is it grown in the wild? Cultivated? Who are the growers? Is it dried? Does it have pesticides? Funguses? Toxins? Is it reproducible?"

This was a problem. The researchers were in touch with Cevallos in Quito, had even bought BIRM from his U.S. distributor, Forest Life Corp., for testing -- at $120 a bottle. But the Ecuadoran doctor wasn't about to spill all of its secrets.

"We knew very little about it," says Bal Lokeshwar. ``We didn't know what was in it, whether it was a single ingredient or a compound. We didn't even know if the plant was cultivated or wild. It was a family secret. He was trying to patent it."

Cevallos was calling the plant Solanum dulcamara, and the Lokeshwars were using that name in their NIH application. But even when Bal Lokeshwar visited the Cevallos family in Quito in 2005 to speak before the Pan American Medical Association about his research with BIRM, he wasn't invited to see the plant.

"I can understand; it's their livelihood," he says.

But the NIH demanded information. At that point Bal Lokeshwar's wife, UM researcher Vinata Lokeshwar, started negotiating.

The NIH wanted a sample of the plant identified and classified by a professional botanist. Luis Lopez, a researcher in Vinata's lab, found one, Dr. Hugo Navarrete, a botanist in Quito at the Pontifica Universidad Catolica del Ecuador.

Vinata Lokeshwar then had to persuade Bonny Cevallos, the Ecuadoran doctor's daughter, to breach the family secrecy enough to deliver one of the plants to the botanist. But when the botanist's report came back, it said the plant wasn't Solanum dulcamara after all -- but a related species.

'Dulcamara is Latin for `bittersweet,' " Bal Lokeshwar points out. ``There are a lot of plants called that in Ecuador."

So now the UM researchers and the NIH know what the plant is, but can't reveal it because of their confidentiality agreement with Cevallos.

In an exchange of e-mails between The Miami Herald and Cevallos in Quito, the doctor said he got his U.S. patent July 31 -- but he still won't say exactly where the plant comes from, or whether it is wild or cultivated.

"This is confidential information and we cannot discuss it with the media," he said.

Finally, the NIH wanted to know whether the chief medicinal component in the plant could be reproduced.

Vinata Lokeshwar scoured the world for experts. In Nigeria, she found Dr. Donatus Ebere Okwu, a plant chemist who had worked with similar plants. In Germany, she found Dr. E. Pascher, who had experience in looking at similar compounds with nuclear magnetic resonance, to learn the plant's chemical makeup.

They reported their findings to the UM researchers and the NIH -- again, confidentially. Finally in August came the good news: The NIH would provide a $1.2 million grant to study BIRM.

"The research into BIRM is preliminary, but we hope the results will provide insight into whether this plant might work," said .Barbara Sorkin, Ph.D., NCCAM program officer, in an e-mail. ``In the long run, this information may help people and their health care providers make more informed choices.

With the grant secure, UM researchers now face three to four years of further pre-clinical trials to make sure BIRM is effective against cancer at doses that remain nontoxic.

Then more tests with rodents to see if it really works, and whether it works best alone or combined with other compounds. And, since prostate cancer in both rats and humans proceeds in slow stages, the question is whether BIRM is better against one stage or

another.

The final stage would be testing in humans.

At that point, Bal Lokeshwar says, UM might try to enlist a major pharmaceutical company to share the cost of testing -- which can reach $100 million -- to win FDA approval to put the drug on the market.

Final success -- if it comes -- is years away.

Bal Lokeshwar stresses that neither he nor UM have financial interests in BIRM. It doesn't bother him that he might do much of the work only to see others profit.

Soloway, too, is interested only in a therapeutic outcome: ``If you could have a safe, active remedy that worked against cancer in a liquid form so you could just take a teaspoon a day, it would be very valuable.''

And even if BIRM succeeds, Bal Lokeshwar says he and his fellow researchers still won't break out the champagne.

``We don't celebrate. We're scientists. Our reward is to do the work, not to win the prize.''

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