HOW INDIANS Llaunder THEIR BLACK MONEY

THE WEEK

JUNE 21, 1998 ■ Rs 10

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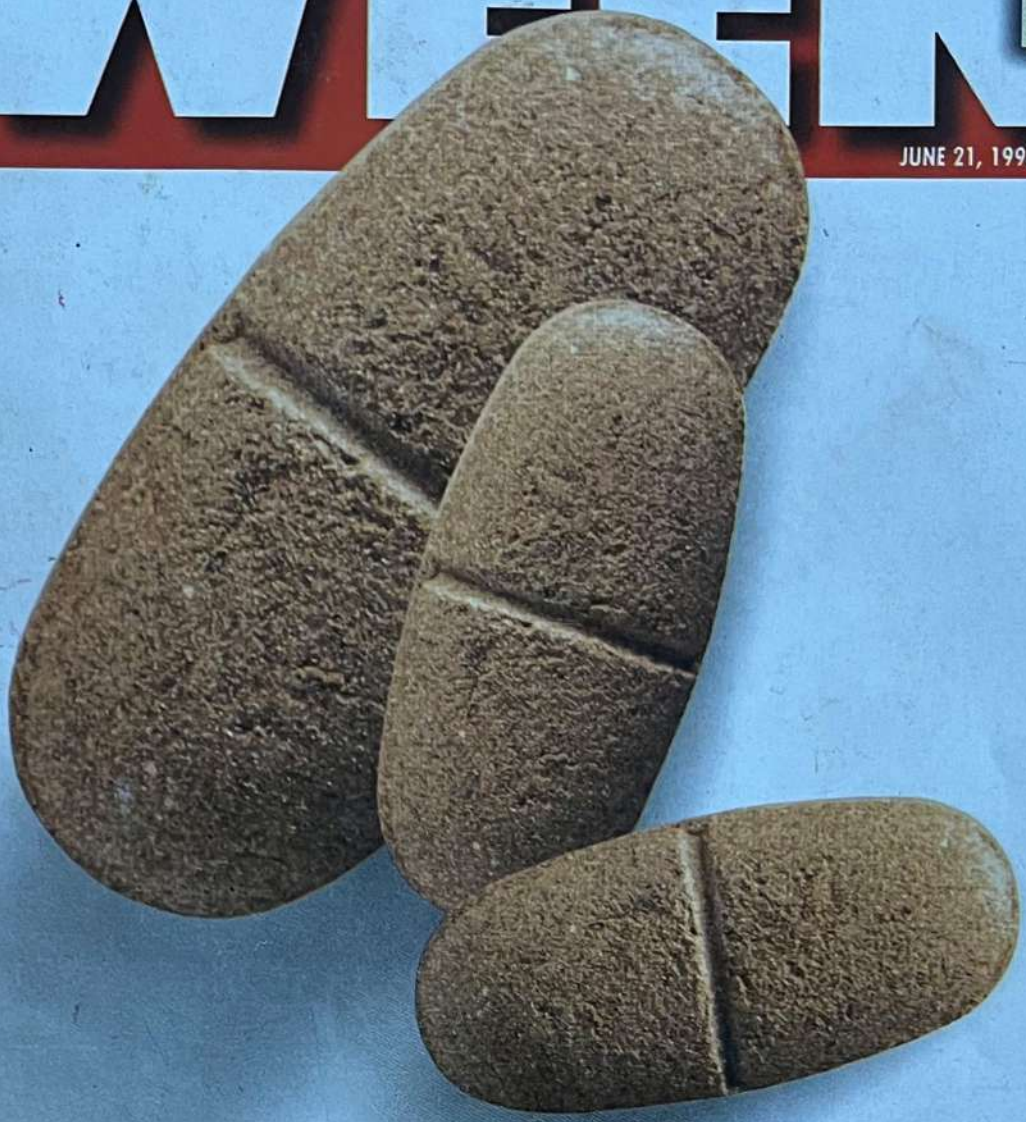
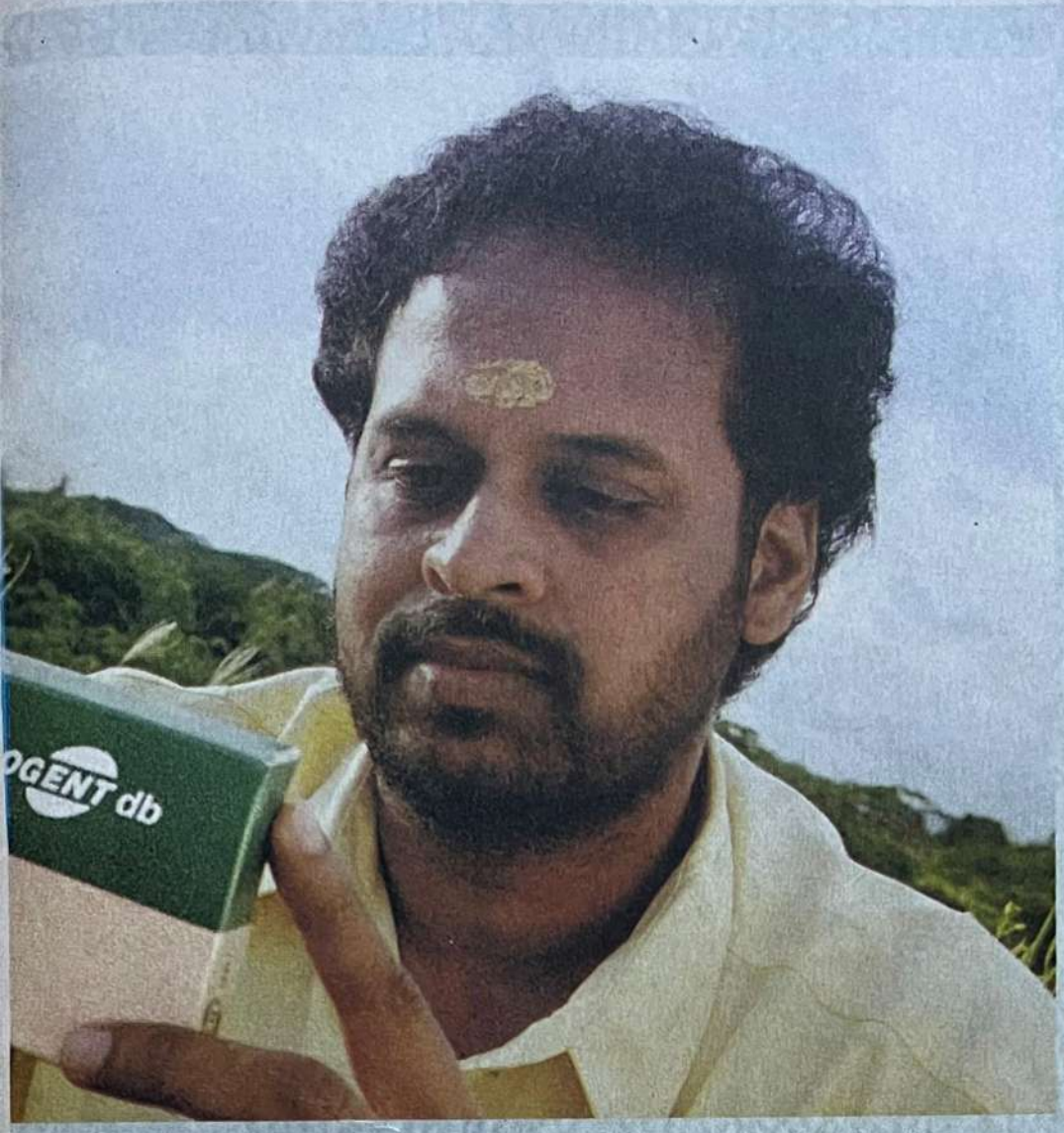


GOODBYE DIABETES

Herbal drug cures; peps up pancreas

CURE FOR DIABETES

The daily dose of insulin could be a thing of the past. Indian research on a new herbal drug indicates that it rejuvenates the pancreas—a first in the medical world—and improves kidney and liver functions. Even the west has evinced interest in it.



PICS: SHAJI G. KUMAR

A pill a day to keep diabetes away: Balaram spent over a decade to prove the efficacy of his wonder drug

BY PRADEEP RAO

ASK Krishnakumar Moorthy where he would be without the herbal drug he has been on for a year, and he doesn't hesitate. "Certainly on insulin—and probably crippled."

Moorthy was a senior sales manager with Dunlop in Calcutta when he was diagnosed with diabetes in 1982. Refusing to believe it, he immersed himself in work. A year later when fatigue and excessive thirst—the first indicators—became unbearable he went back to the doctor, who confirmed that it was indeed diabetes.

The doctor started him on mild anti-diabetic tablets and then prescribed stronger medicine. By last year Moorthy was jabbing 20 units of insulin a day to control his blood sugar level. He had meanwhile left the Dunlop job, which involved much travelling, and become a sedentary stockbroker in Kochi.

Today Moorthy, 56, has a more active work schedule and is completely off insulin. Even the sweetmeats he occasionally takes do not raise his blood sugar level above 185mg.

Moorthy's life partnership with the insulin syringe would have remained intact if a young industrialist, P.N.E. Balaram, had not gifted him a herbal tablet. Balaram had been making the tablets in a corner of his factory in Thrissur, Kerala, and giving them away to diabetic patients. Simultaneously, he was testing it scientifically.

Now the world famous Mayo Clinic of the US has shown an interest in doing the testing—to find out if the herbal preparation really rejuvenates pancreatic cells which produce insulin.

A silent killer, diabetes has no cure in modern medicine; allopathic drugs can achieve only 'disease management', which means they help patients live with it. Living with diabetes is a full-time occupation involving meters, test strips, hospital trips, tablets, insulin shots, diet control—and the constant fear of losing life and limb.

There are a hundred million diabetics in India. A WHO study says, by AD 2000 every fourth diabetic patient will be an Indian.

Balaram's herbal tablet has the potential to prove WHO wrong.

Patients who have taken it vouch for it. Among them are scientists, professors and industrialists. All display a new vigour. "It is a miracle," says K.N. Suryanarayanan, a businessman who took it for a month and lost all unwanted blood sugar.

Balaram, 36, says he makes the medicine from common plants in Kerala, and that he got the formula from an old palm leaf manuscript. Written in Sanskrit, it apparently has a cure for several major diseases.

Balaram had watched his father waste away and die of diabetes. He knew the pain and the fear it caused while he massaged his father's legs and cleaned the carbuncles caused by diabetic neuropathy.

Yet he did not show great interest when an out-of-town Ayurvedic vaid offered him the palm leaf book. They had met at Sri Krishna Temple in Guruvayoor, Thrissur, and soon formed a bond of affection. One day the vaid brought with him a palm leaf bundle wrapped in cloth.

"I was not at all impressed," says Balaram, who now believes that it was a divine force that brought them together. "But before I could say anything the vaid said: 'Don't just dismiss it. Try out the anti-diabetic formula on someone you know.'"

For several weeks, the palm leaves lay untouched in Balaram's house in Thrissur. But every time he went to the Guruvayoor temple he felt a tinge of conscience.

A few months later he made some Sanskrit scholars translate the manuscript into Malayalam. He

MEERA NAIK, 55, former librarian, National Centre for Performing Arts, Mumbai

Blood sugar with glynase 440mg %

Blood sugar with herbal medicine 200mg %

Meera Naik learnt that she was diabetic three and half years ago when her blood sugar level shot up to 440mg %. The doctor put her on glynase (one tablet three times a day) and prescribed a strict diet along with regular exercise. Yet Meera found the classic symptoms of diabetes setting in.

She turned to an Ayurvedic practitioner in Mumbai and took the Ayurvedic drug along with her daily dose of glynase and exercise. This was able to keep the sugar levels from shooting high. About six months ago she heard from Col. Krishnan, an associate of Balaram, about their herbal drug.

She now takes two tablets of the Cogent db three times daily. The difference became evident within the first month. Her sugar level dipped. While she still exercises she is not overly concerned about her diet anymore. "I am feeling much better now," she says. "More energetic and no more body aches."

collected the ingredients, prepared a formulation, and in 1987 gave the first dose to the diabetic father of a close friend. It was just out of curiosity.

After a week the friend came back for more medicine. His father's blood sugar, which had resisted allopathic oral anti-glucose medicines, had fallen sharply.

It changed the way Balaram looked at the medicine. His business antenna was up. He started a quest that would lead to the setting up of a herbal pharmaceutical company.

Instead of merely mixing and selling a 'wonder cure', he travelled the scientific lane, setting up a small lab at his factory in Thrissur and hiring a team of researchers headed by V.S. Parasuraman, a former drugs controller of Kerala.

Over half a decade the team refined the formulation to make it what it is now: a potent drug. Feedback from Balaram's friends and acquaintances who tried it out was exciting. All of them, he says, reported a new feeling of well-being, besides a sharp drop in blood sugar.

MONUMENTAL FINDINGS: RAMADASAN KUTTAN PROVED THAT THE DRUG WAS REJUVENATING THE PANCREAS

He knew the sceptical world of endocrinologists—diabetes specialists—would dismiss it as a quack remedy. He needed scientific validation to convince them.

In 1992 he took the formulation to the Indian Council of Medical Research (ICMR), New Delhi. It asked him to go back home—to the Amala Research Centre in Thrissur or to the Sree Chitra Institute of Medical Sciences in Thiruvananthapuram.

At Amala the director, Dr Ramadasan Kuttan, had long been researching on a herbal cure for cancer. While working with the M.V. Anderson Hospital in New York he isolated circumine from turmeric and published a paper on its anti-cancer properties in several western medical journals in 1985. His work led to global research on circumine, particularly at the National Cancer Institute in Maryland, USA.

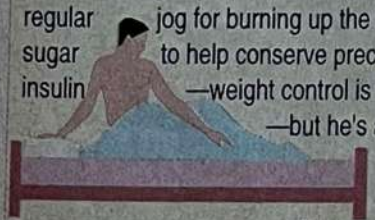
Dr Kuttan, who has published more than 80 international papers, readily agreed to test Balaram's formulation on animals. Balaram used Dr Kuttan's contacts in the US to obtain the protocol for animal testing, and imported the chemical alloxan—researchers use it to induce diabetes in animals.

The research was hush-hush for fear that the pharmaceutical lobby would throw a spanner in the works. Making a plan based on the imported protocol, Dr Kuttan standardised the chemicals and equipment over a few months. And the trials lasted one and

A day in the life of a diabetic

6.00 AM

Ashok Mehra, a diabetic for the last 6 years, gets out of bed. It should have been the regular jog for burning up the blood sugar to help conserve precious insulin —weight control is important —but he's already feeling fatigued. The sugar's up.

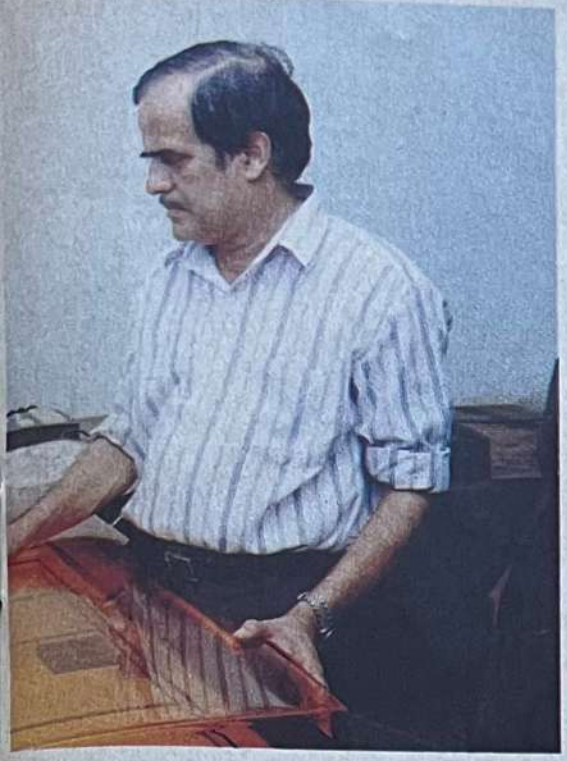


8.00 AM

The jam in the fridge is tempting, but we've overcome that Ashok! Gotta avoid carbohydrates. A glass of sugar-free milk, a few slices of cucumber and some 'ragi' porridge should do it. And yes, the regular dose of Daonil.

9.00 AM

No strength to work. But gotta earn the bread —has carbohydrates, did you say?—gosh, I'm hungry again. Water will do for now, and the cucumbers every now and then. The doc said lots of 'free food' for feeling full is a must for guys like me.



a half years.

He found that the formulation lowered the blood sugar and glycosylated haemoglobin (another indicator of diabetes) and vitalised the liver and the kidney. More startling, the formulation had reversed the damage that alloxan had done to the rats' pancreatic cells. It was a major breakthrough in diabetes research.

"The drug," says Dr Kuttan, "has shown a remarkable ability to rejuvenate the pancreatic beta cells in laboratory tests on rodents. It is the first drug to show such results."

The next step was human testing. Dr Kuttan prepared a protocol and chose ten willing diabetic patients, one of whom dropped out midway. Balaram's researchers put them through a month-long regimen of exercise and diet. When it was clear that the regimen had made no difference to their blood sugar they were given the herbal medicine.

Dr Kuttan monitored their blood sugar and glycosylated haemoglobin levels, and kidney and liver functions every month, and found these normal at the end of six months. All the nine patients had registered a remarkable improvement.

"If these findings are validated in controlled clinical trials among diabetic patients," says Dr Kuttan, "then we are on the threshold of a monumental discovery."

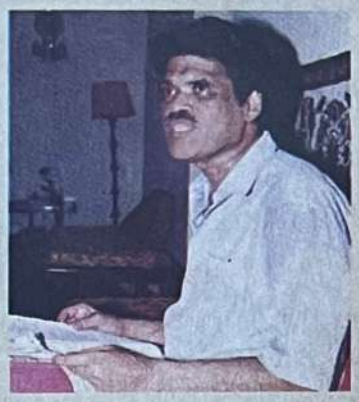
Balaram's rushed the test report to Kerala Health Secretary V. Vijayachandran, who scanned it and passed it on to Prof. R.V. Jayakumar of the Thiruvananthapuram Medical College. An endocrinologist, Jayakumar had started a diabetic clinic at the college and is one of the three principal investigators in a diabetic research project of the ICMR. "The technical report brought out one thing clearly," says Jayakumar. "The herbal drug did have anti-diabetic properties and had shown a promising ability to repair damage to the pancreatic beta cells which are responsible for producing insulin."

To double-check, Jayakumar recommended double-blind, placebo-controlled human trials. The health secretary agreed to fund it. The trials will begin after the ethics committee of the medical college clears the project.

Balaram, meanwhile, got in touch with Mayo Clinic in Minnesota, the world leader in diabetes research. He faxed a report to Mayo's research director Dr Sreekumaran Nair, who belongs to Kerala.

Within weeks Dr Nair flew into Kochi and went back with a pouchful of samples. A fortnight later Dr Nair telephoned Balaram: Mayo would bear half the cost of human trials.

Dr Nair was, however, cautious while talking to THE WEEK: "The preliminary data does show that the drug has repaired the damage to the pancreas, but it needs to be confirmed by careful and well-controlled trials. If the results from the proposed study in Thiruvananthapuram are promising I will be happy to perform some additional studies in the US."



KRISHNAKUMAR MOORTHY, 56, Stockbroker, Kochi.

Blood sugar with glibenclamide 300-320mg % (PP)
Blood sugar with herbal medicine 185mg %

Ever since Moorthy was diagnosed with diabetes, he has painstakingly kept a record of his monthly sugar level checks. The first document in his 16-year-old file is the 1982 Glucose Tolerance Test. His latest test done in April shows 185mg.

He has gone through the whole gamut of anti-diabetic medication starting with Glynase, a mild oral anti-diabetic tablet, in 1983 to insulin. The tablets made no difference to his sugar level that remained at the 200 mg per cent mark.

Three tablets of Daonil and two of glycophage made a difference initially but five years after that its effect started wearing out. Moorthy had reached a stage where only insulin could make a difference. Till early last year he was taking about 20 units of insulin. Then came Balaram's herbal drug. The first month made no difference but the second monthly test showed lowered blood sugar levels. Now he is completely off insulin.

GRAPHICS: M. MUKESH

INTERVIEW: Dr Sreekumaran Nair, Mayo Clinic

I will be happy to do tests in the US

DR SREEKUMARAN NAIR, head of research at Mayo Clinic in Rochester, Minnesota, is working with Dr R.V. Jayakumar of the Thiruvananthapuram Medical College to design a study that will directly compare the benefits and risks of the herbal drug and allopathic medicines. THE WEEK interviewed Dr Nair at his Rochester office in the US over the telephone.

Did you peruse the lab report by Amala Research Centre or did you conduct an independent study?

The preliminary data does show that the drug has repaired the damage to the pancreas but it needs to be confirmed by careful and well-controlled trials. I believe that the major studies should be done in India and we will provide whatever support needed. If the results from the proposed study in Thiruvananthapuram are promising I will be happy to perform some additional studies here.

Do you know how this drug works?

I am not sure how it is acting.

How can a drug rejuvenate dead beta cells in the pancreas? Will the new drug be effective in both types of diabetes?

The pancreas stops secreting insulin completely in Type I diabetic patients (less than 5 per cent of the patients in India are Type I) because of the destruction of insulin secreting islet beta cells. In Type II diabetes (non-insulin dependent) which is the cause of 95 per cent diabetes in India the cells have the ability to secrete insulin but their pancreas is not robust enough to secrete sufficient insulin to overcome insulin resistance. Insulin resistance occurs in people with family history of diabetes. Lack of exercise and weight gain accelerate the onset of diabetes. The drug may have helped surviving beta cells get back to working shape.

The Thiruvananthapuram Medical College is working with your team on preparing a protocol for testing the drug on humans. When do you intend to start the trials?

Yes, Dr Jayakumar is communicating with me. I have agreed to help with the design and performance of a study to assess the effect of this herbal preparation on patients with Type II diabetes.

What parameters are the researchers planning to check?

Insulin secretion rate, blood glucose and glycosylated haemoglobin (a measure of long-term blood glucose). Until the study is completed and the results are analysed I have an open mind. It is important that a drug such as this undergoes careful scientific scrutiny for efficacy and potential side-effects before it can be extensively used.

In fact not everybody is willing to take the results at the face value. "Is this drug just reversing the effect of alloxan damage or is it showing anti-diabetic properties?" wonders Dr R.S. Hariharan, endocrinologist who heads the diabetology department at Madras Medical College.

Dr Hariharan says the improved functioning of the liver and the kidney could have been because the drug had merely reversed the damage that alloxan caused. He makes another research point: "Dr Kuttan should have tested the drug on diabetic bio-bred (BB) rats."

Researchers the world over have two models to test anti-diabetic formulations on animals. One is to use chemicals like alloxan or streptokinase to induce diabetes in rats. The other is to use BB rats—specially bred rats that are hereditarily diabetic. BB rats better mimic Type II diabetes in humans (non-insulin dependent diabetes). Most researchers, however, use the chemical model first because BB rats are difficult to come by.

"IS THIS DRUG REVERSING THE EFFECT OF ALLOXAN DAMAGE OR IS IT SHOWING ANTI-DIABETIC PROPERTIES?" WONDERS DR R.S. HARIHARAN, ENDOCRINOLOGIST.

"It doesn't matter whether alloxan has been used to induce diabetes or BB rats are used," says Dr Prassana Kumar, professor of endocrinology and metabolism at M.S. Ramaiah Medical College, Bangalore. "It is just the first phase. Ultimately the acid test is the human trials." Dr Kuttan, meanwhile, is planning to test the drug on BB rats.

Dr Kumar, who has researched several Ayurvedic anti-diabetic drugs, is concerned more about toxicity. "Lab tests may show no toxic chemicals," he explains, "but several modern drugs that passed such tests showed their ugly side many years after they were introduced."

Balaram's drug, named Cogent db, has cleared toxicity tests, and the state drug controller has issued a licence to start serial production. There is no anxiety to obtain a patent because, as Dr Kuttan said, India does not register product patents, and it

The body's glucose factory

Glucose is essential fuel for the cells. Normal blood glucose level is necessary for the functioning of the organs

Running in order

Glucose enters the blood from two sources: from the **intestine** where carbohydrates are absorbed from digested food, and from the liver.

Liver stores glucose in the form of glycogen, converts it back into glucose and releases it into the blood stream.

Pancreas assists cells to assimilate blood glucose by secreting insulin. This lowers the blood glucose level.

Kinks in the system

Blood sugar level rises in the case of damaged pancreas or when receptors on the cell walls, supposed to absorb the sugar, are defective.

Sugar level rises when the liver fails to detect the high blood sugar level which forces it to release excessive glucose into blood.

When the blood glucose level exceeds 180mg/dl to 200mg/dl it starts spilling into the urine

The herbal drug works by:

- Rebuilding the damaged pancreatic beta cells.
- Correcting receptor sites of cells to help them assimilate the blood sugar.
- Improving the functioning of the liver and kidneys.

The key findings

Normal pancreatic tissue | Damaged tissue | Corrected by the drug

Dr Ramadasan Kuttan's findings are based on the analysis of the pancreatic tissue of diabetic rats given the drug. He compared the tissue with those taken from rats which were injected with alloxan but recieved no drug and with the tissue taken from normal rats. He also studied the liver, kidney and haematological parameters of rats and humans who took the drug.

GRAPHICS: N.V. JOSE

costs $20,000 for a US patent.

While Dr Kuttan is writing a paper on his findings Balaram has put the technical report of the animal trials on the Internet (*www.indianmade.com/cybele*). He is making the blueprint for a Cogent db production plant in Idukki, Kerala.

It wasn't the Web page or the technical reports that persuaded the Coimbatore Arya Vaidya Pharmacy place a huge order for the drug for its 700 retail outlets across the country. The director of the pharmacy, M.V. Gopalan Kutty, had tested it on himself: he was diabetic.

Not that the Web page has gone unnoticed. Subas Kannan, chief executive officer of Malaysia's Oze Marketing Sdn Bhd, saw it four months ago and took some samples to Malaysia. He returned in May to place an order for 100 crore tablets!

Kannan's company markets Australian and Indian herbal products in Malaysia, Singapore and Brunei. Pharmaceutical majors Wockhardt and Cipla are in touch with Balaram for distribution rights elsewhere.

Balaram apparently has a couple of herbal surprises up his sleeve. "The palm leaf manuscript has many more formulae," he said. "But it is not easy to decipher them and prepare the drugs."

Animal trials on one of the drugs have just been concluded at a super-specialty medical institute in south India. The drug has shown "an astounding anti-clogging" property and the research leader says it could be useful against atherosclerosis. ■

SWEET SUCCESS

Going the green way is the hot, and safe, new trend

THE young man behind the herbal drug, P.N.E. Balaram, is not new to herbs: he is a graduate in botany. But it was in electronics that he tried to make a fortune.

Coming from a business family, Balaram set up Ezhuthassan Electronics in collaboration with Toshiba of Japan in 1983 to manufacture Teltronix television, VCR and satellite systems. He captured a sizeable market share in the south, and manufactured a precursor of the DTH (direct-to-home) system enabling TV viewers to receive satellite transmission signals. The project crashed after the Russian satellite ICRAN came spinning down, and the company is enmeshed in legal tangles.

His next venture was the Golden Valley mineral water, which is selling well. "I have sold a chunk of my shares in this company to fund research on the herbal drug," he says.

Ever since he started taking the herbal drug seriously he has been spending ten hours a day, meeting doctors, researchers and patients. He has refused to sell the formula or divulge it, saying it is the will of the Lord of Guruvayoor.

There is a growing body of evidence that herbal anti-diabetic preparations that include neem paan, amla, haldi and other ingredients could help in controlling the blood sugar.

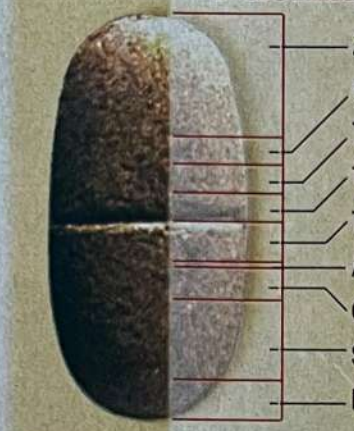
Four years ago the Indian Council of Medical Research (ICMR) started the 'Vijayasar' trials for an anti-diabetic drug. It funded three teams of endocrinologists at the medical colleges in Thiruvananthapuram, Chennai and Cuttack.

After extensive trials the team broke the code of the double-blind trial. (One team puts together the drugs and identical looking placebos while the other team administers the drugs to two groups of patients. This method, known as the double-blind, ensures that neither team knows which patients have taken what. The marked medicines are coded and the code is broken only when the trials are over.) The preliminary results showed that Vijayasar could help in controlling mild Type II diabetes.

There are good allopathic drugs like tolbutamine (Rastinol) which could do the job but Vijayasar is non-toxic as well. However, Vijayasar was found ineffective in severe cases of diabetes.

In January this year doctors at Chennai's Apollo Hospital, Dr Ambedkar Institute of Diabetes and the Kilpauk Medical College tested a herbal anti-diabetic drug on patients. Their experiments showed that the continued dosage of the drug was effective in reducing the serum fructosomine levels (which was checked on days 0,30, 60 and 90) and glycosylated haemoglobin levels. Hyponidd, as the drug is called, is now be-

Packing a punch

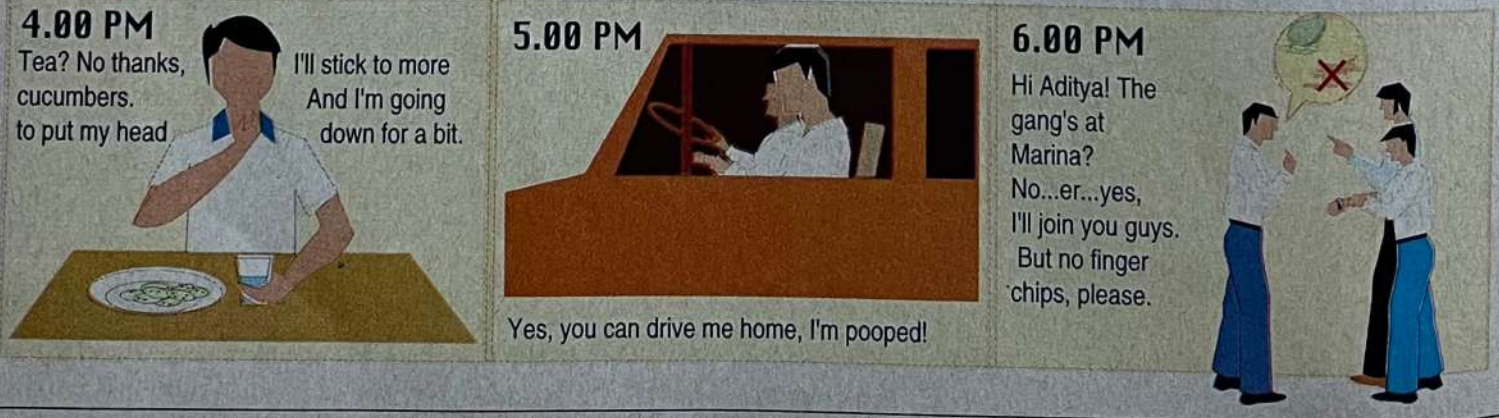


Azidiracta indica bark	3.00 gm
Phyllanthus emblica	0.70 gm
Terminalia bellerica	0.70 gm
Terminalia chebula	0.70 gm
Tribulus terrestris	1.00 gm
Aconitum heterophyllum	0.10 gm
Curcuma longa	0.80 gm
Syzygium cumini	2.00 gm
Rotala aquatica	1.00 gm

MARCH OF THE HERBS: COGENT DB (COMPOSITION GIVEN ABOVE), DIABECON AND HYPONIDD HAVE BEEN TESTED SCIENTIFICALLY

PIC: RAJHEN PAUL

A day in the life of a diabetic



ing made available by its manufacturers—Mumbai-based Charak Pharmaceuticals.

While there has been a resurgence in research in plant-derived formulations the world over, modern methods have not been resigned to the back burner. Scientists in the west are working on new drugs and treatment methods to combat diabetes.

Surgeons and doctors in the US have been experimenting with a technique called islet cell transplantation. The expensive surgery involves transplanting foetal pancreatic islet cells in diabetic patients. The technique was first tried out in 1990 and is now conducted at Cornell Medical Center, New York, and the University of Miami School of Medicine.

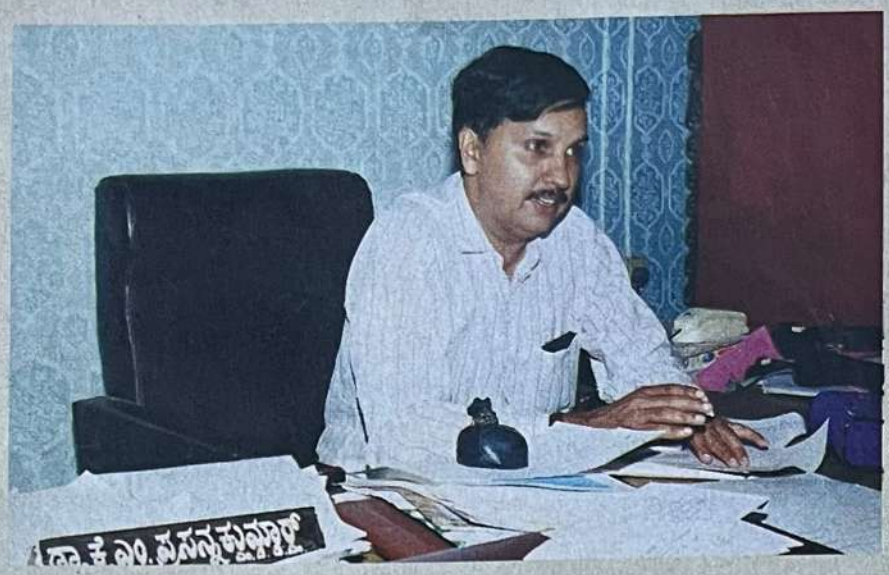
"An islet cell transplantation will cost close to $100,000," says Dr T. Divya, a senior resident at New York Methodist Hospital. "It has to be done in conjunction with a renal transplant and the patient will have to be on long-term immunosuppressive therapy." Over 200 such transplants have been done but only a few have succeeded.

Among the newer drugs available for diabetics are Acarbose and Troglitazone. Acarbose helps keep blood sugar levels manageable soon after a meal by prolonging the digestion. But side effects could include indigestion and cramps. Troglitazone, released in the US early last year, was hailed as a major step towards making diabetes easily manageable. It was approved by the US Food and Drugs Administration and over 20,000 patients have already taken it.

It decreases body insulin resistance, so that the existing insulin in the body can more efficiently transport glucose into the cells.

However, it doesn't start acting until weeks after starting treatment. Early this year the doctors reported liver toxicity problems associated with the drug. At least one patient died of liver failure.

PR



PIC: C.B.YESHWANTH

INTERVIEW: Dr K.M. PRASANNA KUMAR

Let us prove its efficacy

EMINENT endocrinologist Dr Prasanna Kumar of M.S. Ramaiah Medical College, Bangalore, conducted human trials of an Ayurvedic formulation in 1993. He tested it in a double-blind trial on 35 diabetic patients. The results were so promising that he started multicentre trials on 60 patients, and medical colleges in Calcutta, Chennai and Ahmedabad coordinated with him. The Himalaya Drug Company used the data for preparing its newly released Ayurvedic drug called Diabicon.

Dr Kumar has great faith in the Indian medicinal texts. "The first description of diabetes is by an Indian," he says. "You can find a detailed clinical description of both Type 1 and Type 11 diabetes in the *Charakasamhita*. Maybe, the new herbal drug is a cure that our forefathers had found."

Is there any other drug that rejuvenates the pancreatic cells?

I don't know of any. Researchers around the world have not been able to produce a drug that reverses pancreatic beta cell damage. If this herbal drug does that then it would be the first.

Do other traditional systems of medicine offer any permanent cure for diabetes?

At least 30 herbal drugs have been used to reduce blood sugar in varying degrees. Gurmar (Gympema sylvestre) is known to exhibit pancreatic beta cell rejuvenation properties.

Is there anything wrong in using alloxan to induce diabetes in rats? Is it internationally accepted?

Researchers can use chemicals to induce diabetes in animal models or test on diabetic bio-bred (BB) rats. BB rats are difficult to breed and expensive. That is why researchers try out their drugs first on chemically-induced diabetes. The chemicals create a similar physical condition that is found in Type II diabetes. Tests on animal models have to be ratified by carrying out human trials.