

Indian leather workers risk health, life

Unproven stem cell treatment blinded 3 women: docs

NEW YORK, March 16, (Agencies): Three women were left nearly or totally blind by a vision treatment at a stem cell clinic, in what doctors call a dramatic illustration of how risky such clinics can be.

The clinic's method hasn't been proven effective or tested for safety in people, said ophthalmologist Dr Thomas Albini of the University of Miami. He and colleagues, who examined the women after their treatments at a Florida clinic, described the outcome in Thursday's New England Journal of Medicine.

"These women had fairly functional vision prior to the procedure ... and were blinded by the next day," Albini said in an interview.

One woman is totally blind and the others legally blind, and it's very unlikely their vision will improve, he said.

Scientists have long studied the use of stem cells, including those taken from a patient's own body, for treating vision problems and a variety of other diseases. But they and regulators have also issued warnings about clinics that offer unproven stem cell therapies.

The new report says the three women, in their 70s and 80s, paid \$5,000 to be treated in 2015 for age-related macular degeneration. A leading cause of vision loss in people older than 50, the condition damages a part of the retina needed for sharp, central vision.

At least two of the women had gone to the clinic because it listed a macular degeneration study on a federal database, Albini said. The clinic later withdrew the listing before recruiting any patients to participate. The consent form one woman showed Albini's group was simply for a medical procedure not a study, he said.

Each woman was injected in both eyes with a cell preparation derived from her own fat tissue.

"It's very alarming to us as clinicians that somebody would do this to both eyes at the same time," said Albini.

He said all suffered detached retinas.

Andrew B. Yaffa, an attorney in Coral Ga-

bles, Fla., who represented two of the women in lawsuits about the treatment, said both legal cases had been resolved but provided no details.

The clinic is operated by US Stem Cell, Inc. It offers stem cell treatments for a variety of diseases and injuries, according to the company's website. In a statement Tuesday, the Sunrise, Florida-based company said it does not currently treat eye patients. The company said it could not comment on specific cases, but that its clinics "have successfully conducted more than 7,000 stem cell procedures with less than 0.01% adverse reactions reported."

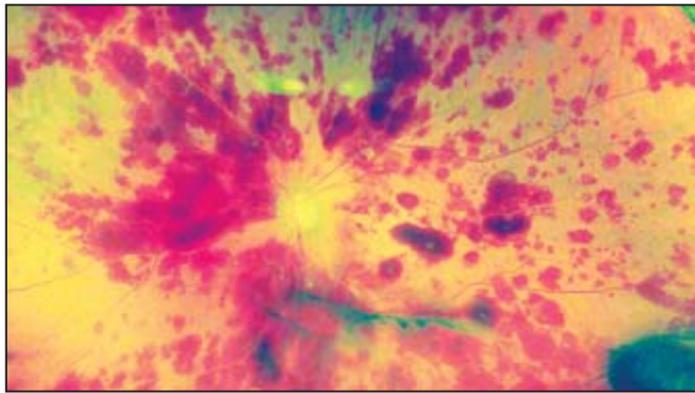
In an editorial accompanying the journal report, stem cell expert Dr George Daley, dean of Harvard Medical School, called the clinic's treatment careless.

"This report joins a small but growing medical literature highlighting the risks of such wanton misapplication of cellular therapy," he wrote. Providing such treatments for profit outside a proper research setting "is a gross violation of professional and possibly legal standards," he said.

Daley contrasted the Florida cases with what he called landmark research reported in the same issue of the journal. In a study he said was conducted with "care and prudence," Japanese researchers treated a woman with the same eye disease, using stem cells created from her skin to create eye tissue for transplant. One year after surgery, her vision had stabilized and there was no sign of lasting side effects, Daley noted.

The federal database where the Florida clinic listed a study is called ClinicalTrials.gov. Albini said a listing there is no guarantee that a study is legitimate.

Many stem cell clinics argue they aren't subject to regulation by the US Food and Drug Administration, which oversees most research in people. So Albini said study participants should get written documentation that a study has been registered with the FDA. And they should "make sure you are being treated by a



This undated image provided by Dr Thomas Albini shows an interior view of the left eye of a patient who suffered a detached retina after undergoing an unproven stem cell treatment. (AP)

licensed physician" with training and experience in treating the disease without stem cells, he said.

ClinicalTrials.gov is overseen by the National Institutes of Health. In a statement to The Associated Press, the NIH said information on the website is provided by the study sponsor or principal researcher, and that posting on the site does not necessarily reflect endorsement by NIH. The site does "does not independently verify the scientific validity or relevance of the trial itself beyond a limited quality control review," NIH said.

The site urges patients to talk to their doctors about whether to join a study, the agency said.

About 2.5 million Indian workers work long hours with toxic chemicals for poverty wages in the country's leather industry, making shoes and clothes for Western brands, a study has

of footwear and leather garments and almost 90 percent of India's footwear exports go to the European Union, the research states.

In small, unregulated factories, workers have no social security cover such as state health insurance or pensions and earn a tiny fraction of the products' global price.

Researchers spoke to Ramu, a low caste Dalit, who worked as a leather handler for a tanning unit where he lost both his eyes when acid splashed in his face. He told researchers his 13-year-old daughter now works in a footwear factory.

The research shows tannery workers often suffer from fever, eye inflammation, skin diseases and cancer as they work with toxic chemicals and rarely have any safety training or protection.

Also:

KUALA LUMPUR, Malaysia: Malaysian authorities raised an alert for a northeastern state after the virulent H5N1 bird flu virus was found to have spread to poultry in more villages.

Some 24,000 birds have been culled in Kelantan state since the H5N1 strain was reported March 6 after several backyard poultry died.

Che Abdullah Mat Nawi, who heads Kelantan's agricultural committee, said Thursday that free-range chickens reared by residents in 20 villages have been affected. He said the state is getting more manpower and resources to survey a wider area to contain the spread of the virus.

"The situation is getting more serious but it is not yet an emergency situation as there is no transmission of the virus from bird to human. We have raised the alert so that we can pool resources from different departments" to curb the spread of the virus, he told The Associated Press.

Che Abdullah said commercial bird farms in the state were not affected by the virus.

The H5N1 strain is highly contagious and linked by the World Health Organization to hundreds of deaths worldwide over the last decade.

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