

Stem-cell doctor did surgeries with 'inadequate' proof

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In this Friday, July 30, 2010 file photo, Dr. Paolo Macchiarini talks to journalists during a press conference, in Florence, Italy. An independent commission investigating Italian stem cell scientist Dr. Paolo Macchiarini, whose work was once considered revolutionary, says that there were numerous problems in how he treated patients and that the scientific basis for his work was "inadequate," it was reported on Wednesday, Aug. 31, 2016. Macchiarini was part of the team that conducted the world's first transplant using a windpipe partly made from a patient's own stem cells. (AP Photo/Lorenzo Galassi, File)

An independent commission investigating Italian stem-cell scientist Dr. Paolo Macchiarini, whose work was once considered revolutionary, says there were numerous problems in how he treated patients and that the scientific basis for his work was "inadequate."

Macchiarini was part of the team that conducted the world's first transplant using a windpipe partly made from a patient's own stem cells.

In a report issued on Wednesday, a group of independent experts commissioned by Sweden's Karolinska University said there were "clear weaknesses in how informed consent was obtained" and that only one of Macchiarini's three patients who got a stem-cell windpipe actually signed a consent form.

Because the patient was not given the option to discuss the operation with an independent expert, the group concluded that if the information had been presented to an ethical board, "it would not have been approved," the report said. Two of the three patients who got the windpipe transplant later died.

The commission also found that in the various transplants performed, three different synthetic materials for the windpipe were used and that the numerous changes should have raised concerns.

"Too little was known about the material in order for it to be able to begin to be used in patients," the report said. It also questioned Macchiarini's use of growth-stimulating drugs in combination with the transplant, pointing out that there was no permit from the regulating body to use the drugs as Macchiarini did and that all three of his patients suffered clotting problems potentially linked to their use.

The commission ultimately concluded that "the scientific foundation was inadequate prior to the transplants," saying that it was "too early" to

perform windpipe transplants seeded with bone marrow cells. It noted there had been no results from experiments on laboratory animals using the specific techniques tried in patients.

In June, Swedish prosecutors said they were investigating Macchiarini for involuntary manslaughter in connection with his two patients who died. The Karolinska Institute fired him in March for breaching medical ethics after he was accused of falsifying his resume and misrepresenting his work.

"The results of all this were devastating for the patients and their families, and we offer them our apologies. What happened is unacceptable," said Melvin Samson, Karolinska University Hospital's director.

"At the same time, we take full responsibility for the fact that our system failed." He said that two departmental heads linked to Macchiarini would "take a time out until further notice."

The hospital itself was slammed for "multiple problems concerning patient safety," as the commission ruled that some laws and other regulations had been broken and that the hospital's lack of an ethical review board had been problematic.

Macchiarini declined to comment. He has previously disputed all of the charges against him.

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