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## **NEW COMPLICATION SEEN IN STEM CELL THERAPY**

### **Stem Cell Recipient Developed Mysterious Masses at Injection Sites**

**Washington, DC (June 15, 2010)** — Following stem cell therapy, an adult patient experienced a new and previously unrecognized complication, which required removal of one of the kidneys, according to a case report appearing in an upcoming issue of the *Journal of the American Society Nephrology* (JASN). The report suggests that stem cell therapy may cause patients to develop blood vessel and bone marrow masses, the long term effects of which are unknown.

Stem cell therapy holds great clinical potential for a variety of diseases. Therapy using stem cells from the blood has generally been viewed as safe, and researchers have planned clinical trials to expand this type of therapy to treat different conditions. However, a new report indicates that a previously undescribed complication may result. The case involves an adult patient with severe kidney disease, who was treated at a private clinic, by direct injection of her own stem cells into her kidneys. After a few months, one kidney developed bleeding and required removal.

Duangpen Thirabanjasak, MD, Kavirach Tantiwongse, MD (Chulalongkorn University, in Bangkok, Thailand) in consultation with Paul Scott Thorne, MD, PhD (The Hospital for Sick Children, the University of Toronto, in Canada and Chulalongkorn University) were involved in the removal and analysis of the kidney. They found that the patient had not benefitted from the treatment but, rather, had developed masses called angiomylproliferative lesions at the injection sites composed of a mixture of blood vessels and bone marrow cells. The remaining kidney eventually failed, and the patient ultimately died from an infection.

“This type of lesion has never been described before in patients, and we believe that this is either formed directly by the stem cells that were injected or that the stem cells caused these masses to form,” said Dr. Thirabanjasak. She noted that because this was a unique occurrence, no one knows how these lesions might have behaved over time.

The authors conclude that their findings should serve as a warning to clinical investigators that the development of blood vessel and bone marrow masses may be a

possible complication of stem cell therapy. Further research is needed to determine the circumstances that may cause these masses to form and to determine strategies to avoid this possible complication from occurring in the future.

In reviewing the results of this report in an accompanying editorial, Andras Nagy, PhD and Susan Quaggin, MD (Mount Sinai Hospital and the University of Toronto) noted that it provides a cautionary note and underscores a growing risk associated with the increased number of private clinics offering stem cell therapies to patients with little or no oversight from the scientific stem cell community. “Premature enthusiasm and protocols that are not fully vetted are dangerous and result in negative publicity for the field of stem cell research, and more importantly, may result in disastrous outcomes with no benefit to the patient,” they wrote.

Disclosures: The authors of the study and editorial reported no financial disclosures.

The article, entitled “Angiomyeloproliferative Lesions Following Autologous Stem Cell Therapy” (doi 10.1681/ASN.2009111156) and accompanying editorial, “Stem Cell Therapy for the Kidney: A Cautionary Tale” (doi 10.1681/ASN.2010050559) will appear online at <http://jasn.asnjournals.org> on June 17, 2010.

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