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‘RENAL ASSIST DEVICE’ REDUCES RISK OF DEATH FROM ACUTE KIDNEY FAILURE

Cell-Filled Device Temporarily Replaces Renal Tubule Function

Washington, DC (Tuesday, March 4, 2008) — For patients with acute kidney injury (AKI), an external device containing human kidney cells promotes recovery of the injured kidneys and significantly reduces the risk of death, according to a preliminary clinical study published in the May *Journal of the American Society of Nephrology*.

The experimental renal tubule assist device (RAD) appears safe and effective for desperately ill patients with AKI. "Deployment of the RAD was associated with remarkably better outcomes for these patients—speeding recovery of kidney function and reducing risk of death by half," comments Dr. H. David Humes of University of Michigan, one of the study authors.

Patients with AKI have sudden loss of kidney function, resulting from a wide range of possible causes (such as blood loss or toxic injury). The goal of treatment is to replace lost kidney function through dialysis and related techniques until the kidneys have time to recover. However, even with treatment, the risk of death during an episode of AKI is 50 percent or higher.

In the new study, 40 of 58 patients with AKI were randomly assigned to treatment with the RAD, in addition to standard renal replacement therapy. The RAD is a conventional blood filter device lined with human renal tubule cells, grown from donor kidneys. "The cells are made available to carry out subtle metabolic and endocrine functions that the patient's failing kidneys can no longer perform, thereby staunching a cascading decline in the patient's health and allowing time for the patient's own organs to recover," Dr. Humes explains.

Outcomes were significantly better for AKI patients treated with the RAD. After one month, 33 percent of patients in the RAD group had died, compared to 61 percent of those treated with renal replacement therapy only. Patients who received the RAD were also more likely to be alive after six months. With adjustment for other factors, the risk of death was about 50 percent lower in the RAD group.

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Patients in the RAD group also had a shorter time to return of kidney function. Overall, kidney function recovered in 53 percent of patients with RAD, compared to 28 percent without RAD. In both groups, about 20 percent of patients survived but never recovered kidney function, requiring chronic dialysis.

Although the initial results are encouraging, the benefits of RAD treatment need to be confirmed in larger studies. In addition, the researchers need to study the effects of changes in the design of the RAD, which are needed to accommodate mass production.

In addition to improving the outcomes of AKI, the results may point the way toward entirely new classes of cell-based and tissue-engineered therapies. "The ability to harness vital processes of cells, to target their living molecular machinery on restoring critical substances which have become disordered by disease, has vast implications for the future of medicine," says Dr. Humes. "Particularly, we are encouraged that we can develop a related device to treat chronic renal failure—a wearable kidney that performs natural functions unachievable through man-made technology alone."

The American Society of Nephrology (ASN) is a not-for-profit organization of 10,500 physicians and scientists dedicated to the study of nephrology and committed to providing a forum for the promulgation of information regarding the latest research and clinical findings on kidney diseases. ASN publishes JASN, the *Clinical Journal of the American Society of Nephrology* (CJASN), and the *Nephrology Self-Assessment Program* (NephSAP).

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