Study explores best pre-transplant weight loss options

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Vanderbilt researchers are comparing two types of weight-loss options to determine which is the most effective in helping obese patients reach a more ideal weight before undergoing kidney transplant surgery.

Obesity is a two-edged sword when it comes to kidney health. Excessive weight is a key factor in the development of acute kidney disease and kidney failure, which can then lead to the need for life-saving dialysis or kidney transplant. Obesity also contributes to significant complications following kidney transplant surgery, such as delayed function of the transplanted organ, poor wound healing, increased wound and skin infections, and even transplant failure and death.

Because of the significant negative impact of obesity on the success of organ transplant surgery, many transplant centers, including the Vanderbilt Transplant Center, do not accept individuals as kidney transplant candidates if they exceed a body mass index (BMI) limit. At Vanderbilt, the limit is 45 kg/m^2. Until weight loss is achieved, severely obese patients are considered too medically complex for kidney transplant surgery, said principal investigator Seth Karp, MD, H. William Scott Jr. Professor and chair of the Department of Surgery and director of the Vanderbilt Transplant Center.

"We're recruiting patients who are obese with kidney failure to participate in a clinical trial to look at which method—one group will receive gastric bypass surgery and another will be provided medically managed weight loss—is the best way to most efficiently reduce weight

before a kidney transplant," said Karp. "The study follows patients for up to five years from the point of intervention, whether it be the gastric bypass or the initial consultation with the Vanderbilt Medical Weight Loss team. At the 18-month mark, we will see if patients have reached medical suitability for kidney transplant. If so, their weight loss can then be a positive factor in their recovery.

"Because patients with acute kidney diseases and kidney failure are typically on dialysis, their ability to exercise to achieve weight loss might be limited. They are also usually dealing with other diseases such as diabetes and high blood pressure. This study hopes to provide clear evidence on the best option for weight loss for these individuals. We're seeing both renal failure and the obesity epidemic increasing, especially in the South. Treatments like these are urgently needed."

Investigators will also track changes in several health-related quality of life (HRQoL) measures throughout the study that relate to physical, mental, emotional and social functioning. Examples include how well patients are able to participate in social activities, their overall satisfaction with life and any changes in mobility they experience.

"Both kidney failure and obesity significantly affect an individual's overall quality of life," Karp said. "For example, if you can't participate in family activities, you're unable to keep a job due to ill health or you are too fatigued to enjoy activities you've enjoyed in the past, you can understandably become less happy with your life. We want to track quality of life issues to see how these change for individuals in the study."

In addition, study participants will be followed for five years to document factors including continued weight change, any surgical complications, the development or regression of diabetes, the development or regression of any other diseases including high blood

pressure, coronary artery disease and skin infections, and any deaths. Health care utilization, including the amount of money spent on healthcare, the number and length of hospitalizations and any procedures required will also be tracked for five years for participants.

The study will follow 75 patients and is currently enrolling. Eligible patients are male or female, 18-59 years old, with a body mass index (BMI) of 40-55 kg/m2, with adequate insurance and an available support person.

Provided by Vanderbilt University