慢性腎臓病患者において侵襲的治療戦略により得るものはない(Late breaking Science II)

ISCHEMIA-CKD試験：進行する慢性腎臓病に侵襲的心臓手術を施行しても心イベント率は低下しない

ISCHEMIA-CKD: Advanced chronic kidney disease treated with invasive heart procedures show no reduction in rate of cardiac events

中等度から重度の心筋虚血を有する慢性腎臓病（CKD）患者にルーチンの侵襲的血行再建術を施行しても、至適薬物療法（OMT）のみを施行された患者に比べ、死亡または心筋梗塞（MI）のリスクは低下しない、とAmerican Heart Association's Scientific Sessions 2019で発表された。対照的に、脳卒中などある一定のアウトカム発症率は侵襲的施術群で上昇したが、施術直後の脳卒中発症は稀であった。またこのISCHEMIA-CKD試験の結果、狭心症症状を有する患者に対する侵襲的治療は、OMTのみの患者に比べ長期症状緩和やQOLを改善しなかった。

Full Text

Heart disease is the leading cause of death for the roughly 500 million people worldwide with chronic kidney disease (CKD). Yet such patients have been excluded from most of the major, relevant cardiovascular clinical trials that are meant to guide treatment approaches for them.

Today, an international, federally funded study reported on comparing the value of two treatment strategies specifically for patients with advanced chronic kidney disease that also had significant, but stable disease in their coronary arteries.

Presented in a Late Breaking Science session at the American Heart Association's Scientific Sessions 2019, the study found that patients with CKD that underwent routine, invasive procedures – like stent implants or bypass surgery – when compared with patients that received only the lifestyle advice and medications (e.g. aspirin, statins), saw no reduction in risk for two disease-related outcomes: death and myocardial infarction (MI). In contrast, rates of certain outcomes such as stroke was increased in the invasive procedure group, although strokes immediately following the procedure were rare.

Called ISCHEMIA-CKD (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches - Chronic Kidney Disease), the study also found that for patients with symptoms of angina, invasive treatments did not result in better, long-term symptom relief and quality of life than among those that received only optimal medical therapy (OMT – medications and lifestyle advice).

Both patient groups in the study received OMT, with one group undergoing invasive procedures soon after having an abnormal stress test, and the other treated invasively only if symptoms worsened despite intensive drug therapy, or in the case of an MI. Several forms of stress test were included in the study.

"Physicians and patients need to consider that in our study invasive treatments did not lead to reduction in death or heart attack in patients with CKD," says ISCHEMIA-CKD principal investigator Sripal Bangalore, MD, professor of medicine, at NYU Langone Health, and director of cardiac catheterization laboratory (H+H/Bellevue). "Risks for damage to both the heart and kidneys from invasive procedures are higher in these patients, which makes other options, like intensive medication therapy, more attractive, except in cases of emergencies."

Led by researchers at NYU Grossman School of Medicine with data and statistics managed by Duke Clinical Research Institute, the study randomly assigned 777 patients in 30 countries to receive one of the two treatment strategies, making it the largest study in history for patients with chronic disease in their kidneys. The quality of life component was led by researchers at Saint Luke's Mid America Heart Institute and Duke.

Funded by the National Heart, Lung, and Blood Institute, ISCHEMIA-CKD studied patients with advanced CKD and stable ischemic heart disease (SIHD).

For the study, "invasive" treatment meant routine catheterization, followed by revascularization when suitable – in most cases involving angioplasty followed by the placement of a rigid stent. In other cases, improved blood flow was accomplished by cardiac bypass surgery.

Measures were in place to reduce procedure-related heart and kidney damage, including proper hydration and careful limits on contrast agents used to create images of heart blockages. Despite these precautions, no long-term benefit was observed in patients who had an invasive procedure soon after a stress test, versus only optimal medical therapy.

Specifically, ISCHEMIA-CKD found that the invasive strategy of catheterization, followed by revascularization, was associated with higher risk of stroke, although strokes immediately or soon after the procedure were rare, suggesting that they were caused by the advanced disease of the patients, versus risk from the procedures, say the investigators. Of the patients enrolled in the trial, one in four died within 3 years.

Investigators also measured whether either treatment strategy reduced symptoms of angina. The patients enrolled in ISCHEMIA-CKD were minimally symptomatic, with nearly half of them having no angina. The investigators say it is well known that patients with advanced CKD are less likely to report symptoms of angina because their nerves do not register chest pain as well. The study found no substantial benefit at reducing angina or improving quality of life in patients treated with the invasive strategy. Further, researchers say, the study may not apply to patients who are very symptomatic or who come into the hospital with an MI.

"Increasing trends in obesity and diabetes have increased the prevalence of CKD significantly throughout the world," says ISCHEMIA studies chair Judith Hochman, MD, the Harold Snyder Family Professor of Medicine and Senior Associate Dean for Clinical Sciences, at NYU Langone Health. "Our findings provide guidance on how to best treat this vulnerable patient population."

The team plans to follow the study patients for another five years to determine whether either strategy is associated with better survival over this longer observation period.

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