インターベンション治療は薬物療法と大して変わらない(Late breaking Science II)

ISCHEMIA試験：インターベンション治療を施行された患者が薬物療法施行患者に比べ心イベント発生率が低い、とのエビデンスはない

ISCHEMIA: No evidence of lower cardiac event rates in patients treated with interventional procedures compared to medication

重症ではあるが安定した心疾患患者に対する早期の侵襲的治療は至適薬物療法に比べ有益性はない、とAmerican Heart Association's Scientific Sessions 2019のLate Breaking Science sessionで報告された。ISCHEMIA試験では、ルーチンのステント留置やバイパス手術などの侵襲的治療を施行された患者において、薬物投与および生活習慣改善のアドバイスのみを受けた患者に比べ、主要な冠動脈疾患関連イベントの発生率は低下しなかった。しかし、狭心症症状を有する患者においては、侵襲的治療により症状の緩和およびQOLの改善が良好であり、それは4年間持続した。

Full Text

An international study found no benefit of an early invasive strategy compared to optimal medical therapy for patients with severe but stable heart disease according to a Late Breaking Science presentation at the American Heart Association's Scientific Sessions 2019.

Presented in a Late Breaking Science session at the American Heart Association's Scientific Sessions 2019, the study found that patients who underwent routine, invasive procedures – like stent implants or bypass surgery – when compared with patients that received only medications (e.g. aspirin, statins) and lifestyle advice, saw no reduction in the rate of occurrence for a group of five events: cardiovascular death, myocardial infarction (MI), hospitalization for unstable angina, hospitalization for heart failure, or resuscitation after cardiac arrest.

Called ISCHEMIA (International Study of Comparative Health Effectiveness with Medical and Invasive Approaches), the trial also found no overall difference between the two treatment strategies in the rates of cardiovascular death or MI.

At the same time, the investigators found that for patients with symptoms of angina, invasive treatments resulted in better symptom relief and quality of life that persisted for four years. Among those with daily or weekly angina at the start of the study, 50 percent of those treated invasively were angina- free after a year, compared to 20 percent of those treated with medications and lifestyle advice alone.

Both patient groups in the study received "optimal medical therapy" (OMT), the term for medications and lifestyle advice, with one group undergoing invasive procedures soon after having an abnormal stress test, and the other treated invasively only if symptoms worsened despite drug therapy, or in the case of an MI.

Led by researchers at NYU Grossman School of Medicine and Stanford University, with data management and statistics led by the Duke Clinical Research Institute (DCRI), the study randomly assigned 5,179 patients at 320 sites in 37 countries to receive one of the two treatment strategies, making it more than twice as large as any previous study of its kind. The quality of life component was led by researchers at Saint Luke's Mid America Heart Institute and DCRI.

"In line with evidence from prior studies, our results suggest that routine use of heart procedures was not superior in reducing risk for the five-part disease endpoint or death overall compared to treatment only with optimal medical therapy," says ISCHEMIA study chair Judith Hochman, MD, the Harold Snyder Family Professor of Medicine and Senior Associate Dean for Clinical Sciences, at NYU Langone Health. "On the other hand, patients symptomatic to start that got heart procedures, over the years, had fewer symptoms and felt better."

Funded by the National Heart, Lung, and Blood Institute, ISCHEMIA studied patients with stable ischemic heart disease (SIHD). The "vast majority" of patients in the study were determined to have moderate or severe ischemia caused by atherosclerosis.

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.

The study design reflects clinical practice, where patients with abnormal stress tests often undergo an angiogram and revascularization, with a stent implant or bypass surgery.

The rate of procedure-related stroke and death was "extremely" low in ISCHEMIA, but the risk of MIs related to procedures may explain, says Hochman, why those that had an invasive procedure had a rate of events higher by two percentage points over the first year than those that received optimal medical therapy alone (5.3 percent with invasive vs. 3.4 percent for the five-part endpoint).

By year two, the event rate for the study disease endpoints was roughly the same between the two approaches (9 percent vs. 9.5 percent). By four years, the rate of events was two percentage points lower in patients treated with heart procedures than in those that received medications and lifestyle advice alone (13.3 percent with invasive vs. 15.5 percent). Overall, say the investigators, the trend shifts over time showed no significant evidence of a difference in rates between strategies.

Lastly, the team was surprised to see that the overall rate of heart-related events over the duration of the ISCHEMIA trial was lower than projected ten years ago. This is a testament, say the investigators, to recent advances in drug therapies and revascularization techniques.

"Based on our results, we recommend that all patients take medications proven to reduce the risk of a heart attack, be physically active, eat a healthy diet, and quit smoking," says ISCHEMIA co-chair David Maron, MD, Director of Preventive Cardiology and the Stanford Prevention Research Center at Stanford University. "Patients without angina will not see an improvement, but those with angina of any severity will tend to have a greater, lasting improvement in quality of life if they have an invasive heart procedure. They should talk with their physicians to decide whether to undergo revascularization."

Moving forward, the research team plans to follow the study patients for another five years, to determine whether either strategy is associated with better survival over a longer observation period.