心内膜炎に対する抗菌薬の経口投与への切り替えは失敗ではない(Abstract 19-LB-20241)

POET:感染性心内膜炎において部分的経口抗菌薬治療は安全かつ有効である

POET: Partial oral antibiotic therapy safe and effective in infectious endocarditis

静注抗菌薬治療から経口抗菌薬治療に切り替えられた心内膜炎患者は、従来の静注抗菌薬治療を継続された患者に比べ、長期生存率が良好であり合併症が少なかった、と American College of Cardiology's 68th Annual Scientific Session で発表され、同時に *New England Journal of Medicine* に掲載された。追跡期間中央値 3.5 年後、主要評価項目イベントを来したのは部分的経口治療を受けた患者では 26.4% であり、静注治療群では 38.2% で、統計学的に有意な差があった。今回のトライアルでは、一定の細菌種により引き起こされた左心系感染性心内膜炎患者のみが組み入れられた。

Full Text

Patients with endocarditis who were switched from intravenous to oral antibiotic therapy had better long-term survival and fewer complications than similar patients who remained on conventional intravenous antibiotic therapy, according to research presented at the American College of Cardiology's 68th Annual Scientific Session.

While initial six-month data had shown that partial treatment with oral antibiotics was similar in efficacy and safety to conventional intravenous therapy for left-sided infectious endocarditis, longer follow-up (median of 3.5 years) demonstrates this therapeutic approach is better for patients, said Henning Bundgaard, MD, PhD, DMSc, professor of cardiology at the Heart Center at the National University Hospital in Copenhagen, Denmark, and the study's lead author.

"In stabilized patients with left-sided infectious endocarditis, a switch from intravenous to oral antibiotic therapy showed superior efficacy and safety compared with continued intravenous treatment," he said. "These findings clearly support a change in the standard of care for this condition."

People with pre-existing heart valve disease, previous endocarditis, prosthetic heart valves or other implanted cardiac devices have an elevated risk for infectious endocarditis. The condition most often occurs on the left side of the heart in the mitral or aortic valve. Men are diagnosed with infectious endocarditis about twice as often as women.

The current study, known as POET, is the largest randomized trial of patients with infectious endocarditis, and was designed to test whether oral antibiotic therapy for left-sided infectious endocarditis was at least as effective and safe as intravenous treatment.

Clinical guidelines from several professional organizations currently recommend treating left-sided infectious endocarditis with intravenous antibiotics for up to six weeks. During the initial treatment phase, patients often need intensive care and close monitoring. Because intravenous antibiotics are logistically difficult to administer outside of a hospital, most patients remain in the hospital for the duration of their treatment.

Studies have suggested that intravenous treatment during long hospital stays may put patients at increased risk for complications. Oral antibiotics would allow patients to leave the hospital sooner and complete their treatment at home. Studies in other conditions have shown that patients with shorter hospital stays generally had better outcomes.

A total of 400 patients (average age 67 years; 77 percent male) with left-sided infectious endocarditis were enrolled in the study. Study participants had to be in stable condition and to have had a satisfactory response to at least 10 days of intravenous antibiotic treatment before randomization. They were then randomly assigned to either continue with intravenous antibiotics or switch to oral treatment for an average of 17 days after they were diagnosed. Intravenously-treated patients remained in the hospital until they completed antibiotic therapy. Patients who switched to oral treatment were discharged from the hospital a median of three days after making the switch.

The study's primary endpoint was a composite of death from any cause, unplanned cardiac surgery, embolic events (e.g., stroke) and relapse of infection with the same pathogen from the time of randomization until the end of follow-up.

After a median of 3.5 years of follow-up, 53 patients (26.4 percent) in the group receiving partial oral treatment had a primary-endpoint event, compared with 76 patients (38.2 percent) in the intravenously treated group, a statistically significant difference. Eighty-seven patients died; of these, 54 (27.1 percent) were treated intravenously and 33 (16.4 percent) were treated with oral medications, a significant difference. No significant differences in outcome were seen for relapse of infection, unplanned cardiac surgery or embolic events. The magnitude of the difference between the two groups is sufficient to conclude that oral treatment is superior to intravenous treatment, Bundgaard said.

Only patients with left-sided infectious endocarditis caused by certain bacterial species were enrolled in the trial, Bundgaard said, and the results may not apply to the approximately 25 percent of patients whose conditions are caused by other bacteria. In addition, although patients with antibiotic-resistant bacteria were not excluded from the trial, none were enrolled. Bundgaard and his colleagues plan to conduct additional analyses to compare quality of life and treatment costs in the groups receiving intravenous and partial oral treatment.

This study was funded by the Danish Heart Foundation and the Danish Capital Regions Research Foundation.

This study was simultaneously published online in the *New England Journal of Medicine* at the time of presentation.

ACC2019特集