Empagliflozin Improves Quality of Life in HFrEF

Empagliflozin improved health-related quality of life among patients with heart failure with preserved ejection fraction (HFrEF), showing similar results as an earlier trial of patients with reduced ejection fraction. The analysis of the EMPEROR-Preserved trial, published in Circulation, also found that empagliflozin reduced the risk of major heart failure outcomes independent of patients’ quality of life at baseline.

The analysis included 5942 patients. Compared with placebo, patients treated with empagliflozin had significant improvement in quality of life as early as 12 weeks and sustained the benefit over 52 weeks. Regardless of patients’ baseline quality of life, empagliflozin consistently reduced time to cardiovascular death or heart failure hospitalization.

The drug’s effects on quality of life, while statistically significant, were modest. However, the authors noted, “the magnitude of the treatment effect in EMPEROR-Preserved is similar to that seen in other large-scale double-blind trials of drug therapies, particularly in patients with HFrEF...”

In February, the US Food and Drug Administration expanded its approval of empagliflozin, marketed as Jardiance, for reducing the risk of cardiovascular death and hospitalization among all adults with heart failure, including those with preserved ejection fraction.

Gefapixant Curbs Chronic Cough

Researchers on 2 international phase 3 trials reported that gefapixant, an investigational oral P2X3 receptor antagonist, effectively treated refractory or unexplained chronic cough, for which there are currently no approved therapies.

The trials included 2049 participants who had cough for an average of almost 12 years. They were randomly assigned to receive placebo or 15 mg or 45 mg of gefapixant twice per day. Participants were treated for 12 weeks in the COUGH-1 trial and for 24 weeks in the COUGH-2 trial; each trial offered extension periods for a total of 52 weeks of treatment.

In both trials, reported in The Lancet, the higher dose of gefapixant was superior to placebo for significantly reducing the frequency of coughs. In COUGH-1, the estimated reduction in cough frequency at week 12 was 53% in the placebo group and 62% in the higher-dose gefapixant group. In COUGH-2, the estimated reduction in cough frequency at week 24 was 57% in the placebo group and 63% in the in the higher-dose gefapixant group.

However, in its review of the novel drug, the US Food and Drug Administration in January requested additional information "related to measurement of efficacy," according to pharmaceutical company Merck.

Long-Acting RSV Antibody Injection Protects Healthy Infants

A single dose of nirsevimab protected healthy late-preterm and term infants against medically attended respiratory syncytial virus (RSV) over an entire season, according to the findings of a phase 3 trial reported in the New England Journal of Medicine. The investigational monoclonal antibody with an extended half-life was previously shown to protect healthy preterm infants against RSV.

The study’s 1490 participants with a gestational age of at least 35 weeks were randomly assigned to receive an intramuscular injection of nirsevimab or placebo before the start of an RSV season.

Nirsevimab was 74.5% effective against medically attended RSV-associated lower respiratory tract infection, which occurred in 1.2% of the nirsevimab group and in 5% of the placebo group. The treatment appeared to have lower efficacy for infants younger than 3 months or weighing less than 5 kg when they received the injection. Hospitalization due to RSV occurred in 0.6% of the nirsevimab group and in 1.6% of the placebo group, resulting in 62.1% efficacy against this outcome. About 7% of both groups experienced serious adverse events, none apparently related to the study drug or to placebo.

Researchers are also actively developing RSV vaccines, with clinical trials currently underway.

Exercise Improves Shoulder Function After Breast Cancer Surgery

Participating in a supervised exercise program soon after breast cancer surgery can improve patients’ shoulder function, postoperative pain, and health-related quality of life, according to a trial conducted at 17 breast cancer centers in England.

The trial’s 392 participants had a high risk of developing shoulder problems following surgery. Most had undergone axillary node clearance surgery and had received radiotherapy. The women were randomized to receive a physical therapist-led program of 3 to 6 sessions focused on shoulder mobility, stretching, and strengthening exercises or to usual care consisting of written information on exercises.

At 12 months, women in the exercise group reported better arm function, less pain, and better quality of life than the usual care group and were more confident about returning to their regular activities. There was no difference between groups in the rate of wound healing, lymphedema, or other postoperative complications.

A cost-effectiveness analysis found that implementing exercise cost less than usual care over 12 months. The findings appeared in Health Technology Assessment.

— Anita Slomski

Note: Source references are available through embedded hyperlinks in the article text online.