Cardiac medication may help reduce stiffness caused by certain muscle diseases

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Preliminary research finds that for patients with nondystrophic myotonias (NDMs), rare diseases that affect the skeletal muscle and cause functionally limiting stiffness and pain, use of the anti-arrhythmic medication mexiletine resulted in improvement in patient-reported stiffness, according to a preliminary study in the October 3 issue of *JAMA*.

Data on treatment of NDMs are largely anecdotal, consisting of case series and a single-blind, controlled trials of several medications including mexiletine, according to background information in the article.

Jeffrey M. Statland, M.D., of the University of Rochester Medical Center, Rochester, New York, and colleagues in the Consortium for Clinical Investigation of Neurologic Channelopathies conducted a study to determine the effects of mexiletine for symptoms and signs of myotonia (prolonged failure of muscle relaxation after contraction) in patients with NDMs. The randomized study, part of the National Institutes of Health-funded Rare Disease Clinical Research Network, was conducted at seven neuromuscular referral centers in four countries between December 2008 and March 2011 and included 59 patients with NDMs. Patients (33 men, 26 women; average age, 43 years) received either oral 200-mg mexiletine or placebo capsules three times daily for four weeks, followed by the opposite intervention for four weeks, with 1-week washout in between. The main outcome measured for the study was patient-reported severity score of stiffness recorded on an interactive voice response (IVR) diary (scale of 1 = minimal to 9 = worst

ever experienced). Secondary outcomes included IVR-reported changes in pain, weakness, and tiredness; clinical myotonia assessment; quantitative measure of handgrip myotonia; and Individualized Neuromuscular Quality of Life summary quality of life score (INQOL-QOL, percentage of maximal detrimental impact).

Data from 57 participants who made telephone calls to the IVR diary in weeks 3 to 4 of period 1 or 2 were included in the analysis. The researchers found that mexiletine was associated with significantly improved stiffness as reported on the IVR diary in both treatment periods. For period 1, the treatment effect was 2.53 for mexiletine vs. 4.21 for placebo; for period 2, 1.60 for mexiletine vs. 5.27 for placebo.

There were significant improvements with mexiletine in most other outcomes in the study, including patient-reported outcomes, quality of life scales, and quantitative measures of myotonia (improved myotonia as measured on clinical examination by overall handgrip times in seconds).

"The most common adverse effect was gastrointestinal (9 mexiletine and 1 placebo). Two participants experienced transient cardiac effects that did not require stopping the study (1 in each group). One serious adverse event was determined to be not study related," the authors write.

"Our study provides preliminary evidence of the effectiveness of mexiletine for symptoms and signs of myotonia in NDMs," the researchers write. "The clinical significance of the improvement in stiffness score on the IVR diary is supported by the broad improvement in clinical, quantitative, and electrophysiological measures of myotonia."

"The study by Statland et al provides important information that should help inform the treatment of patients with myotonia," writes Eric P. Hoffman, Ph.D., of the Children's National Medical Center, and Henry

J. Kaminski, M.D., of George Washington University, Washington, D.C., in an accompanying editorial.

"The success of this trial should encourage the Consortium for Clinical Investigation of Neurologic Channelopathies (CCINC) group to take the lead with larger phase 3 trials. Even more exciting would be development of novel agents that can produce therapeutic benefit with much greater effect sizes. Most important, the National Institutes of Health, industry, and patient advocacy groups should attempt to replicate the success of the CCINC through establishment of more clinical research consortia focused on rare disorders."

More information: *JAMA*. 2012;308[13]:1357-1365.
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