

Study: statin therapy associated with lower risk of pancreatitis

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Although some studies have suggested that use of lipid-lowering therapies may increase the risk of pancreatitis, an analysis that involved pooling of data from previous studies and included more than 150,000 participants found that statin therapy was associated with a reduction in the risk of pancreatitis in patients with normal or mildly elevated triglyceride levels, according to an article in the August 22/29 issue of *JAMA*.

"Pancreatitis has a clinical spectrum ranging from a mild, self-limiting episode to a severe or fatal event. Case reports and pharmacoepidemiology studies have claimed that statins may cause pancreatitis, although few of these studies comprehensively considered confounding factors. Very few large <u>randomized trials</u> of statin therapy have published data on incident pancreatitis," according to background information in the article. "Although <u>lipid</u> guidelines recommend fibrate therapy to reduce pancreatitis risk in persons with hypertriglyceridemia, fibrates may lead to the development of <u>gallstones</u>, a risk factor for pancreatitis."

David Preiss, M.D., Ph.D., of the University of Glasgow, United Kingdom, and colleagues examined the associations between use of a statin or a fibrate and the incidence of pancreatitis by conducting collaborative meta-analyses of published and unpublished data from large randomized clinical trials. The authors conducted a search of the medical literature to identify relevant studies for inclusion in the analysis.



In 16 placebo- and standard care-controlled statin trials with 113,800 participants conducted over 4.1 years, 309 participants (0.27 percent) developed pancreatitis (134 assigned to statin, 175 assigned to control; a 23 percent lower risk of pancreatitis for those assigned to statin therapy). In 5 dose-comparison statin trials with 39,614 participants conducted over 4.8 years, 156 participants (0.39 percent) developed pancreatitis (70 assigned to intensive dose, 86 assigned to moderate dose; an 18 percent lower risk for the intensive dose group).

In the combined data set of 21 trials, 465 participants (0.30 percent) developed pancreatitis (of whom 204 were assigned to statin therapy or intensive-dose statin therapy and 261 were assigned to placebo, standard care, or moderate-dose statin therapy, respectively), a 21 percent lower risk.

Seven randomized clinical trials of fibrate therapy (4 with published data and 3 with unpublished data regarding incident pancreatitis) provided data on 40,162 participants over a weighted average follow-up period of 5.3 years. Baseline average triglyceride levels in the trials varied from 145 mg/dL to 184 mg/dL. During this time, 144 participants (0.36 percent) developed pancreatitis (84 assigned to fibrate therapy, 60 assigned to placebo), but the risk difference was not statistically significant.

"Although the present results for both statins and fibrates should be considered hypothesis-generating and the number of pancreatitis cases was small in this trial population at low risk of pancreatitis, the analysis raises questions regarding the choice of lipid-modifying agents in patients with hypertriglyceridemia. In those with slightly elevated triglyceride levels, statins appear better supported by the available data than fibrates for preventing pancreatitis. Lifestyle modifications also remain important to improve lipid profiles in such individuals. In patients with severe hypertriglyceridemia, a trial comparing fibrates and



statins for preventing pancreatitis would be clinically valuable," the authors write.

More information: *JAMA*. 2012;308[8]:804-811.

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