

糖尿病患者においてロスバスタチンはアトルバスタチンよりも選択肢として優れている可能性がある (Presentation #2127)

LISTEN: ロスバスタチンはアトルバスタチンよりも早期には血糖値に対して好ましい作用を有する

LISTEN: Rosuvastatin initially has more favorable effect on glucose levels compared to atorvastatin

2型糖尿病患者に対するコレステロール降下薬スタチン系薬剤に関して言うと、ロスバスタチンはアトルバスタチンよりも選択肢として好ましい可能性があるとの日本のスタディ結果が、2014年 European Society of Cardiology Congress ホットラインセッションで発表された。LISTEN トライアルは高コレステロール血症を有する2型糖尿病患者を1日5mgのロスバスタチン(514人)または1日10mgのアトルバスタチン(504人)を内服する群にランダムに割り付けた。スタディ終了時に両群ともに非HDLコレステロールの低下を示し、ロスバスタチン群とアトルバスタチン群とで統計学的に有意ではない差が認められた(それぞれ-32.86%対-31.01%)。同様に、1年後のLDLコレステロール低下も両群間で有意な差はなかった(それぞれ-34.79%および-32.78%)。しかし3か月後に、LDL低下はロスバスタチン群で有意に大であった(-39.38%対-36.39%、 $p=0.0106$)。血糖値は両群ともに上昇し、12か月後の値は両群間に有意差はなかった。しかし、初期の血糖値上昇はアトルバスタチン群(3か月後および6か月後はそれぞれ121.4および126.0mg/dL)でロスバスタチン群(それぞれ118.8および122.9mg/dL)より急激であり、この差は統計学的に有意であった($p=0.0104$)。

Full Text

When it comes to cholesterol-lowering statin medications for patients with type 2 diabetes, rosuvastatin may be a better choice than atorvastatin, according to the findings of a new study presented at ESC Congress 2014.

"Statins have been shown to slightly increase the risk of new-onset diabetes but few studies have been done to investigate their impact on existing diabetes. Such data would greatly contribute to decision-making when these patients are treated in routine clinical settings," said Hisao Ogawa, M.D., Ph.D., investigator of the LISTEN (Lipid lowering with highly potent Statins in hyperlipidemia with Type 2 diabetes patients) trial.

Results of the trial, presented as an ESC Hot Line, suggest rosuvastatin may have an initially more favorable effect on glucose levels compared to atorvastatin, making it a wiser choice especially in diabetes patients who struggle to keep glucose levels down, said Professor Ogawa, from the Graduate School of Medical Sciences at Kumamoto University in Kumamoto, and Deputy Director General of the Hospital, National Cerebral and Cardiovascular Center, Suita, Osaka, Japan.

The study randomized patients with type 2 diabetes and high cholesterol to either 5mg of rosuvastatin daily ($n=514$) or 10mg of atorvastatin daily ($n=504$) for a year.

An increase in statin dose was allowed only if a patient's cholesterol levels were not controlled adequately according to Japanese guidelines, but decisions about adjusting diabetes medication were left to the treating physicians' discretion.

The primary endpoint of the trial was the change from baseline in non-HDL cholesterol (total cholesterol minus HDL) and glycated hemoglobin (HbA1c).

At the end of the study both groups had a reduction in non-HDL cholesterol, with non-statistically significant difference between the rosuvastatin and atorvastatin groups (-32.86% and -31.01%, respectively).

Similarly, the reduction in LDL ("bad cholesterol") was not significantly different between the groups at one year (-34.79% and -32.78% mg/dL respectively).

However, at three months, LDL reduction was significantly greater in the rosuvastatin group (-39.38% vs. -36.39%, $p=0.0106$). Blood glucose levels increased in both groups, with no significant difference between them at 12 months (mean change of 0.11% and 0.12% in the rosuvastatin and atorvastatin groups respectively).

However, the initial increase in blood glucose was more abrupt in the atorvastatin group (121.4 and 126.0 mg/dL at 3 and 6 months) compared to the rosuvastatin group (118.8 and 122.9 mg/dL at 3 and 6 months), a difference that was statistically significant ($p=0.0104$).

"This would have influenced physicians' behavior to change the intensity of diabetes treatment more significantly in the atorvastatin group," noted Professor Ogawa. In fact, more patients on atorvastatin were given an increase in their diabetic therapy to control their initial abrupt rise in glucose (64 vs. 45 subjects; HR 1.46, $p=0.05$).

There was a similar rate of adverse and serious adverse events in both groups (20.7% and 3.7% in the rosuvastatin group and 20.0% and 2.8% in the atorvastatin group), with 4.5% and 5.9% respectively deemed connected to the study drug.

"A statin's impact on glucose metabolism should also be considered along with its cholesterol-lowering potency when making treatment choices for diabetic patients with high cholesterol," said Professor Ogawa. "Our results suggest rosuvastatin might be more preferable to atorvastatin due to its different influence on glucose levels."

He noted that the study used Japanese-approved dosages of rosuvastatin (5 mg) and atorvastatin (10 mg), which are small compared to standard North American or European doses (10-20 mg and 20-40 mg respectively). "Therefore our results might have underestimated the effects of statins."

The study was funded by AstraZeneca and by the non-profit Hokkaido Kenkoukagaku Institute.

Professor Ogawa reports receiving remuneration for lectures from AstraZeneca, Bayer, Daiichi Sankyo, MSD, Sanofi, and Takeda; trust research/joint research funds from Bayer, and Daiichi Sankyo; and scholarship funding from AstraZeneca, Astellas, Boehringer Ingelheim, Bristol-Myers Squibb, Chugai, Daiichi Sankyo, Dainippon Sumitomo Pharma, Kowa, MSD, Novartis, Otsuka, Pfizer, Sanofi, and Takeda.

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