

Efficacy and Safety of Pitavastatin in Menopausal Women with Dyslipidemia



Atsushi Imai*, Satoshi Ichigo, Hiroshi Takagi, Ichiro Kawabata, Kazutoshi Matsunami and Masashi Hori

Department of Obstetrics and Gynecology, Institute of Endocrine-Related Cancer, Japan

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*Corresponding author: Atsushi Imai, Department of Obstetrics and Gynecology, Institute of Endocrine-Related Cancer, Matsunami General Hospital, Kasamatsu, Gifu 501-6062, Japan, Tel: 81583880111; Email: aimai@mghg.jp

Abstract

Dyslipidemia is highly common in women, particularly after the menopause. Menopause, caused by ovarian dysfunctions, is associated with an increase in total and low-density lipoprotein-cholesterol (LDL-C) and a decrease in high density lipoprotein-cholesterol (HDL-C). Pitavastatin (2 mg/day, orally), one of new generation statin, in addition to its strong LDL-C lowering effect, revealed a higher efficacy to increase HDL-C level and improved elevated triglyceride (TG) level in Japanese peri- and postmenopausal women. Pitavastatin may be an effective treatment option in (post-)menopausal women with dyslipidemia, in conjunction with suggested lifestyle modification.

Keywords: Pitavastatin; Dyslipidemia; Low-Density Lipoprotein-Cholesterol; High Density Lipoprotein-Cholesterol; Triglyceride

Opinion

Lowering lipid levels, in particular low-density lipoprotein cholesterol (LDL-C) levels, attenuates the risk of cardiovascular disease, with HMG-CoA reductase inhibitors known as statins [1,2]. However, certain patients still experience atherosclerotic events, despite significant decrease of elevated LDL-C levels, because of risk factors other than LDL-C level. Low high-density lipoprotein cholesterol (HDL-C) and high triglyceride (TG) levels have been reported to represent independent risk factors for cardiovascular disease [1,2]. Many types of statins are clinically available, but the choice of them usually depends on its efficacy for LDL-C reduction. Pitavastatin has a LDL-C-lowering effect similar to or even superior to that of other statins, but a significantly higher ability to increase HDL-C levels [3,4]. Dyslipidemia is highly common in women, particularly in postmenopausal women. Menopause, caused by ovarian hormone depletion, has been shown to be associated with an increase in total and LDL-cholesterol and a decrease in HDL-C [5,6]. These circumstance findings prompted us to examine the effects of pitavastatin on HDL-C and TG levels in peri- and postmenopausal population, besides a LDL-C-lowering action.

This retrospective study included 11 peri- and postmenopausal women (mean age \pm SD; 63 ± 8.3 years, range; 50-72) with dyslipidemia. Exclusion criteria included chronic use of drug considered to affect lipid metabolism (including estrogen derivatives) within 1 year. The data were collected from 11 patients treated with pitavastatin (Livalo®, Kowa Pharmaceutical Co. Ltd., Japan, 2mg/day orally) in combination with lifestyle modification

for at least 5 years in our patient clinic from September 2009 to December 2017. The TG, HDL-C and LDL-C levels at baseline were 205.5 ± 66.2 mg/dl, 52 ± 8.2 mg/dl, 168 ± 40 mg/dl, respectively. Their changes during pitavastatin therapy are presented as percent of baselines. Paired t-tests were used to analyze in each size change from baseline. Statistical significance was defined as $P < 0.05$. The patients treated with pitavastatin and lifestyle modification advice exhibited significantly decreased LDL-C and TG levels and increased HDL-C level (Figure 1). These effects were seemed to continue over 6 months and sustained until 5 years. There were no serious adverse drug effects.

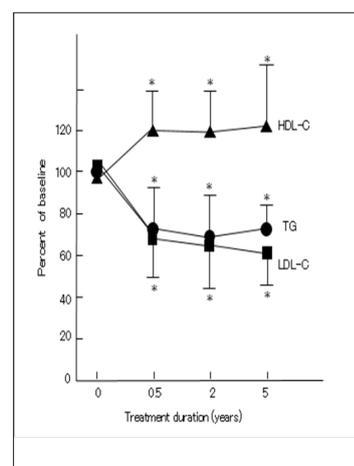


Figure 1.

Pitavastatin may positively affect the low HDL-C and high TG levels, in addition to a LDL-C-lowering effect. It also positively improves the quality and functionality of HDL particle functions [3,4]. In Japanese post-menopausal women, one previous report exhibited increased reactive hyperemic index and decreased LDL-C level without any significant effects on HDL-C and TG with 4-week pitavastatin treatment [7]. In our observation for up to 5 years, pitavastatin (2mg/day) reduced LDL-C in peri- and postmenopausal women with primary hypercholesterolemia or mixed dyslipidemia and also provided significantly greater reductions in several secondary lipid measures. This preliminary study has a number of limitations. In particular, the sample size and treatment duration of the observation were insufficient to draw adequate conclusions regarding long term safety and efficacy for menopausal dyslipidemia managements. Further studies are awaited to accumulate evidence in greater numbers of cases, longer duration treatment, and treatment of an even premenopausal and elderly populations. However, our observation may provide useful information for the management of menopausal and elderly women with dyslipidemia, in combination with lifestyle modification advice.

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