A STRONG MENTAL ATTITUDE CREATE MORE MIRACLES THAN ANY WONDER DRUG

Abstract
A. ABSTRACT

**Background:** Despite the established efficacy of statins, many patients do not achieve recommended LDL cholesterol goals. Contributing factors may be inadequate dosing, increased risk for adverse effects with high dose monotherapy, and increased potential for intolerance and adverse effects with combinations. Lipid lowering agent that acts via different pathway may allow additional patients to achieve recommended cholesterol goals.

**Objective:** This study sought to determine the efficacy and safety of ezetimibe and atorvastatin and their combination* in hyperlipidemic patients with special reference to their long term effects in Indian population.

**Methods:** 52* patients in each group with baseline total cholesterol (TC) level 150 to 300 mg/dl and/or, LDL-C level 150 to 250 mg/dl and/or, triglyceride level 150 mg/dl to ≤ 350 mg/dl were assigned to receive one of the following for 52 weeks: ezetimibe (10 mg/day); atorvastatin (10 mg/day); and ezetimibe (10 mg) plus atorvastatin (10 mg/day). The primary efficacy end point was percent reduction in LDL-C.

**Results:** Ezetimibe with atorvastatin significantly reduced* total cholesterol, LDL-C, triglycerides, TC/HDL-C, LDL-C/HDL-C, and homocysteine levels when compared with ezetimibe alone and
atorvastatin monotherapy. Coadministration of ezetimibe with atorvastatin provided a significant additional 3% TC reduction, 13% LDL-C reduction, 16% triglyceride reduction, 2% TC/HDL-C reduction, and 10% LDL-C/HDL-C reduction versus atorvastatin alone. Ezetimibe plus atorvastatin reduced TC level 31%, LDL-C 48%, triglyceride 34%, TC/HDL-C 35%, LDL-C/HDL-C 49%, Lp(a) 12.2%, creatine kinase 3.1%, c-reactive protein 7.1%, homocysteine 8.5%, creatinine 6.3%, and elevated HDL-C 5.4%, SGOT 3.6%, SGPT 4.8%, alkaline phosphatase 3.2%, serum urea 2.1%, and serum uric acid 25.1%, whereas ezetimibe reduced total cholesterol level 13.2%, LDL-C 19.5%, triglyceride 3.2%, TC/HDL-C 15.8%, LDL-C/HDL-C 22%, Lp(a) 11%, creatine kinase 2.9%, c-reactive protein 7.8%, homocysteine 5.1%, creatinine 4.2% and elevated HDL-C 3.5%, SGOT 3.4%, SGPT 4.2%, alkaline phosphatase 2.5%, serum urea 2.5% and serum uric acid 18.4%. Atorvastatin alone reduced total cholesterol 28.2%, LDL-C 35%, triglyceride 18.5%, TC/HDL-C 32.6%, LDL-C/HDL-C 39%, Lp(a) 14.5%, creatine kinase 2.1%, c-reactive protein 6.9%, homocysteine 7.3%, creatinine 5.1%, and elevated HDL-C 6.2%, SGOT 3%, SGPT 3.8%, alkaline phosphatase 2.8%, serum urea 3% and serum uric acid 21.2%. LDL-C reduction with combined therapy was significantly higher than that observed with either of ezetimibe or atorvastatin. The reduction observed in TC/HDL-C and c-reactive protein were similar in combination therapy and atorvastatin.
monotherapy. No cases of creatine kinase elevations ≥ 10 times upper limit of normal or myopathy were observed in any of the three groups.

**Conclusion:** 52 weeks treatments with ezetimibe alone, atorvastatin alone and ezetimibe plus atorvastatin in low doses were well tolerated in patients with hyperlipidaemia. Coadministration of ezetimibe with atorvastatin was well tolerated and more efficacious, with safety profile similar to ezetimibe alone and atorvastatin alone in patients with hyperlipidaemia.

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