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Study of Efficacy and Tolerability of Atorvastatin Alone or in Combination with Fenofibrate in Hyperlipidemia Patients with and without Type II Diabetes Mellitus in Tertiary Care Hospital

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Running Title: Efficacy and tolerability of atorvastatin alone or in combination with fenofibrate in hyperlipidemia patients with and without type ii diabetes mellitus in tertiary care hospital.

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ABSTRACT

Purpose: This study evaluated the effect and tolerability of Atorvastatin – Fenofibrate combination on lipid profile in comparison to Atorvastatin alone in patients with Hyperlipidemia with and without Type 2 Diabetes mellitus.

Methods: This prospective, parallel, comparative study includes total 99 Hyperlipidemia patients with and without Type 2 Diabetes mellitus, studied for a period of 6 months. These patients were randomly assigned to atorvastatin(10 mg/day, n = 49), and combination of both(Atorvastatin 10 mg/day + Fenofibrate 160 mg/day, n = 50).

Results: By assessing the efficacy of both therapies in Hyperlipidemia with Type 2 Diabetes mellitus patients, percentage decrease in parameters like, TC, TG and RBC were 14%, 16%, and 18% in Atorvastatin group as compared to 22%, 32%, and 29% in Atorvastatin+Fenofibrate group. The increase in HDL-C level was 17% in Atorvastatin+Fenofibrate group as compared to 12% in Atorvastatin group. Where as in only Hyperlipidemia without Type 2 Diabetes mellitus patients, the percentage decrease in parameters like, TC, and TG were, 13%, and 14%, in Atorvastatin group compared to 25% and 28%, in Atorvastatin+Fenofibrate group. The increase in HDL-C level was 19% in Atorvastatin+Fenofibrate group as compared to 12% in Atorvastatin group and the increase in RBS was 3% in Atorvastatin group as compared to 4% in Atorvastatin+Fenofibrate.

Conclusion: The efficacy of percentage decrease lipid parameters was slightly better treated with combination therapy than compare to monotherapy in Type 2 Diabetes mellitus patients. Both monotherapy and combination therapy were safe and well tolerated.

Keywords: Hyperlipidemia, Type II Diabetes mellitus, Atorvastatin, Fenofibrat

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