

Efficacy and tolerability of 12-weeks treatment with lipanthyl supra or trichol in Indonesian patients with dyslipidemia

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Abstrak

Hubungan antara dislipidemia dengan terjadinya aterosklerosis dan penyakit jantung koroner sudah terbukti dalam banyak studi. Penelitian ini bertujuan mengevaluasi perubahan kadar lipid setelah pemberian fenofibrat produksi lokal (trichol) atau lipanthyl supra pada pasien dislipidemia di RSJPD Harapan Kita secara teracak (randomized) dan tersamar (double-blinded). Sebanyak 68 pasien dengan kadar HDL ≤ 40 mg/dL; trigliserida $200-600$ mg/dl; dan/atau LDL ≥ 130 mg/dL diikutsertakan sebagai subyek penelitian. Subyek dirandomisasi untuk mendapatkan lipanthyl 160 mg satu kali/hari atau trichol 300 mg satu kali/hari. 61 pasien mengikuti uji klinik ini sampai selesai. Kadar lipid sebelum terapi (data dasar) dan 4, 8, 12 minggu setelah terapi diperiksa dan dianalisis. Dibandingkan dengan data dasar, terapi selama 12 minggu mampu meningkatkan kadar HDL sebesar 18.8% dan 14.3% ($P < 0.001$), menurunkan kadar trigliserida sebesar 38.2% dan 37.2% ($P < 0.001$), meningkatkan kolesterol total sebesar 3.1% ($P = 0.114$) dan 8.4% ($P < 0.005$), menurunkan rasio kolesterol total/HDL sebesar 17.6% dan 18.4% ($P < 0.001$), meningkatkan ApoA-1 sebesar 15.0% dan 9.7% dan menurunkan kadar fibrinogen sebesar 13.8% dan 6.4% untuk lipanthyl dan trichol. Tidak ada perbedaan yang bermakna pada kadar LDL untuk kedua grup. Hal yang menarik adalah trichol mampu menurunkan tingkat kolesterol total ($P < 0.05$) lebih baik dibanding lipanthyl. Efek samping yang diakibatkan oleh kedua perlakuan tidak berbeda bermakna. Terapi dengan trichol dan lipanthyl mampu memperbaiki kadar lipid pasien dislipidemia. Kedua obat meningkatkan kadar HDL dan menurunkan kadar trigliserida secara bermakna. Selain itu, penurunan kadar kolesterol total secara bermakna dapat dicapai setelah 12 minggu terapi dengan trichol tetapi tidak dengan lipanthyl. (Med J Indones 2007; 16:159-67)

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The relation of dyslipidemia with the development and progression of atherosclerosis and coronary artery diseases has been demonstrated. This study compared the lipid modifying effects of locally-manufactured fenofibrate (trichol) versus lipanthyl supra in a randomized double-blind controlled study. A total of sixty-eight patients with levels of HDL cholesterol ≤ 40 mg/dL; triglyceride of $200-600$ mg/dL; or LDL of ≥ 130 mg/dL were recruited to this study and were randomized to either receive trichol 300 mg once daily or lipanthyl 160 mg once daily. Sixty one patients completed the study. Lipid levels before and 4, 8, and 12 weeks after the treatments were measured and analyzed. Compared to baseline values, 12-weeks treatment with either lipanthyl or trichol significantly increased plasma HDL by 18.8% and 14.3% respectively ($P < 0.001$), decreased triglyceride by 38.2% and 37.2% ($P < 0.001$), but with no significant change in LDL levels. Furthermore, we observed a decreased in total cholesterol levels compare to baseline by 8.4% ($P < 0.05$) and 3.1% ($P = 0.114$), in total cholesterol/ HDL ratio by 17.6% and 18.4% ($P < 0.001$), in fibrinogen level by 13.8% and 6.4% and an increase in ApoA-1 by 15.0% and 9.7% for lipanthyl and trichol, respectively. Interestingly, the decrease in total cholesterol level is significantly higher in trichol than lipanthyl groups ($P < 0.05$). The adverse events of both treatments were comparable. The lipid-modifying

effects of 300 mg daily dose of trichol is comparable to that of 160 mg daily dose of lipanthyl. Both drugs efficiently increased the plasma HDL levels and decreased plasma triglycerides concentration. Besides, a significant reduction of total cholesterol was achieved after 12 weeks treatment with trichol, but not lipanthyl. (Med J Indones 2007; 16:159-67)