

INTISARI

Neuropati diabetik (ND) merupakan komplikasi umum DMT2 yang menyebabkan nyeri neuropatik. Terapi kombinasi gabapentinoid dengan vitamin B12 banyak digunakan secara klinik, namun bukti perbandingan efektivitas dan keamanan antara kombinasi pregabalin dengan vitamin B12 (PB12) dan gabapentin dengan vitamin B12 (GB12) di Indonesia masih terbatas. Penelitian ini bertujuan membandingkan efektivitas dan keamanan dari kombinasi GB12 dan PB12 dalam menurunkan nyeri.

Desain penelitian ini adalah analitik observasional dengan rancangan kohort retrospektif dengan pengambilan data secara *consecutive sampling* di Rumah Sakit Akademik Universitas Gadjah Mada. Sebanyak 66 subjek penelitian pasien DMT2 dengan neuropati perifer yang menerima terapi kombinasi GB12 atau kombinasi PB12 selama sekitar 2 bulan. Data demografi, skor nyeri (*Visual Analog Scale/VAS*) dan efek samping dikumpulkan dari rekam medis. Analisis statistik menggunakan uji *Chi-Square/Fisher's Exact* untuk melihat kesetaraan pada karakteristik subjek, uji *Mann-Whitney* untuk melihat perbedaan efektivitas terapi, regresi logistik biner untuk melihat hubungan terapi terhadap penurunan VAS, analisis *Kruska-wallis* untuk melihat perbedaan efektivitas pada setiap dosis agen terapi, analisis *Kruska-wallis* dan *Mann-Whitney* untuk seleksi variabel perancu, dan regresi linear berganda untuk menganalisis faktor perancu.

Hasil penelitian menunjukkan bahwa kelompok PB12 mengalami penurunan skor VAS signifikan dibandingkan GB12 dengan median (min-max) adalah -2 (-4 – 2) vs 0 (-6 – 4); $p=0,004$. Pasien pada kelompok kombinasi PB12 memiliki *odds ratio* 5,33 dibandingkan kombinasi GB12 untuk mencapai penurunan nyeri $\geq 30\%$ ($p=0,002$). Efek samping GB12 vs PB12 yang dilaporkan yaitu edema (2 vs 3), vertigo (1 vs 1) dan gemetar (0 vs 1). Analisis multivariat menunjukkan bahwa PB12 tetap signifikan setelah menganalisis Durasi DMT2 dan penggunaan obat lain. Tidak ada perancu yang secara signifikan memengaruhi penurunan nilai VAS.

Berdasarkan penelitian diatas, disimpulkan bahwa PB12 lebih efektif dalam menurunkan nyeri neuropati diabetik dibandingkan GB12, dengan profil keamanan yang setara. Temuan ini memberikan bukti pendukung untuk pertimbangan terapi pada populasi Indonesia.

Kata kunci: Neuropati Diabetik, Gabapentin, Pregabalin, Vitamin B12, Efektivitas

ABSTRACT

Diabetic Neuropathy (DN) is a common complication of type 2 diabetes mellitus (T2DM) that causes neuropathic pain. Although combination therapy with gabapentinoids and vitamin B12 is widely used in clinical practice, comparative evidence on the effectiveness and safety between the combination of pregabalin with vitamin B12 (PB12) and gabapentin with vitamin B12 (GB12) in Indonesia remains limited. This study aimed to compare the effectiveness and safety of the GB12 and PB12 combinations in reducing pain.

This study employed an observational analytic design with a retrospective cohort approach, using consecutive sampling data collection at the Academic Hospital of Universitas Gadjah Mada. A total of 66 study subjects, consisting of T2DM patients with peripheral neuropathy who received either the GB12 combination therapy or the PB12 combination therapy for approximately two months, were included. Demographic data, pain scores (Visual Analog Scale/VAS), and adverse effects were collected from medical records. Statistical analysis utilized the Chi-Square/Fisher's Exact test to assess baseline characteristic comparability, the Mann-Whitney test to evaluate differences in therapy effectiveness, binary logistic regression to examine the relationship between therapy and VAS reduction, Kruskal-Wallis analysis to compare effectiveness across different doses of therapeutic agents, Kruskal-Wallis and Mann-Whitney analyses for confounding variable selection, and multiple linear regression to analyze confounding factors.

The results demonstrated that the PB12 group experienced a significant reduction in VAS scores compared to the GB12 group, with a median (min-max) of -2 (-4 – 2) vs. 0 (-6 – 4); $p=0.004$. Patients in the PB12 combination group had an odds ratio of 5.33 compared to the GB12 combination group for achieving a $\geq 30\%$ pain reduction ($p=0.002$). The reported adverse effects for GB12 vs. PB12 were edema (2 vs. 3), vertigo (1 vs. 1), and tremor (0 vs. 1). Multivariate analysis revealed that PB12 remained significantly associated with greater pain reduction after adjusting for T2DM duration and the use of other medications. No confounding factors were found to significantly influence the reduction in VAS scores.

Based on this study, it is concluded that PB12 is more effective in reducing diabetic neuropathic pain compared to GB12, with an equivalent safety profile. These findings provide supporting evidence for therapeutic consideration in the Indonesian population.

Keywords: Diabetic Neuropathy, Gabapentin, Pregabalin, Vitamin B12, Efficacy