

ABSTRACT

CHANGES IN VISION RELATED QUALITY OF LIFE AFTER KETOROLAC INTRAVITREAL INJECTION COMPARED WITH BEVACIZUMAB INTRAVITREAL INJECTION IN DIABETIC MACULAR EDEMA

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Introduction and objective

Visual acuity has been the main outcome measure used in clinical practice to assess function, including in the treatment for diabetic macular edema (DME), however it may not optimally measured a patient's self-assessment of well-being, expectations and demands. The purpose of our study was to compare the changes in vision related quality of life (VR-QoL) in patients with DME undergoing intravitreal ketorolac injection or intravitreal bevacizumab injection.

Methods

In this randomized, double-blind, noninferiority trial, 50 patients with DME based on ocular computed tomography (OCT) examination were enrolled to IVK injection (n = 25) and IVB injection (n = 25). The 25-item National Eye Institute Visual Function Questionnaire (NEI VFQ-25) with interview method was used to measure the VR-QoL after 1 months following IVK or IVB treatment. The statistical analysis compared scores between the two groups for all sub-scales of the NEI VFQ-25 questionnaire. Noninferiority margin was set at -3.1.

Results

The demographic characteristics and clinical findings before the treatments were similar in both groups. One month after IVK injection, significant improvements were observed in composite scores, general health, general vision, distance visual activities and mental health ($p < 0.05$). Patients in the IVB group also had significant improvements in composite scores, general health, general vision, near visual activities, mental health, role difficulties and peripheral vision ($p < 0.05$). The changes in composite scores and all subscale scores were lower in the IVK group than in the IVB group ($p > 0.05$). The improvements in best corrected visual acuity (BCVA) were higher in the IVB group than the IVK group ($p = 0.072$).

Conclusion

Among patients with DME, IVK injection compared with IVB injection failed to meet the criterion for noninferiority for VR-QoL outcomes. In the IVB and IVK group there were improvement in quality of life score.

Keywords: Diabetic macular edema, Intravitreal ketorolac, Intravitreal bevacizumab, VFQ-25

INTISARI

PERUBAHAN KUALITAS HIDUP TERKAIT PENGLIHATAN PADA INJEKSI INTRAVITREAL KETOROLAK DIBANDINGKAN DENGAN INJEKSI INTRAVITREAL BEVACIZUMAB PADA PASIEN EDEMA MAKULA DIABETIKA

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Pendahuluan dan tujuan

Ketajaman visual menjadi ukuran hasil utama digunakan klinis menilai fungsi, termasuk dalam pengobatan edema makula diabetika (DME), namun mungkin tidak optimal mengukur penilaian pasien tentang kesejahteraan, harapan dan tuntutan. Penelitian ini bertujuan membandingkan perubahan kualitas hidup penglihatan (*VR-QoL*) pasien EMD menjalani injeksi intravitreal ketorolak atau bevacizumab.

Metode

Desain penelitian ini adalah eksperimental uji acak ganda terkontrol, *double-blind*, *noninferiority*. Penelitian pada 50 pasien EMD berdasarkan *ocular computed tomography (OCT)* dibagi dua kelompok yaitu injeksi intravitreal ketorolak ($n = 25$) dan bevacizumab ($n = 25$). Wawancara dengan 25 pertanyaan kuesioner *National Eye Institute Visual Function Questionnaire (NEI VFQ-25)* untuk mengukur *VR-QoL* satu bulan pasca injeksi. Analisis statistik membandingkan perubahan skor antara kedua kelompok untuk semua subskala dari kuesioner NEI VFQ-25. Batas *margin noninferiority* ditetapkan pada angka -3,1.

Hasil

Karakteristik demografi sebelum terapi menunjukkan kondisi homogen kedua kelompok. Satu bulan setelah injeksi intravitreal ketorolak, terdapat peningkatan skor signifikan skor total, kesehatan umum, penglihatan umum, aktivitas penglihatan jauh dan kesehatan mental ($p < 0,05$). Pasien kelompok bevacizumab mengalami peningkatan signifikan skor total, kesehatan umum, penglihatan umum, aktivitas penglihatan dekat, kesehatan mental, kesulitan peran dan penglihatan perifer ($p < 0,05$). Perubahan semua skor menunjukkan ketorolak lebih rendah dibanding bevacizumab ($p > 0,05$). Perbaikan visus *best corrected visual acuity (BCVA)* menunjukkan lebih tinggi bevacizumab dibanding ketorolak ($p = 0,072$).

Kesimpulan

Perubahan kualitas hidup terkait penglihatan pada pasien edema makula diabetika mendapat intravitreal ketorolak lebih inferior dibandingkan bevacizumab. Pada kelompok ketorolak dan bevacizumab didapatkan peningkatan skor kualitas hidup.

Kata kunci: Edema makula diabetika, injeksi ketorolak intravitreal, injeksi bevacizumab intravitreal, VFQ-2PCR