

Penggunaan Denosumab pada Tata Laksana Giant Cell- Tumour: Meta Analisis = Denosumab in the Management of Giant Cell Tumor: A Meta Analysis

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Abstrak

Pendahuluan: World Health Organization (WHO) mendefinisikan Giant Cell-Tumour (GCT) merupakan tumor tulang yang bersifat jinak, mempunyai sifat dan kecenderungan untuk agresif lokal. Tujuan tata laksana GCT adalah menghilangkan jaringan tumor, mempertahankan fungsi tulang yang terkena, serta mencegah rekurensi. Sampai saat ini belum ada konsensus seragam untuk tata laksana GCT primer.

Denosumab merupakan antibodi monoklonal yang berikatan dengan RANKL. Dengan adanya ikatan antara denosumab dengan RANKL, ikatan antara RANKL dengan RANK tidak terjadi, sehingga diharapkan tidak terjadi pertumbuhan tumor. Akan tetapi masih ada beberapa masalah yang masih menjadi pertanyaan antara lain: apakah pemakaian denosumab menurunkan angka rekurensi dibandingkan tata laksana konvensional sebelumnya, bagaimana efikasi denosumab pada tata laksana GCT, serta berapa dosis dan lama terapi denosumab diberikan. Dengan belum adanya pedoman baku penggunaan denosumab, dan belum adanya telaah sistematis serta penelitiannya di Indonesia, maka meta-analisis ini dilakukan untuk menjawab pertanyaan-pertanyaan tersebut dalam membantu menyusun pedoman penggunaannya sehingga menghasilkan kebijakan baru dalam tata laksana GCT di Indonesia.

Metode: Telah dilakukan pencarian dalam lima database menggunakan kata kunci ("DENOSUMAB" AND ("GIANT CELL TUMOR" OR "GCT") AND "OUTCOME"). Penilaian risiko bias studi dengan desain randomized controlled trial dilakukan dengan Cochrane Collaboration's tool for assessing risk of bias, sedangkan penilaian risiko bias studi dengan desain nonrandomized controlled trial dan kohort dilakukan dengan Newcastle-Ottawa Quality Assessment Form for cohort study.

Hasil Setelah diseleksi, didapatkan 21 studi yang dilakukan penilaian risiko bias. Meta-analisis menemukan bahwa terdapat 85,5% (IK95%: 74,9-96,0%) pasien mendapatkan perbaikan klinis; perbaikan radiologis pada 82,4% (95% IK: 73,3-91,4%) pasien; perubahan histopatologis pada 96,5% (95% IK: 93,6-99,3%) pasien; serta rekurensi sebesar 27,2% (95% IK: 18,7-35,7%) dan rekurensi pada denosumab dibanding kontrol yakni RR: 2,6 (95% CI: 1,66-4,09); total kejadian efek samping berat pada rahang sebesar 2,7% (95% IK: 1,4-4,0%).

Kesimpulan: Administrasi Denosumab pada pasien GCT sebagai terapi sistemik memiliki efikasi yang baik dalam perbaikan klinis; perbaikan radiologis; penurunan aktivitas sel GCT; potensi efek samping yang rendah; akan tetapi angka kejadian rekurensi lebih tinggi dibanding kontrol. Meski demikian, studi komparatif eksperimen acak terkontrol dirasa perlu lebih banyak untuk meningkatkan kualitas hasil studi.

.....Introduction: The World Health Organization (WHO) defines GCT as a benign bone tumor, with the nature and tendency for local aggressiveness. The goal of GCT management is to remove tumor tissue, maintain the function of the affected bone, and prevent recurrence. To date there has been no uniform consensus for primary GCT management. Denosumab is a monoclonal antibody that binds to RANKL. With the bond between denosumab and RANKL, the bond between RANKL and RANK does not occur, so that no tumor growth is expected. However, there are still a number of questions that remain questionable,

among others: whether the use of denosumab reduces recurrence rates compared to previous conventional management, how the efficacy of denosumab in the management of GCT, and how much dose and duration of denosumab therapy is given. With no standard guidelines for using denosumab, and no systematic study and research in Indonesia. This meta-analytic study was conducted to answer these questions in helping to develop guidelines for their use so as to produce new policies in the management of GCT in Indonesia.

Methods: Five databases have been searched using keywords ("DENOSUMAB" AND ("GIANT CELL TUMOR" OR "GCT") AND "OUTCOME"). After being selected, 21 studies were carried out with a bias risk assessment with the Newcastle-Ottawa Quality Assessment Form for cohort studies for studies with cohort designs and nonrandomized controlled trials while for one study a randomized controlled trial was conducted with the Cochrane Collaboration's tool for assessing risk of bias with results 4 poor quality studies.

Results: The meta-analysis found that there were 85.5% (CI 95%: 74.9-96.0%) patients received clinical improvement, there was a reduction in VAS scale pain in 98.9% (CI 95%: 96.5-101.4%) patient; radiological improvement in 85.5% 82.4% (95% CI: 73.3-91.4%) patients; histopathological changes in 96.5% (95% CI: 93.6-99.3%) patients; and recurrence of 27.2% (95% CI: 18.7-35.7%) and recurrence in denosumab compared to controls namely RR: 2.6 (95% CI: 1.66-4.09); the total incidence of severe side effects on the jaw was 2.7% (95% CI: 1.4-4.0%).

Conclusions: Denosumab administration in GCT patients as a systemic therapy has good efficacy in clinical improvement; radiological repair; decreased GCT cell activity; low potential for side effects; however the recurrence rate is higher than the control. However, comparative studies of randomized controlled trials are deemed necessary to improve the quality of study results.