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Basiliximab

Updated: September 21, 2017.

OVERVIEW

Introduction

Basiliximab is a chimeric mouse-human monoclonal antibody to CD25, the alpha subunit of the IL-2 receptor, which is found on the surface of T cells. Basiliximab has potent immunosuppressive activity and is used for prevention of organ transplant rejection. Basiliximab has not been linked to serum enzyme elevations during therapy or implicated in cases of clinically apparent liver injury.

Background

Basiliximab (ba" si lix' i mab) is a recombinant humanized monoclonal IgG1 kappa antibody to the alpha subunit of the IL2 receptor (CD25). The IL2 receptor is found on T cells and its engagement results in activation of T cells and generation of pro-inflammatory cytokines. Inhibition of the receptor with antibody results in prevention of activation and proliferation of T cells and inhibition of T cell responses. Basiliximab has been shown to decrease the rate of acute cellular rejection after solid organ transplantation and to improve long term graft and patient survival. Basiliximab was approved for use in the United States in 1998 for renal transplantation and continues to be used, typically in induction regimens starting at the time of or shortly before transplantation. It is also used off-label for liver, heart and lung transplantation. Basiliximab has been under evaluation in several autoimmune diseases. Basiliximab is available in powder form in single dose vials of 10 and 20 mg under the brand name Simulect. The recommended regimen of basiliximab is two doses of 20 mg each, each dose given intravenously, the first 2 hours before and the second 4 days after transplantation. The dose in children is 10 mg in the same schedule. Basiliximab should be prescribed only by physicians with experience in immunosuppressive therapy and management of organ transplant patients. Common side effects include infusion reactions, chills, fever, skin rash, fatigue, diarrhea, nausea, headache, anorexia, leukopenia and infections. Rare, but potentially severe side effects include acute hypersensitivity reactions, anaphylaxis, capillary leak syndrome, cytokine release syndrome and progressive multifocal leukoencephalopathy.

Hepatotoxicity

Because basiliximab is typically given at the time of renal or liver transplantation, its role in causing serum aminotransferase or alkaline phosphatase elevations is usually difficult to define. In general, side effects including liver test abnormalities have been no more frequent after basiliximab therapy as with placebo or comparator treatments. There have been no reports of clinically apparent liver injury attributable to basiliximab infusions. Basiliximab is a monoclonal antibody and is metabolized in the liver, but is unlikely to have intrinsic toxicity.

Basiliximab has potent immunosuppressive activity and might be expected to cause reactivation of chronic hepatitis B. Neither problem has been reported with basiliximab, possibly because patients undergoing solid organ transplantation are usually screened for hepatitis B and routinely given prophylaxis against reactivation. Similarly for chronic hepatitis C, the immunosuppression that is given to prevent transplant rejection can worsen hepatitis C, but basiliximab infusions at the time of transplant do not appear to affect the course of subsequent hepatitis C. In prospective studies, basiliximab based, corticosteroid-free immunosuppressive regimens have not had a clear advantage over standard regimens in ameliorating chronic hepatitis C.

Likelihood score: E (unlikely cause of clinically apparent liver injury).

Drug Class: Transplant Agents, Monoclonal Antibodies

Other Drugs in the Subclass, Monoclonal Antibodies: Alemtuzumab, Daclizumab, Muromonab

PRODUCT INFORMATION

REPRESENTATIVE TRADE NAMES

Basiliximab – Simulect®

DRUG CLASS

Transplant Agents

COMPLETE LABELING

Product labeling at DailyMed, National Library of Medicine, NIH

CHEMICAL FORMULA AND STRUCTURE

DRUG	CAS REGISTRY NO.	MOLECULAR FORMULA	STRUCTURE
Basiliximab	**179045-86-4**	Monoclonal Antibody	Not Available

ANNOTATED BIBLIOGRAPHY

References updated: 21 September 2017

Reuben A. Hepatotoxicity of immunosuppressive drugs. In, Kaplowitz N, DeLeve LD, eds. Drug-induced liver disease. 3rd ed. Amsterdam: Elsevier, 2011, pp. 569-91.

(Review of hepatotoxicity of immunosuppressive agents mentions rituximab and problems of reactivation of hepatitis B, but also states that "the biological immunosuppressants are largely free from hepatotoxicity, with the exception of the TNF alpha antagonists").

Chabner BA, Barnes J, Neal J, Olson E, Mujagiv H, Sequist L, Wilson W, et al. Targeted therapies: tyrosine kinase inhibitors, monoclonal antibodies, and cytokines. In, Brunton LL, Chabner BA, Knollman BC, eds. Goodman & Gilman's the pharmacological basis of therapeutics. 12th ed. New York: McGraw-Hill, 2011, pp. 1731-53.

(Textbook of pharmacology and therapeutics).

New monoclonal antibodies to prevent transplant rejection. Med Lett Drugs Ther 1998; 40 (1036): 93-4. PubMed PMID: 9774964.

(Concise review of the efficacy and safety of basiliximab and daclizumab, two monoclonal antibodies to the IL2 receptor, shortly after their approval for use in transplantation in the US; no mention of ALT elevations or hepatotoxicity for either).

Nashan B, Moore R, Amlot P, Schmidt AG, Abeywickrama K, Soulillou JP. Randomised trial of basiliximab versus placebo for control of acute cellular rejection in renal allograft recipients. CHIB 201 International Study Group. Lancet 1997; 350 (9086): 1193-8. PubMed PMID: 9652559.

(Among 380 kidney transplant recipients given basiliximab or placebo on day 0 and 4 after transplant followed by standard immunsuppressive therapy, acute rejection within 6 months was less with basiliximab [30% vs 44%], but the pattern and frequency of side effects were similar and "no clinically relevant differences were found between the two groups in terms of changes in laboratory indices").

Marino IR, Doria C, Scott VL, Foglieni CS, Lauro A, Piazza T, Cintorino D, et al. Efficacy and safety of basiliximab with a tacrolimus-based regimen in liver transplant recipients. Transplantation 2004; 78: 886-91. PubMed PMID: 15385809.

(Among 50 patients undergoing liver transplantation who received basiliximab on days 0 and 4 after transplant, 88% remained rejection-free and the infusions were well tolerated with no immediate side effects).

Lladó L, Xiol X, Figueras J, Ramos E, Memba R, Serrano T, Torras J, et al.; Thosin Study Group. Immunosuppression without steroids in liver transplantation is safe and reduces infection and metabolic complications: results from a prospective multicenter randomized study. J Hepatol 2006; 44: 710-6. PubMed PMID: 16487622.

(Among 198 patients undergoing liver transplantation given induction therapy with basiliximab and treated with tacrolimus, rates of acute rejection, recurrent hepatitis C and survival were similar with or without corticosteroids, but new onset hypertension and diabetes were less; no immediate side effects of basiliximab were reported).

Schmeding M, Sauer IM, Kiessling A, Pratschke J, Neuhaus R, Neuhaus P, Neumann UP. Influence of basiliximab induction therapy on long term outcome after liver transplantation, a prospectively randomised trial. Ann Transplant 2007; 12: 15-21. PubMed PMID: 18290565.

(Among 99 patients undergoing liver transplantation with or without basiliximab induction, the incidence and severity of rejection and both graft and patient survival were similar; basiliximab had no discernable acute adverse reactions).

Gras JM, Gerkens S, Beguin C, Janssen M, Smets F, Otte JB, Sokal E, Reding R. Steroid-free, tacrolimus-basiliximab immunosuppression in pediatric liver transplantation: clinical and pharmacoeconomic study in 50 children. Liver Transpl 2008; 14: 469-77. PubMed PMID: 18383091.

(Among 50 children undergoing liver transplantation who received basiliximab and tacrolimus without corticosteroids, 3 year patient and graft survival were excellent [96% and 94%] and no adverse events attributable to basiliximab were observed).

Kandus A, Arnol M, Omahen K, Oblak M, Vidan-Jeras B, Kmetec A, Bren AF. Basiliximab versus daclizumab combined with triple immunosuppression in deceased donor renal transplantation: a prospective, randomized study. Transplantation 2010; 89: 1022-7. PubMed PMID: 20075788.

(Among 212 patients given induction therapy before renal transplantation with either basiliximab or daclizumab, there were no differences in rates of rejection, graft or patient survival or adverse events; no mention of ALT elevations or hepatotoxicity).

Cai J, Terasaki PI. Induction immunosuppression improves long-term graft and patient outcome in organ transplantation: an analysis of United Network for Organ Sharing registry data. Transplantation 2010; 90: 1511-5. PubMed PMID: 21057388.

(Since 2003, most solid organ transplant recipients have received induction therapy and analyses of the UNOS registry for this period show highest rates of patient and graft survival with alemtuzumab [89% 5 year patient survival] as compared to antithymocyte globulin [89%], basiliximab [84%], daclizumab [77%], steroids [75%] or no induction [71%]).

Klintmalm GB, Davis GL, Teperman L, Netto GJ, Washburn K, Rudich SM, Pomfret EA, et al. A randomized, multicenter study comparing steroid-free immunosuppression and standard immunosuppression for liver transplant recipients with chronic hepatitis C. Liver Transpl 2011; 17: 1394-403. PubMed PMID: 21850690.

(Among 295 patients undergoing liver transplantation for chronic hepatitis C treated with daclizumab, mycophenolate and tacrolimus or a corticosteroid containing regimen without daclizumab, there were no differences between groups in graft or patient survival or in biochemical and histological severity of recurrent hepatitis C).

Ponticelli C. Basiliximab: efficacy and safety evaluation in kidney transplantation. Expert Opin Drug Saf 2014; 13: 373-81. PubMed PMID: 24266670.

(Review of efficacy and safety of basiliximab concludes that it "can significantly decrease the risk of acute rejection in kidney transplant recipients without increasing adverse events").

Tan Y, Xiao H, Wu D, Luo Y, Lan J, Liu Q, Yu K,et al. Combining therapeutic antibodies using basiliximab and etanercept for severe steroid-refractory acute graft-versus-host disease: A multi-center prospective study. Oncoimmunology. 2017; 6: e1277307. PubMed PMID: 28405499.

(Among 65 patients with severe, steroid-resistant graft-vs-host disease after hematopoietic cell transplant treated with baxiliximab and etanercept, the complete response rate was 75% and there were no reports of severe hepatic adverse events).

Melis M, Biagi C, Småbrekke L, Nonino F, Buccellato E, Donati M, Vaccheri A, et al. Drug-induced progressive multifocal leukoencephalopathy: a comprehensive analysis of the WHO adverse drug reaction database. CNS Drugs 2015; 29: 879-91. PubMed PMID: 26507833.

(Among 1617 reports of PML entered into the WHO VigiBase between 1968 and 2014, commonly associated drugs included rituximab [519], natalizumab [618], rituximab [519], methotrexate [244] and cyclophosphamide [215], but also alemtuzumab [38], ATG [11] and basilixumab [4]).