Nursing care for patients who received therapy with monoclonal antibodies

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Introduction

Immunotherapy with monoclonal antibodies (Mabs) is a new type of leukemia treatment, being gradually introduced into the practice of Russian hematological clinics. Most drugs comprise a part of the extended access group, and do not have instructions in Russian. Aim of the present study was to consider the strategy of care for the patients who received therapy with monoclonal antibodies, and to suggest recommendations for the nurses working with monoclonal antibodies.

Materials and methods

The study included 45 patients. All the patients received treatment and medical care in the BMT Department No.1, at the R.Gorbacheva Memorial Institute for Children Oncology, Hematology and Transplantation. Their median age was 8.7 years (4 months to 17 years old). Acute lymphoblastic leukemia (ALL) was diagnosed in 80% (n=36), acute myeloblastic leukemia (AML) was found in 13.3% (n=6), and acute biphenotypic leukemia was detected in 6.7% (n=3) (ABL). The therapy with Blinatumomab was applied to 36 patients, Mylotarg was administered in 6 cases, and 5 patients received Inotuzumab ozogamicin.

Results

62.2% of the patients (n=28) exhibited febrile fever. After therapy with Mabs, a related hematopoietic stem cell transplantation (HSCT) was performed for 35.5% of patients (n=16), 26.7% of patients (n=12) received haploidentical HSCT, and 37.8% (n=17) did not underwent HSCT. Against the August 2018, 64.4% (n=29) of patients were alive.

Conclusion

Most patients were treated with monoclonal antibodies as the third-line therapy. Treatment and care for such patients require special attention. Also, in the absence of instructions in Russian language, it is necessary to compile an operation procedure for preparing a solution with monoclonal antibodies.

Keywords

Immunotherapy, Mylotarg, monoclonal antibodies, Blinatumomab, Inotuzumab.

Сестринский уход за пациентами, получившими терапию моноклональными антителами

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Введение

Иммунотерапия моноклональными антителами – это новый вид лечения лейкозов, постепенно вводимый в практику российских гематологических клиник. Большинство препаратов входят в группу расширенного доступа, и не имеют инструкции на русском языке.

Цель работы

Рассмотреть тактику ухода за пациентами, получившими терапию моноклональными антителами. Предложить рекомендации для медицинских сестер, работающих с моноклональными АТ.

Материалы и методы

В исследование было включено 45 человек, все они являлись пациентами отделения трасплантации костного мозга для детей №1 (ОТКМ №1) НИИ ДОГиТ им. Р. М. Горбачевой. Медиана возраста составила 8,7 лет (4 мес. – 17 лет). У 80% (n=36) диагностирован острый лимфобластный лейкоз (ОЛЛ), у 13,3% (n=6) острый миелобластный лейкоз (ОМЛ), а у 6,7% (n=3) был выявлен острый бифенотипический лейкоз (ОБЛ). Терапию Блинатумомабом получило 36 пациентов, Милотаргом – 6 человек, а Инотузумаб озогамицин получили 5 пациентов.

Результаты

У 62,2% (n=28) встречалась фебрильная лихорадка. После терапии моноклональными АТ 35,5% (n=16) была проведена родственная трансплантация гемопоэтических стволовых клеток (ТГСК), 26,7% (n=12) получили гаплоидентичную ТГСК, а 37,8 (n=17) не получали ТГСК. На август 2018 года живы 64,4% (n=29) пациентов.

Выводы

Большинство пациентов получили терапию моноклональными АТ в качестве 3-й линии терапии. Лечение и уход за такими пациентами требуют особого внимания. Также, за неимением инструкции на русском языке, необходимо составить регламент приготовления раствора с моноклональным АТ.

Ключевые слова

Иммунотерапия, Милотарг, моноклональные антитела, Блинатумомаб, Инотузумаб.

A pilot study of ruxolitinib combined with cyclophosphamide for graft-versus-host disease prophylaxis and relapse prevention in patients with myelofibrosis: a prospective study

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Introduction

Allogeneic stem cell transplantation (allo-HSCT) is currently the only treatment modality with curative potential in patients with myelofibrosis (MF), although transplant-associated complications and relapses significantly reduce the application of this method. JAK1/JAK2 inhibitor ruxolitinib is effective in reducing symptomatic splenomegaly and myelofibrosis-related symptoms. At the same time it has significant immunomodulatory effect, and is used for the treatment of steroid-refractory acute and chronic graft-versus-host disease (GVHD). This study evaluated calcineurin inhibitor-free GVHD prophylaxis regimen with ruxolitinib in combination with posttransplant cyclophosphamide (PTCy).

Patients and methods

Twenty patients at a median age of 51 (32-61) years were enrolled in the study. Two patients were diagnosed with post-essential thrombocythemia myelofibrosis, 4, with post-polycythemia vera myelofibrosis; 14, with primary myelofibrosis. By the DIPSSplus scale, 11 patients had intermediate-2, 8 patients had high-risk disease and 1 patient was transplanted in blast crisis. Fifteen patients were positive for *JAK2V617F*; 3 were *CALR*-positive; and 2 were *MPL*-positive before alloHSCT. All patients were treated with JAK1/2 inhibitors before alloHSCT, with median treatment duration of 6 months (3-22) at a dose of 30-45 mg. The disease stabilization occurred in 11 patients; clinical improvement, in 8, and the disease progression was observed in 1 case. Splenectomy was performed in 7 patients, due to poor spleen response. Reduced-intensity conditioning (fludarabine 180 mg/m^2 plus busulfan 8-10 mg/kg) followed by allo-HSCT performed from full-matched related (n=3) or unrelated donor (n=10), and mismatched HSCT (HLA 9/10) from unrelated (n=2) or haploidentical donor (n=5). Graft-versus-host disease (GVHD) prophylaxis consisted of posttransplant cyclophosphamide 100 mg/kg at day +3, +4 and ruxolitinib 5-7.5 mg bid from day+5 to day +50 (n=2), and day +100 (n=18). G-CSF-mobilized peripheral blood progenitor cells (n=19) and bone marrow (n=1) were used as stem cell sources. Median number of CD34+cells/kg was 6.7x10^6 (1.4-12.0). The trial is registered on clinicaltrials.gov, NCT02806375.

Results

Median follow-up time was 18 (6.6–36.1) months. Primary engraftment was documented in 18 patients. Median time to leukocyte engraftment was 32 days (18-61), to platelet engraftment, 38 days (15-219). One patient received second transplantation from the same donor due to primary graft failure. He died in cytopenia accomplished by sepsis. Severe poor graft function was documented in 11 patients. In 7 of these cases, it resolved spontaneously with a median duration of 79 days (16-470). Three patients recovered after CD34+ boost administration. Dose reduction of ruxolitinib to 10 mg/day due to poor graft function was performed in 8 patients. Three out of four deaths occurred before engraftment: one patient was lost due to *Pseudomonas aeruginosa* sepsis, one death was associated with gastrointestinal bleeding, and one patient deceased due to primary graft failure and sepsis. One patient died due to thrombotic microangiopathy and sepsis on D+115. Twenty-nine percent of