(p=0,048) и составила 18,2% и 44,8%, соответственно. 10-летняя ОВ в 3 группе пациентов не достигнута. ОВ в 3 группе пациентов ниже на 15% по сравнению с пациентами высокой группы риска ДХА.

Заключение

Обнаружение ДХА у пациентов с ХМЛ считается неблагоприятным прогностическим фактором в плане ответа на терапию ИТК, однако значение влияния ДХА на исходы алло-ТГСК до сих пор не были вполне определено. В нашем исследовании не было получено статистически достоверной разницы в ОВ между реципиентами, имеющими ДХА высокого и низкого риска, однако было определено, что мутации в BCR/ABL KD представляют неблагоприятный прогностический фактор, приводящий к снижению ОВ у пациентов с ХМЛ после алло-ТГСК.

Ключевые слова

Хронический миелолейкоз, Ph-хромосома, дополнительные хромосомные аберрации, BCR/ABL, алло-ТГСК.

Nursing care for patients who received monoclonal antibody therapy

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Introduction

Immunotherapy with monoclonal antibodies is a new type of leukemia treatment, gradually introduced into the practice of Russian hematological clinics. Most drugs are part of the extended access group, and do not have instructions in Russian. Aim of our work was to consider management and care of patients who received therapy with monoclonal antibodies, suggestion of recommendations for the nurses working with monoclonal antibody-based drugs.

Materials and methods

The study included 45 patients. All patients received treatment and were observed at the department of bone marrow transplantation No.1. The median of age was 8.7 years (4 months to 17 years). 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 – to 6 people, and 5 patients received Inotuzumab ozogamicin.

Results

62.2% of patients (n=28) had the febrile fever. After therapy with monoclonal AB, a compatible 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 receive HSCT. As of August 2018, 64.4% (n=29) of patients were alive.

Conclusions

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

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. Целью работы было рассмотрение тактики ухода за пациентами, получившими терапию моноклональными антителами. Предложены рекомендации для медицинских сестер, работающих с препаратами моноклональных антител.

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.

Toxicity and efficacy gemtuzumab ozogamicin with chemotherapy in patients with relapses or refractory acute myeloid leukemia

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Introduction

The remission rate in patients (pts) with acute myeloid leukemia (AML) is achieved approximately in 70-80% after induction chemotherapy (CT). In pts with relapsed AML the main goal of therapy is to achieve remission followed by allogeneic bone marrow transplantation (allo-HSCT). However, the frequency of second remission rate in the refractory/relapsed AML (RR AML) does not exceed 50%. Introduction of targeted drugs is the most promising strategy in modern therapy of hematological malignancies, in particular RR AML. Gemtuzumab ozogamicin (GO) is a recombinant, humanized anti-CD33 monoclonal antibody covalently attached to the cytotoxic antitumor antibiotic calicheamicin, which effectiveness depends on more than 75% expression of CD33-glycoprotein on leukemic blasts. The aim of this work was evaluation of GO effects in combination with chemotherapy in AML treatment.

Patients and methods

The study included 75 pts with RR AML. The median age was 36 (18-76) years. 30 (40%) pts were with primary refractory (Ref) AML, 45 (60%) pts were with relapsed AML. Pts with the first relapse (Rel1) comprised 73% (33), with the second or subsequent relapse (Rel≥2), 27% (12); the early relapse (eRel) was observed in 34 (76%) of cases, and late relapse (lRel) were registered in 11 (23%) of cases. The following distribution of ELN-2017 molecular genetic risk groups was observed: favorable, 15 (20%) pts; intermediate, 28 (37%) pts; unfavorable, 32 (43%) pts. All the pts received GO at the dose of 3 mg/m^2 per administration (no more than 5 mg) from 1 to 3 times [one/two times – 26 (35%) pts, three times – 49 (65%) pts], in combination with high-dose CT (HDCT) (FLAG + Ida, HAM, HDAC, ICE, HAI) or standard and low doses of CT (SLCT) (7 + 3, LDAC, AzaIdaAraC, MetA) in 46 (61%), and 29 (39%) pts, respectively. Allo-HSCT was performed after GO in 21 pts (3 – related, 7 – unrelated, 11 – haplo), including 3 second allo-HSCTs from another donor. In 10 pts GO therapy was performed in a relapse of AML after allo-HSCT. The median timing of HSCT after GO therapy was 67 (17-157) days.

Results

The 2-year OS was 34% (95%CI 17-51). The overall response (OR) was 52% (39/75): complete remission was achieved in 23 (31%) pts, complete remission with incomplete hematologic recovery – 13 (17%) pts, partial remission – 3 (4%) pts. The median duration of the OR was 81 (6-701) days. OR in the group which received one/two doses of GO was achieved in 31% (8/26), after three doses of GO, in 63% (31/49), p=0.007. In combination of GO and SLCT, the OR was 35% (10/29); with GO+HDCT, 63% (29/46), p=0.016. Dependence on the ELN 2017 risk group: in favorable group OR was obtained in 93% (14/15) pts, in the intermediate group, in 40% (14/28) pts; in unfavorable, in 34% (11/32) pts, p=0.006. OR was achieved in 30% (9/30) of pts with Ref AML, 64% (21/33) in Rel1 and 75% (9/12) in Rel>2, p=0.006. No statistically significant correlation was found in OR occurence between eRel or LRel (65% *vs* 73%, p=0.624), and for different CD33 expression on blast cells for the pts with CD33 levels over 60% or below 60% (40% *vs* 52%, 0.496). Depending on the timing of relapse: OR was 65% (22/34) in the pts with eRel,