BLINATUMOMAB

"LOVE IT OR LEAVE IT"

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INTRODUCTION

The treatment of Acute Lymphoblastic Leukemia (ALL) has not change much in the last 20 years. In 2015 we had the approval of Blinatumomab. It is the first FDA approved BiTE therapy for relapse and MRD Acute Lymphoblastic Leukemia. Indicated for Adults and pediatrics. BiTE is short for "bispecific T cell engager". BiTEs are antibodies with two arms. A bispecific CD19-directed CD3 T-cell engager that binds to CD19 expressed on the surface of cells of B-lineage origin and CD3 expressed on the surface of T cells. Blinatumomab mediates the formation of a synapse between the T cell and the tumor cell, upregulation of cell adhesion molecules, production of cytolytic proteins, release of inflammatory cytokines, and proliferation of T cells, which result in redirected lysis of CD19+ cells. An exciting new drug to add to the army of treatments for ALL which is long overdue. We introduced this drug into the LAC/USC ALL treatment plan in 2015.

BACKGROUND

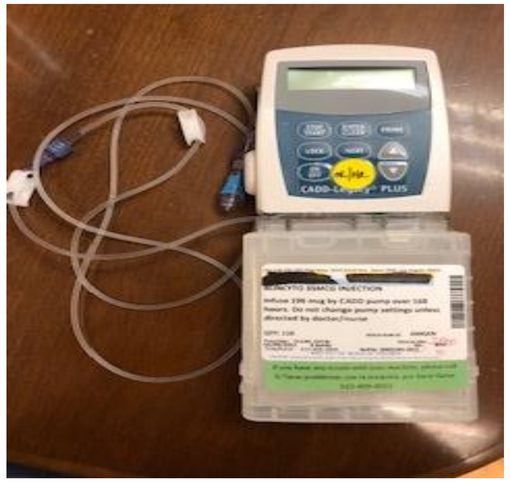
Blinatumomab is the first FDA approved BiTE therapy for relapse and MRD All for Adults and pediatrics. As exciting as it sounds the logistics of administration and side effect management is very complicated for the patient and the nursing staff. Working at a very large county hospital we have a very large multi-cultural, multiple languages, lower socioeconomic patient population. Ensuring the safety of this patient population on a drug that infuses for 28 days straight via a central line and has a variety of intense and serious side effects was a complicated effort for this population. It is very important that the instructions for preparation (including admixing) and administration are strictly followed to minimize medication errors (including underdose and overdose) This drug is delivered at a constant flow rate using an infusion pump that is programmable, lockable, non-elastomeric, and has multiple alarms. The patients are encouraged not to drive or operate heavy machinery. They have to maintain their CVC , CADD pump and try to manage a regular lifestyle with a pump attached 24/7.This proved to be a complicated issue for many of our patients who needed to work and drive . Our first few Patients were not well organized and as the treatment population grew it was evident, we needed a plan/pathway with a navigator to care for this complicated treatment option. The initial treatment plan problems included excessive cost of drug , CVC issues, side effects and mixed drugs that could not be given . Clearly, we needed a navigator, treatment plan and pathway for this patient population..

OBJECTIVES

A team of Nursing and Pharmacy was created to follow this patient population from beginning to end of every treatment. A well-organized education program in the patients primary language focusing on side effects ,demo and return demo with pump and CVC were repeated until patient felt comfortable . In addition, practice on the pump and CVC were done with the patient and an additional friend/ family member. Each visit a detailed physical assessment ,CVC care and lab evaluation were done before each drug was mixed . Side effect assessment and management was a priority with population along with 24/7 phone contact for any questions , concerns, problems.

PROCESS

Pharmacy and nursing meet to develop guidelines to organize the care for the blinatumomab treatment. It is very important that the instructions for preparation (including admixing) and administration are strictly followed to minimize medication errors (including underdose and overdose) This drug is delivered at a constant flow rate using an infusion pump that is programmable, lockable, and has an alarm. Education included training on the CADD Pump' alarm and pump number visuals were the focus along with start and stop instructions. Next care of the CVC was a major focus. Side effects management was a major teaching point , encouraging the patients to identify symptoms as well express them to the medical staff. The patients are encouraged not to drive or operate heavy machinery. They have to maintain their CVC ,pump and try to manage a regular lifestyle with a pump attached 24/7.This proved to be a complicated issue for many of our patients who need to work and drive. Each visit a detailed physical assessment ;CVC care and lab evaluation were done before each drug was mixed . Side effect management was also a battel with this population who did not express their symptoms. The other issue was keeping there CVC intact while pump was attached. We mostly used PICC for the treatment.

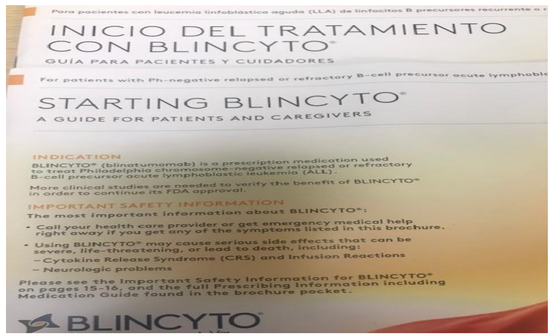


LESSONS LEARNED

Our first few Patients were not well organized . CVC issues, side effects and mixed drugs that could not be given were initial issues. Clearly, we needed a navigator for this patient population. The treatment process where the patient had to carry a pump around for 28 days was a heavy burden emotionally and a main reason for patients to constantly debated continuing treatment. We developed A well-organized education program in their primary language .We ensured there was lots of practice on the pump and CVC with the patient and family/ friends. A 24/7 contact number was provided for guidance should any problems arise . We needed to focus each visit on the CVC first . If it was not in working order no drug was mixed until the CVC was available for use. In addition, detailed physical assessment and lab evaluation was done before each drug was mixed . The two major categories of side effects were Cytokine release and Neurological toxicities. Cytokine release was straight forward and 90% of the time was identified during the inpatient setting. The neurological symptoms were harder to identify and could occur at any time during treatment . Simple symptoms such as headache ,unable to process words, confusion ,vision and hearing changes would sneak up on us. Side effect assessment / management was a battel with this population who did not express their symptoms and spoke multiple languages. The biggest battle administering this drug was ensuring they received their Chemotherapy treatments safely due to the already mentioned barriers.

EVALUATION

From 2017 to present we had the largest volume of patients with 48 treated . Once we got our treatment process organized to meet the patients' needs, we had the administration process down to a fine science . Of the 48 patients, 43 had a complete response and went to transplant. This treatment process was complicated for our patient and nursing staff considering the patient population. The first reaction to Blinatumomab, was leave it! This positive outcome of complete remissions and getting patient to transplant and possible cure for the high-risk disease of ALL was amazing for the patient and nursing staff. Our reaction now, Blinatumomab we love it !!



LAC+USC AMAZING NURSING TEAM