The effect of Bovine colostrum on the absolute neutrophil counts of Pediatric patients with Acute Lymphocytic Leukemia undergoing Chemotherapy: A double blind randomized placebo controlled study

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Keywords

Neutropenia, ALL, ANC, bovine colostrum, chemotherapy

Background

Children with cancer represent a unique population in the practice of pediatrics. Demise from cancer is not precisely due to cancer itself but from the complications associated with the disease and its treatment. Chemotherapy is the most common mode of treatment of pediatric cancer. The introduction of chemotherapy regimens has improved survival in children with cancer, but has increased the risk of infections. Changes in the blood counts mainly leukopenia and neutropenia in patients with Acute Lymphoblastic Leukemia (ALL) are common adverse events following chemotherapy. Chemotherapy-induced neutropenia commonly occurs three to seven days after chemotherapy drugs are administered and continues for several days before recovering to normal levels These commonly delays further administration of chemotherapeutic agents thereby potentially affecting therapeutic outcomes. Treatment for neutropenia depends on the cause. In patients with impaired inflammatory response coupled with granulocytopenia, urgent empiric treatment with antibiotics of broad-spectrum activity is warranted to decrease the risk of sepsis. For chemotherapy-induced neutropenia, the usual strategy in recent years has been the injection with a man-made protein that is similar to the naturally occurring protein, which is the granulocyte-colony stimulating factor (G-CSF). These are usually given shortly after the last treatment in a chemotherapy cycle and are continued for up to two weeks, but their costs limit their use. In cancer patients it has been suggested that fortification with good nutrition is the foundation for building a strong immune system. Although boosting the immune system is not the definitive treatment for cancer, this is incredibly important in the fight against cancer and infection. Bovine colostrum has shown some promises in different fields of medicine and one claim is its use in prevention of neutropenia. However, there are no studies to support such claim

Objective

The general objective of this study is to determine the efficacy of a 1-week supplementation of bovine colostrum (Pro-Ig) in preventing neutropenia among patients with acute lymphocytic leukemia (ALL) undergoing standard chemotherapy. The specific objectives are: 1) To determine and compare the absolute neutrophil counts of patients among the study groups; 2) To determine and compare the incidence of anemia, leukopenia and thrombocytopenia between the study groups; 3) To evaluate the occurrence of clinically or culture proven infection and 4) To identify other untoward events or side effects on the use of bovine colostrum.

Study Design

A Double-Blind Randomized Placebo Controlled Trial

Setting

The study was done at a tertiary government hospital.

Patients/participants: Pediatric patients aged 6 months to 18 years old diagnosed with ALL, and undergoing standard chemotherapy that met the inclusion criteria were invited to participate in the study. Sample size was determined by total enumeration in the study period of 8 months. Both the investigator and the participants are blinded to the test products. Baseline CBC levels were determined (from a tertiary hospital laboratory) and the absolute neutrophilic count (ANC) were computed by multiplying the WBC count with the neutrophils plus bands then the result is multiplied by 1000. Eligible participants were randomly assigned to either the treatment group or the placebo group. Assignment was done by simple randomization. Each participant received either the bovine colostrum (Pro-Ig) or the placebo and was blinded to the test article he/she received. The test products were dissolved in 2 tablespoon of water until all the contents were dissolved and were given to the participants per orem twice a day for 7 days (after breakfast & after dinner) under the supervision of the nurse on duty/and or parent/guardian for in-patients and the guardian/parent/s for out-patients. The administration of the test products which were given orally 2x a day commenced on Day 1 of the standard chemotherapy and daily thereafter until 7 days, thereby completing 14 doses, before the outcomes were evaluated. After 7 days of treatment with the test article, a complete blood count and platelet count were repeated at the same tertiary hospital laboratory only The primary outcome measure (ANC) and various CBC parameters for each treatment group were computed and analyzed using Levene's test for equality of variances to determine whether there are significant differences between the treatment groups before interventions were given. Dependent T-test was applied to determine significant differences before and after the treatment on each group and an independent t-test in comparing primary outcome measure between the two groups.

Results:

A total of 21 subjects were enrolled, 10 of them received the placebo while 11 received the bovine colostrum. Majority (85.71%) of the subjects were on the age 1-9 years age group and 66.7% were males. Treatment groups were homogenous as there was no significant difference on the demographics and baseline parameters before the intervention was given. Results showed that there was significant increase in the Absolute Neutrophil Count (ANC) of patients given bovine colostrum as compared to the placebo group with a p-value of 0.007 which is statistically significant. There was also significant increase in the WBC and platelet counts among those who were given Bovine Colostrum with p-values of <0.001 and 0.001 respectively. No incidence of infection or untoward effects on both treatment groups

Conclusion

The administration of bovine colostrum during chemotherapy showed some promising effects on the WBC, platelet and ANC of patients undergoing chemotherapy as noted in this study. After the intervention, there was a striking change on the values of WBC, neutrophils, monocytes and ANC among the Bovine Colostrum group in which all of these parameters increased significantly while their values have all decreased among the placebo group. This study shows that Bovine Colostrum is effective and safe in preventing leukopenia, neutropenia and thrombocytopenia among ALL patients undergoing chemotherapy thereby preventing delays in chemotherapy.