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Clinical Efficacy Evaluation of Wheat Grass Tablets as Supportive Treatment in Leukemia Patients.

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ABSTRACT

Wheat grass is a natural anti-oxidant, which supports the body during chemotherapy and radiation treatments. In the present study, clinical efficacy of wheat grass tablets as a supportive treatment in leukemia patients was studied. Thirty patients of clinically diagnosed with leukemia cancer divided into two groups. Group-I included 15 patients and were kept on chemotherapy treatments alone. Group-II included 15 patients and kept on chemotherapy treatments along with wheat grass tablets. Patients of both groups were instructed to visit the facility every month. Patients were asked about experienced adverse events and improvement in lifestyle. The clinical efficacy was assessed by comparing Side Effect Index (SEI) and changes in laboratory parameters. Treatment of wheat grass tablets along with chemotherapy significantly reduce the severity of nausea, vomiting, bone pain, fever, skin rash, hair loss, mouth ulceration, anorexia and loss of weight as compared to alone chemotherapy treatment. Wheat grass tablets supportive treatment increased haemoglobin count, red blood cell (RBC) count, platelets count and decreased white blood cell (WBC) count, alkaline phosphatase, serum glutamic oxalo acetic Transaminase (SGOT), serum glutamic pyruvic Transaminase (SGPT) and blood urea nitrogen (BUN). Wheat grass tablets improved leukemia patient's lifestyle and decreased adverse event incidences.

Keywords: Wheat grass Tablet, Chemotherapy, Leukemia, Side Effect Index

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INTRODUCTION

Cancer is a disease characterized by out-of-control cell growth. Leukemia is cancer that starts in the tissue that forms blood. Leukemia is either chronic or acute. There are four common types of leukemia [1];

- Chronic lymphocytic leukemia: Affects lymphoid cells and usually grows slowly.
- Chronic myeloid leukemia: Affects myeloid cells and usually grows slowly at first.
- Acute lymphocytic (lymphoblastic) leukemia: Affects lymphoid cells and grows quickly.
- Acute myeloid leukemia: Affects myeloid cells and grows quickly.

There are many treatment options available for leukemia like chemotherapy, targeted therapy, biological therapy, radiation therapy and stem cell transplant. Many people with leukemia are treated with chemotherapy. Chemotherapy uses drugs to destroy leukemia cells. Chemotherapy kills fast-growing leukemia cells, but the drug can also harm normal cells that divide rapidly, which causes many side effects like anemia, low RBC, low WBC, hair loss /thinning hair, bleeding/bruising due to low platelet count, dry skin, rashes, fatigue, diarrhea, constipation, nausea, vomiting, muscle and nerve problems, lung problems, difficulty in breathing, coughing excessively, fertility and sexuality problems, etc.

Leukemia and its treatment can lead to health problems, so supportive care before, during and/or after cancer treatment is needed. Supportive care is treatment to prevent or fight infections, to control pain, to relieve the side effects of therapy and to improve comfort and quality of life during treatment. Supportive treatment includes anti-emetics, analgesics, anesthetics, antibiotics, anti-fungal, anti-allergic, anti-diarrhoeal, colony-stimulating factors (CSFs) and RBC transfusion.

Wheat grass has been traditionally used, since ancient times, to treat various diseases and disorders. Dr. Ann Wigmore claimed that wheat grass is a safe and effective treatment for ailments such as high blood pressure, cancer, obesity, diabetes, gastritis, ulcers, anemia, asthma and eczema [2,3]. Wheat grass Juice taken during chemotherapy may reduce myelotoxicity without diminishing efficacy of chemotherapy [4,5, and 6]. Wheat grass contains abscisic acid and laetrile which may have anti-cancer activity [2]. Wheat grass extract has antioxidant activity, which inhibits proliferation of leukemia cells and induces apoptosis; thus, this finding may represent a novel therapeutic approach for the treatment of leukemia [7]. It was also concluded that wheatgrass juice is an effective alternative (natural) for blood transfusion. Its use in terminally ill cancer patients should be encouraged [3, 8, and 9].

There is no direct evidence that wheat grass juice may prevent myelotoxicity when applied with chemotherapy, therefore the present investigation was planned to study the clinical effectiveness of wheat grass tablets as a supportive treatment in leukemia patients who were subjected to chemotherapy.

MATERIALS AND METHODS

The clinical study of wheat grass tablet on patients of leukemia cancer was carried out at Bharat Cancer Research Centre, Surat, Gujarat, India. Ethics committee approval was taken before conducting the clinical study. A total of thirty patients of clinically diagnosed with leukemia cancer, who were subjected to chemotherapy treatment, age ranged between 20-70 years, who met all the inclusion criteria and none of the exclusion criteria, based on history and clinical examination were recruited in this study. All the patients were signed the informed consent before participating in the study.

All thirty patients were divided into following two groups;

- Group-I (Alone): Included 15 patients and were kept on chemotherapy treatments alone.
- Group-II (With Wheat grass Tablet): Included 15 patients and were kept on chemotherapy treatments along with wheat grass tablets as a supportive treatment. The patients of this group were given wheat grass tablets with dosage regimen of 2 tablets (Wheat grass powder 500 mg), 3 times a day for 270 days (9 months).

Patients of both groups were instructed to visit the facility very month as follow:

V1:ScreeningVisit1:Day0
V2:Visit2:Day30
V3:Visit3:Day60
V4:Visit4:Day90
V5:Visit5:Day120
V6:Visit6:Day150
V7:Visit7:Day180
V8:Visit8:Day210
V9:Visit9:Day240
V10:Visit10:Day270

On day 0 (screening visit), blood samples of suspected patients with leukemia cancer were taken to check the blood laboratory parameters. The patients were recruited into study after the assessment of eligibility criteria. Instructions were given by physician about the dose administration and subsequent visits. One very visit, blood samples of the patients were taken to check effects of wheat grass tablets on blood laboratory parameters. Patients were asked about experienced adverse events and improvement in life style. The improvement in life style was assessed by physical well-being, social/family well-being, emotional well-being and functional well-being. The clinical efficacy of wheat grass tablet (WGT) was measured:

By Side Effect Index (SEI) that included headache, nausea, vomiting, bone pain, fever, skin rash, hair loss, mouthful ceration, anorexia, loss of weight and over all life quality as determined from patient and assessment by a physician.

By changes in complete blood count, alkaline phosphatase, SGOT, SGPT and BUNa long with supportive treatment in patients of leukemia.

The severity of side effects was evaluated by score as mentioned in Table1.

Table1: side effect index (sei) score

score	severity
0	notobserve/not change
1	Rarely
2	Mild
3	mild to moderate
4	Moderate
5	Severe

STATISTICAL ANALYSIS

The results were presented as mean \pm SEM. Statistical difference between the means of various groups was evaluated using student's paired test. Data were considered as statistically significant at 'P' value of 5% ($P \leq 0.05$).

RESULTS AND DISCUSSION

Total thirty leukemic patients, subjected to chemotherapy treatment were enrolled into study. These subjects were divided into two groups. Fifteen patients of group-I (Alone) were kept on chemotherapy treatments alone. Fifteen patients of Group-II (With Wheat grass Tablet) were kept on chemotherapy treatments and wheat grass tablets asa supportive treatment. The clinical efficacy was assessed by comparing Side Effect Index and by comparing changes in laboratory parameters. The effects of wheat grass tablet on Side Effect Index are presented in Table2.

Table 2: effect of wheat grass tablet on side effect index

Parameter	Alone (mean±sd)	With wgt (mean ± sd)
Headache	1.53 ± 0.64	1.53 ± 0.516
Nausea	1.00 ± 0.00	0.133 ± 0.35*
vomiting	1.67 ± 0.49	0.73 ± 0.46*
bone pain	2.73 ± 0.46	1.53 ± 0.64*
Fever	1.53 ± 0.64	0.13 ± 0.35*
skin rash	1.60 ± 0.51	0.27 ± 0.46*
hair loss	2.87 ± 0.35	2.00 ± 0.00*
mouth ulceration	1.53 ± 0.64	0.00 ± 0.00*
anorexia	1.53 ± 0.52	0.13 ± 0.35*
loss of weight	2.87 ± 0.35	2.00 ± 0.0*
overall lifestyle	1.89 ± 2.80	0.85 ±0.16*

(*p<0.05,statisticallysignificant)

Treatment of wheat grass along with chemotherapy significantly reduce the severity of nausea, vomiting, bone pain, fever, skin rash, hair loss, mouthulceration, anorexia and loss of weight as compare to chemotherapy standard treatment. Overall lifestyle of leukemia patients was improved with supportive treatment of wheat grass tablets.

Blood samples of leukemia patients were collected at the start of study and during every visit to assess the effect on laboratory parameters. The parameters recorded were haemoglobin, RBC, WBC, Platelets, Alkaline Phosphatase, SGOT, SGPT and BUN. The effects of wheat grass tablet on laboratory parameter sare presented inTable3.

Table 3: effect of wheat grass table to laboratory parameters

parameters	alone(mean±sd)	withwgt(mean±sd)
haemoglobin (13.5-17.5 gm/dl)	6.5 ± 1.53	8.07 ±0.94*
rbc (4.52-5.90 million/mm ³)	3.03 ±0.70	3.96 ±0.41*
wbc (4.4 to 11.3 x 10 ³ /ul)	11.06 ±1.84	9.91 ± 4.80
platelets (150 – 450 x 10 ³ /ul)	102.3 ± 16.13	189.0 ±15.33*
alkaline phosphatas (38-94 iu/l)	128.6 ± 11.71	81.38 ±22.58*
sgot (8-38 u/l)	75.60 ± 16.10	26.90 ± 8.60*
sgpt (4-44 u/l)	87.21 ±11.14	30.07 ± 5.58*
bun (8-20 mg/dl)	40.43 ±3.88	23.20 ± 2.97*

(*p<0.05,statisticallysignificant)

The haemo globin count was increased significantly in group of patients treated with wheat grass tablets (8.07±0.94gm/dL) than the group of patients treated with alone chemotherapy (6.5± 1.53gm/dL). It may be due to induction of hematopoietic effect of wheat grass. Wheat grass supportive treatment increased RBC count, platelets count and decreased WBC count, alkaline phosphatase, SGOT, SGPT and BUN.

CONCLUSION

There are many options for treatment of leukemia like chemotherapy, radiation the rapy and stem cell transplant. The treatment duration is usually long and very painful. Chemotherapy treatment produces lots of side effects and also affects the lifestyle of patients. Hence, the present investigation was aimed to study the clinical efficacy of wheat grass tablets as a supportive treatment in leukemia patients, who were subjected to chemotherapy treatment.

Treatment of wheatgrass tablets along with chemotherapy significantly reduce these verity of nausea, vomiting, bone pain, fever, skin rash, hair loss, mouthulceration, anorexia and loss of weight as compare to chemotherapist and ard treatment. Over all lifestyle of leukemia patients was improved with supportive treatment of wheatgrass tablets. Wheatgrass tablets supportive treatment increased RBC count, platelets count and decreased WBC count, alkaline phosphatase, SGOT, SGPT and BUN.

The result of present clinical efficacy study revealed that wheat grass tablets improved patient's lifestyle as well as decreased the adverse event incidence. It supports the result of pilot study conducted by Bar-Sela Getal. 2004[6]. It was found that wheatgrass Juice taken during FAC chemotherapy (5-fluorouracil, doxorubicin, cyclophosphamide chemotherapy) reduced myelotoxicity, dose reduction and need for Granulocyte colony-stimulating factor (GCSF) support, without diminishing efficacy of chemotherapy.

Result of the clinical study indicated that wheatgrass tablets may be one of the effective supportive treatments for leukemia in term of reducing adverse events and improving patient lifestyle. It was found that wheatgrass tablets helped to produce healthier blood levels while receiving the chemotherapy thus *decreasing* the need for blood building medications.

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