CHAPTER 10

PUBLICATIONS AND PRESENTATIONS
#30517 Summary

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Title and Abstract
Title: CLINICAL EFFICACY EVALUATION OF WHEATGRASS TABLETS AS A SUPPORTIVE TREATMENT IN LEUKEMIA PATIENTS

Abstract
Aims: Wheatgrass is a natural anti-oxidant, which supports the body during chemotherapy and radiation treatments. In this project, the clinical efficacy of wheatgrass LIVENG as a supportive treatment in leukemia patients was studied.

Materials and Methods: Thirty patients of clinically diagnosed with leukemia were divided into two groups. Group-I included 15 patients and was kept on chemotherapy treatments alone. Group-II included 15 patients and was kept on chemotherapy treatments along with wheatgrass tablets. Patients were asked to visit the hospital every month. Patients were asked about their dietary habits and improvement, if any. The clinical efficacy was assessed by comparing Side effect Index (SEI) and changes in laboratory parameters.

Results: Treatment of wheatgrass tablets along with chemotherapy significantly reduces the severity of chloasma, vomiting, bone pain, fever, skin rash, hair loss, mouth ulceration, anorexia and loss of weight as compared to alone chemotherapy treatment. Wheatgrass tablets can significantly reduce the blood cell (EBC) count, platelet count and decrease the white blood cell (WBC) count. Marked phosphatase, serum glutamic oxaloacetic transaminase (SGOT), serum glutamic pyruvic transaminase (SGPT) and blood urea nitrogen (BUN) have been significantly reduced.

Conclusions: Wheatgrass tablets improved leukemia patient’s lifestyle and decreased adverse event incidence.

Indexing
Keywords: Wheatgrass tablet, chemotherapy, leukemia, Side effect Index

Contributors and Supporting Agencies

References
Supportive Treatment of Wheatgrass Tablets in Leukemia

**Article Title:** CLINICAL EFFICACY EVALUATION OF WHEATGRASS TABLETS AS A SUPPORTIVE TREATMENT IN LEUKEMIA PATIENTS

**Short Running Title:** Supportive Treatment of Wheatgrass Tablets in Leukemia

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**ABSTRACT**

Wheatgrass is a natural anti-oxidant, which supports the body during chemotherapy and radiation treatments. In the present study, clinical efficacy of wheatgrass tablets as a supportive treatment in leukemia patients was studied.

**Materials and Methods:** 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 wheatgrass tablets. Patients of both groups were instructed to visit the facility at every month. Patients were asked about perceived adverse events and improvement in lifestyle. The clinical efficacy was assessed by comparing Side Effect Index (SEI) and changes in laboratory parameters.

**Results:** Treatment of wheatgrass tablets along with chemotherapy significantly reduce the severity of nausea, vomiting, bone pain, fever, skin rash, hair loss, mouth ulceration, anemia and loss of weight as compare to alone chemotherapy treatment. Wheatgrass tablets supportive treatment increased hemoglobin count, red blood cell (RBC) count, platelets count and decreased white blood cell (WBC) count, alkaline phosphatase, serum glutamic pyruvic transaminase (SGPT) and blood urea nitrogen (BUN).

**Conclusion:** Wheatgrass tablets improved leukemia patient’s lifestyle and decreased adverse event incidences.

**Key Words:** Wheatgrass Tablet, Chemotherapy, Leukemia, Side Effect Index
Supportive Treatment of Wheatgrass Tablets in Leukemia

Introduction: Cancer is a disease characterized by out-of-control cell growth. Leukemia is cancer that starts in the cells that form 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 platelet count, dry skin, rash, fatigue, diarrhea, constipation, nausea, vomiting, muscle and nerve problems, lung problems, difficulty in breathing, coughing excessively, fertility and sexual 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-allergics, anti-diarrheals, colony-stimulating factors (CSFs) and RBC transfusion.

Wheatgrass has been traditionally used, since ancient times, to treat various diseases and disorders. Dr. Ann Wigmore claimed that wheatgrass is a safe and effective treatment for ailments such as high blood pressure, cancer, obesity, diabetes, gastritis, ulcers, anemia, asthma and eczema (2, 3). Wheatgrass Juice taken during chemotherapy may reduce myelotoxicity without diminishing efficacy of chemotherapy (4, 5, 6). Wheatgrass contains alphabetic acid and isorhamnetin which may have anti-cancer activity (2). Wheatgrass extract has an 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, 9).

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

Materials and Methods: The clinical study of wheatgrass 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 20-50 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 into study.

All thirty patients were divided into following 2 groups:
- Group-I (Alone): Included 15 patients and were kept on chemotherapy treatments alone.
- Group-II (With Wheatgrass Tablet): Included 15 patients and were kept on chemotherapy treatments along with wheatgrass tablets as a supportive treatment. The patients of this group were given wheatgrass tablets with dosage regimen of 2 tablets (Wheatgrass powder 200 mg), 3 times a day for 270 days (9 months).

Patients of both groups were instructed to visit the facility at every month as follow:
- V1: Screening Visit 1: Day 0
- V2: Visit 2: Day 50
- V3: Visit 3: Day 100
- V4: Visit 4: Day 150
- V5: Visit 5: Day 200
- V6: Visit 6: Day 250
- V7: Visit 7: Day 300
- V8: Visit 8: Day 350
- V9: Visit 9: Day 400
- V10: Visit 10: Day 450

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. On every visit, blood samples of the patients were taken to check effects of wheatgrass tablets on blood laboratory parameters. Patients were asked about experienced adverse events and improvement in lifestyle. The improvement in lifestyle was assessed by physical well-being, social and family well-being, emotional well-being and functional well-being. The clinical efficacy of wheatgrass tablet (WGT) was measured.

1. By Side Effect Index (SEI) that included headache, nausea, vomiting, bone pain, fever, skin rash, hair loss, mouth ulceration, anorexia, loss of weight and overall life quality as determined from patient and assessment by a physician.
2. By changes in complete blood count, alkaline phosphatase, SGOT, SGPT and BUN along with supportive treatment in patients of leukemia.
Publications and Presentations

10.2 QBD-2013 Poster Presentation

This certificate acknowledges that Mr. Jigisha K. Salunkhe presented a poster titled "The pharmacological Evaluation of Tinospora cordifolia against cancer" at the Quality by Design and Process Analytical Techniques: New Paradigm in Drug Development Seminar organized by Amity University, Noida, on May 3-4, 2013 at V. R. Shankar College of Pharmacy & Research, Varkala, Thiruvananthapuram.