

A Prospective Study – On the Impact of Probiotics in Patients Undergoing Radical Radiation Therapy

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Abstract—Radiation therapy is a widely used modality in cancer treatment; however, it is associated with Significant gastrointestinal toxicities, particularly radiation-induced diarrhea, mucositis, and abdominal discomfort. These adverse effects compromise patient compliance and quality of life. This prospective, randomized controlled study was conducted to evaluate the protective role of probiotics in patients undergoing radical radiation therapy. A total of 60 patients were Enrolled and divided into control and treatment groups. The treatment group received probiotic supplementation containing Lactobacillus and Bifidobacterium species. Clinical outcomes were assessed using standardized grading scales for diarrhea, stool consistency, abdominal pain, and quality of life indices. The results demonstrated a statistically significant reduction in the severity and frequency of gastrointestinal symptoms in the probiotic group.

The study demonstrated a statistically significant reduction in gastrointestinal toxicity in the probiotic group compared to the control group. The findings suggest that probiotics may serve as a safe and effective adjunct therapy in patients undergoing radiation therapy.

Index Terms—Probiotics, Radiation Therapy, Diarrhea, Gastrointestinal Toxicity, Cancer, Lactobacillus, Bifidobacterium, Quality of Life

I. INTRODUCTION

Probiotics are live microorganisms that provide health benefits when administered in adequate amounts.

***Common Probiotic Strains**

- ☐ Lactobacillus
- ☐ Bifidobacterium
- ☐ Saccharomyces boulardii

***Mechanism of Action of Probiotics**

Probiotics act through:

- ☐ Restoration of gut microbiota
- ☐ Strengthening intestinal barrier
- ☐ Inhibition of pathogenic bacteria
- ☐ Modulation of immune response

***Role of Probiotics in Radiation Therapy**

Probiotics help in:

- ☐ Reducing diarrhea
- ☐ Improving gut integrity
- ☐ Enhancing patient tolerance to therapy

Overview of Cancer:

Cancer is a complex group of diseases characterized by uncontrolled cell growth, invasion, and metastasis. It remains one of the leading causes of death globally. According to global health estimates, cancer incidence continues to rise due to lifestyle changes, environmental exposure, and aging populations.

***Cancer develops due to:**

- ☐ Genetic mutations
- ☐ Environmental carcinogens
- ☐ Lifestyle factors (smoking, diet, alcohol)

***Modalities of Cancer Treatment**

The management of cancer involves multiple treatment strategies:

Surgery:

- ☐ Removal of tumor mass
- ☐ Most effective in localized cancers

Chemotherapy:

- ☐ Use of cytotoxic drugs
- ☐ Targets rapidly dividing cells

Radiation Therapy:

Radiation therapy uses high-energy radiation to destroy cancer cells. It is one of the most widely used cancer treatment modalities.

*Types of Radiation Therapy

- ☐ External Beam Radiation Therapy (EBRT)
- ☐ Internal Radiation Therapy (Brachytherapy)
- ☐ Systemic Radiation Therapy

II. AIM AND OBJECTIVE

The primary aim of this study is to evaluate the impact of Probiotics on gastrointestinal toxicity in patients undergoing Radiation Therapy.

Objectives of the Study:

* Primary Objectives:

- ☐ To assess the effect of probiotics on the incidence of radiation-induced diarrhea.
- ☐ To evaluate the severity of gastrointestinal symptoms in patients receiving probiotics.

*Secondary Objectives:

- ☐ To evaluate improvement in stool consistency
- ☐ To assess reduction in abdominal pain and discomfort
- ☐ To determine the impact on patient quality of life (QOL)
- ☐ To evaluate the safety and tolerability of probiotic supplementation
- ☐ To analyze the relationship between radiation dose and GI toxicity
- ☐ To observe patient compliance and treatment adherence
- ☐ To evaluate potential reduction in use of anti-diarrheal medications

*Significance of Objectives:

The defined objectives help to:

- ☐ Generate clinical evidence for probiotic use
- ☐ Improve supportive care in oncology
- ☐ Enhance patient comfort and treatment compliance

III. LITERATURE REVIEW

First proposed the concept of Probiotics, suggesting that consumption of beneficial bacteria could improve

gut health and prolong life. His work laid the foundation for the therapeutic use of probiotics in various gastrointestinal disorders. Élie Metchnikoff (1907)

Provided a comprehensive definition and scope of probiotics through an international consensus. Their study emphasized that probiotics must be live microorganisms that confer health benefits when administered in adequate amounts. They also highlighted their potential role in modulating gut microbiota and improving host immunity. Hill C., et al. (2014)

Conducted one of the earliest clinical studies evaluating probiotics in patients undergoing Radiation Therapy. Their findings demonstrated that probiotic supplementation significantly reduced the incidence of radiation-induced diarrhea, suggesting a protective effect on the intestinal mucosa. Delia P., et al. (2002)

Performed a randomized double-blind study to assess the efficacy of probiotics in preventing gastrointestinal complications during radiation therapy. The study reported a significant decrease in both the frequency and severity of diarrhea in patients receiving probiotics compared to the control group. Urbancsek H., et al. (2001)

Evaluated the use of *Lactobacillus casei* in patients undergoing pelvic radiotherapy. The study concluded that probiotic supplementation improved stool consistency and reduced the occurrence of severe diarrhea, thereby enhancing patient compliance with treatment. Giralt J., et al. (2008)

Investigated the combined use of *Lactobacillus* and *Bifidobacterium* in a randomized controlled trial. Their results showed a significant reduction in radiation-induced diarrhea and improved quality of life in the probiotic group. Chitapanarux I., et al. (2010)

IV. DRUG PROFILE

Probiotics are defined as live microorganisms which, when administered in adequate amounts, confer a health benefit on the host. They are widely used to maintain intestinal microbial balance and improve gastrointestinal health. In patients undergoing Radiation Therapy, probiotics help reduce gastrointestinal toxicity and improve overall tolerance to therapy.

* Classification of Probiotics

1 Bacterial Probiotics

- ☐ Lactobacillus
- ☐ Bifidobacterium
- ☐ Streptococcus thermophilus

2 Yeast Probiotics

- ☐ Saccharomyces boulardii

*Common Probiotic Strains and Their Functions:

Strain	Function
Lactobacillus acidophilus	Improves digestion
Lactobacillus rhamnosus	Reduces diarrhea
Bifidobacterium bifidum	Enhances immunity
Saccharomyces boulardii	Enhances immunity

V. MATERIALS AND METHODS

The methodology of a clinical study forms the backbone of research, ensuring that the data generated is reliable, reproducible, and scientifically valid. In the present study, a structured and systematic approach was adopted to evaluate the clinical effectiveness of probiotics in patients undergoing Radiation Therapy. The study design was carefully selected to minimize bias, improve accuracy, and allow meaningful statistical interpretation of results.

VI. RESULT

This chapter presents the results obtained from the prospective study evaluating the impact of probiotics in patients undergoing Radiation Therapy, along with detailed interpretation and discussion.

VII. CONCLUSION

Probiotics can be recommended as a routine adjunct therapy in patients undergoing radiation therapy to minimize gastrointestinal complications. The findings of this study strongly support that probiotics represent a scientifically validated, safe, and effective adjunct therapy in patients undergoing radiation therapy. They not only alleviate gastrointestinal toxicity but also

address the underlying biological disruptions caused by radiation, thereby improving overall treatment outcomes.

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