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Research Article

Impact of Probiotic Therapy on Radiation Associated Gastrointestinal Adverse Effects in Patients Undergoing Pelvic Irradiation: A Randomised Clinical Trial

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ABSTRACT

Background: Pelvic radiotherapy is an essential component of treatment for gynecological malignancies; however, radiation-induced gastrointestinal toxicity remains a common adverse effect affecting treatment tolerance and quality of life. Radiation-induced intestinal injury is associated with mucosal inflammation, barrier disruption, and alterations in gut microbiota. Probiotics have shown potential in maintaining intestinal homeostasis and reducing radiation-associated gastrointestinal complications.

Aim: To evaluate the efficacy of probiotic supplementation in reducing acute radiation-induced gastrointestinal toxicity in patients receiving pelvic radiotherapy for gynecological malignancies.

Materials and Methods: This prospective randomized controlled study was conducted from September 2024 to February 2026 and included 50 patients undergoing pelvic radiotherapy. Patients were randomized into two groups: Group A (n=25) received oral probiotic supplementation containing *Lactobacillus* and *Bifidobacterium* species, initiated before radiotherapy and continued until completion of treatment; Group B (n=25) received standard supportive care. Gastrointestinal toxicity was assessed weekly including diarrhea severity, abdominal pain, use of antidiarrheal medication.

Results: Baseline demographic, clinical, and treatment-related characteristics were comparable between both groups. The mean daily frequency of loose stools during radiotherapy was lower in the probiotic group compared with controls, although not statistically significant (1.09 ± 0.86 vs 1.45 ± 1.13; p=0.21). Probiotic supplementation significantly reduced loose stool frequency during the 14 days after completion of radiotherapy (0.65 ± 0.49 vs 1.40 ± 1.05; p=0.003). The number of days with more than one loose stool was significantly lower in the probiotic group during radiotherapy (7.97 ± 5.82 vs 15.36 ± 9.04 days; p=0.001) and during post-radiotherapy follow-up (3.64 ± 2.43 vs 6.96 ± 3.72 days; p<0.001). Abdominal pain severity was also significantly reduced among patients receiving probiotics (0.33 ± 0.56 vs 0.84 ± 0.96; p=0.009).

Conclusion: Probiotic supplementation significantly reduces the severity and duration of radiation-induced gastrointestinal symptoms, particularly diarrhea and abdominal pain, in patients undergoing pelvic radiotherapy. Probiotics may serve as a safe, cost-effective supportive intervention to improve treatment tolerance and quality of life. Larger multicenter studies with microbiome analysis and long-term follow-up are required to validate these findings.

Keywords: Probiotics, Radiation-Induced Gastrointestinal Toxicity, Pelvic Radiotherapy, Radiation-Induced Diarrhea, Radiotherapy Toxicity.

INTRODUCTION

Radiotherapy remains a cornerstone in the management of cancer, with nearly half of all cancer patients receiving radiation during the course of their treatment; either with curative intent or for palliation.[1] despite significant advances in radiation delivery techniques, injury to adjacent normal tissues continues to represent a major limitation of this treatment modality.

The gastrointestinal tract is particularly susceptible to radiation-induced damage because of the rapid turnover and high proliferative activity of intestinal epithelial cells.[2] Exposure of pelvic organs to radiation commonly results in acute inflammatory changes within the bowel mucosa. Over time, these acute effects may progress to chronic fibrotic alterations, leading to complications such as intestinal narrowing, strictures, and bowel obstruction, which can occasionally require complex surgical management.[3,4]

Patients experiencing pelvic radiation injury may develop a spectrum of gastrointestinal symptoms, including abdominal discomfort, diarrhea, increased bowel frequency and urgency, fecal incontinence, intestinal obstruction, and impaired nutrient absorption.[5] These manifestations collectively contribute to the condition known as pelvic radiation disease.[6] Evidence suggests that the severity of acute intestinal toxicity during radiotherapy may influence the development of long-term bowel dysfunction. Therefore, strategies aimed at reducing early radiation-related gastrointestinal injury may potentially improve long-term outcomes and enhance patients' quality of life following cancer treatment. With increasing cancer survival rates due to improved therapeutic approaches, minimizing treatment-related toxicities has become an important aspect of comprehensive cancer care.

Radiation exposure has been demonstrated to compromise intestinal epithelial barrier integrity, resulting in increased mucosal permeability and inflammation.[7] Furthermore, several studies have reported significant alterations in intestinal microbial composition following irradiation, with patients experiencing more severe treatment-related diarrhea showing greater reductions in microbial diversity.[8–11]

The intestinal microbiome plays a critical role in maintaining mucosal homeostasis and regulating inflammatory responses. Experimental studies have demonstrated that supplementation with beneficial bacterial strains, particularly lactobacilli, can reduce bacterial translocation and attenuate inflammatory changes following intestinal injury.[12] Observations from animal models further support the influence of gut microorganisms on radiation sensitivity; germ-free mice demonstrate increased resistance to radiation-induced intestinal injury, suggesting that microbial populations contribute to modulation of epithelial response following radiation exposure.[13,14] Although antibiotic-based approaches have been explored to alter intestinal radiosensitivity, no standardized or consistently effective strategy has been established for clinical use.[15]

Probiotic therapy has emerged as a promising approach for protecting intestinal tissue against radiation-associated damage by modifying the gut microbial environment. Several studies have explored the potential role of probiotics in reducing gastrointestinal complications associated with radiotherapy and chemotherapy.[16–21] Proposed mechanisms include enhancement of intestinal barrier function, stimulation of protective mucus production, reduction of epithelial permeability, suppression of inflammatory pathways, and restoration of microbial balance. Pre-treatment or "conditioning" of the intestinal mucosa with probiotics may improve the ability of normal intestinal tissue to tolerate radiation-induced stress and reduce treatment-related gastrointestinal symptoms. Based on this rationale, the present randomized controlled study was designed to assess the efficacy of probiotic supplementation in reducing radiation-induced gastrointestinal toxicity in patients receiving pelvic radiotherapy.

MATERIALS AND METHODS

Current prospective randomized controlled clinical study was conducted from Sep. 2024 to Feb 2026, total of 50 patients were enrolled and randomized into two groups:

Group a (Probiotic group): 25 patients received probiotic supplementation.

Group B (Control group): 25 patients received standard supportive care.

Inclusion Criteria includes female patient age ≥18 years with histologically confirmed gynecological malignancy, planned for external beam radiotherapy to pelvis and ECOG performance status 0–2. Patients with active gastrointestinal infection, inflammatory bowel disease, previous pelvic radiotherapy, current probiotic supplementation and on long-term antibiotics were excluded.

Intervention

Patients in Group A received oral probiotic supplementation containing:

Lactobacillus species

Bifidobacterium species

Probiotics were started before initiation of radiotherapy and continued until completion of treatment.

Outcome Assessment
Patients were assessed weekly during radiotherapy.

Primary Assessment:
Stool frequency

Secondary Assessments:
Abdominal gas
Defecation urgency
Faecal leakage
Abdominal pain
Presence of mucus in faeces
Rectal mucus discharge
Use of antidiarrheal medication

Statistical Analysis
Data will be analysed using SPSS version 26.Continuous variables will be expressed as mean ± standard deviation.Categorical variables will be compared using Chi-square/Fisher exact test. A p-value <0.05 will be considered statistically significant.

RESULT
Total of 50 patients were enrolled and randomized into two groups of probiotics and control group of 25 patients in each group.

Table 1.Baseline Demographic and Clinical Characteristics of Study Participants

Characteristic	Probiotic group (n=25)	Control group (n=25)	p value
Age (yrs), mean ± SD	56.8 ± 12.4	57.6 ± 11.8	0.82
Body weight (kg), mean ± SD	62.4 ± 9.6	63.1 ± 10.2	0.80
Smoking status Current smoker Former smoker Non smoker	 3 (12%) 7 (28%) 15 (60%)	 2 (8%) 8 (32%) 15 (60%)	0.91
Previous treatment received Surgery Chemotherapy	 15 (60%) 14 (56%)	 16 (64%) 15 (60%)	0.77
Primary cancer diagnosis Cervical cancer Endometrial cancer Vaginal/Vulval cancer	 18 (72%) 5 (20%) 2 (8%)	 19 (76%) 4 (16%) 2 (8%)	0.92
Radiotherapy technique 3DCRT IMRT	 8 (32%) 17 (68%)	 7 (28%) 18 (72%)	0.76
Total external beam radiotherapy dose (Gy), mean ± SD	50.8 ± 5.6	51.4 ± 5.2	0.70
Received brachytherapy	14 (56%)	15 (60%)	0.77
Received concurrent chemotherapy	15 (60%)	16 (64%)	0.77

As described in table 1, the groups were similar in terms of mean age, body weight, smoking status, treatment history, primary cancer type, total external radiation dose received, brachytherapy received and the number of participants that had chemotherapy concomitant to the radiation therapy with p value >0.05.
Almost all the participants experienced loose stools during their radiation therapy.The mean daily number of loose stools, from day 7 after initiation of radiation therapy until the last day with radiation therapy, was lower in the probiotics group (1.09 ± 0.86) compared with placebo (1.45 ± 1.13) but with no statistical significance (p= 0.21).The probiotic benefit on the severity of loose stools was more prominent during the 14 days after the end of radiation therapy, probiotics group (0.65 ± 0.49) and control group (1.4 ± 1.05) with p value of 0.003. Probiotics group has mean of 7.97 ± 5.82 days with >1 loose stool and control group has 15.36 ± 9.04 days (p=0.001) from day 7 after initiation of radiation therapy until the last day with radiation therapy.The results were similar also during the 14 days after radiation therapy, probiotic group with a mean of 3.64 ± 2.43 days with >1 loose stools

and control group with 6.96 ± 3.72 days (p<0.001) as described in table 2.

Table 2. Effect of Probiotic Supplementation on Radiation-Induced Loose Stools

Outcome parameter	Probiotic group (n=25)	Control group (n=25)	p value
Mean daily number of loose stools during radiotherapy (Day 7 after initiation of RT until completion)	1.09 ± 0.86	1.45 ± 1.13	0.21
Mean daily number of loose stools during 14 days after completion of RT	0.65 ± 0.49	1.40 ± 1.05	0.003
Number of days with >1 loose stool during radiotherapy (Day 7 after initiation of RT until completion)	7.97 ± 5.82	15.36 ± 9.04	0.001
Number of days with >1 loose stool during 14 days after completion of RT	3.64 ± 2.43	6.96 ± 3.72	<0.001

There was a significant benefit from the usage of the probiotic product on the severity of abdominal pain (table 3). The mean daily severity score reported in the control group was 0.84 ± 0.96 compared with 0.33 ± 0.56 (P = .009) in probiotic group. The severity score for the symptom defecation urgency was reduced compared with control, (0.62 ± 0.54vs0.95 ± 0.73 respectively; P = .076). No differences were identified between the probiotic groups and the placebo with regards to the severity of the other gastrointestinal symptoms as shown in table 3.

Table 3.Gastrointestinal Symptoms during Radiation Therapy

Symptoms	Probiotic group (n=25)	Control group (n=25)	p value
Abdominal gas*	1.12 ± 0.64	1.22 ± 0.67	0.592
Defecation urgency	0.62 ± 0.54	0.95 ± 0.73	0.076
Faecal leakage	0.08 ± 0.14	0.32 ± 1.02	0.255
Abdominal pain	0.33± 0.56	0.84± 0.96	0.009
Presence of mucus in faeces	0.3 ± 0.54	0.48 ± 1.3	0.527
Rectal mucus discharge	0.04 ± 0.08	0.31 ± 1.14	0.249
Concomitant medication against diarrhea	0.34± 0.48	0.54 ± 0.64	0.218
Concomitant medication against abdominal pain	0.05 ± 0.08	0.35 ± 0.94	0.125

* Abdominal gas on scale of 0-3, rest symptoms- number of occasions per day.

DISCUSSION

Pelvic radiotherapy is an integral component of treatment for various gynecological, gastrointestinal, and genitourinary malignancies. However, radiation-induced gastrointestinal toxicity remains one of the most frequent dose-limiting adverse effects, affecting patient comfort, nutritional status, treatment compliance, and long-term quality of life. Long-term follow-up studies among gynecological cancer survivors have demonstrated that radiation-related gastrointestinal symptoms may persist years after completion of therapy, emphasizing the

importance of preventive strategies during treatment.[22]

The present prospective randomized study evaluated the role of probiotic supplementation in reducing radiation-induced gastrointestinal toxicity in patients undergoing pelvic radiotherapy. Fifty patients were randomized into probiotic and control groups, with 25 patients in each arm. Baseline demographic characteristics, disease-related variables, radiation parameters, and concurrent treatment details were comparable between groups, suggesting adequate randomization and minimizing potential confounding effects.

In our study, almost all patients developed loose stools during pelvic radiotherapy, reflecting the high incidence of acute bowel toxicity associated with pelvic irradiation. Although the mean daily frequency of loose stools during radiotherapy was lower in the probiotic group compared with the control group (1.09 ± 0.86 vs 1.45 ± 1.13), the difference was not statistically significant (p=0.21). However, a significant protective effect of probiotic supplementation was observed during the 14 days following completion of radiotherapy, with a lower mean daily loose stool frequency in the probiotic group compared with controls (0.65 ± 0.49 vs 1.40 ± 1.05; p=0.003). Furthermore, probiotic administration significantly reduced the number of days with more than one loose stool both during radiotherapy (7.97 ± 5.82 vs 15.36 ± 9.04 days; p=0.001) and during the post-radiotherapy follow-up period (3.64 ± 2.43 vs 6.96 ± 3.72 days; p<0.001).

Our findings are consistent with previous clinical trials evaluating probiotics during pelvic radiotherapy. Delia et al. reported that probiotic supplementation reduced the frequency and severity of radiation-induced diarrhea, suggesting that modification of intestinal flora may provide protection against radiation-related mucosal injury.[23]Salminen et al. were among the earliest investigators to demonstrate preservation of intestinal integrity during radiotherapy using live Lactobacillus acidophilus cultures, providing early evidence supporting the protective role of beneficial bacteria in radiation-induced intestinal damage.[24]

Chitapanarux et al. performed a randomized controlled trial among cervical cancer patients receiving radiotherapy and demonstrated that supplementation with Lactobacillus acidophilus and Bifidobacteriumbifidum significantly reduced radiation-induced diarrhea compared with placebo.[25] Similarly, Giralt et al. reported in a multicenter randomized placebo-controlled trial that Lactobacillus casei DN-114001 supplementation reduced radiation-associated diarrhea among patients receiving pelvic irradiation.[26] These findings support the results of the current study, particularly regarding reduction in severity and duration of diarrhea episodes.

More recently, Linn et al. conducted a randomized double-blind placebo-controlled study evaluating probiotics in cervical cancer patients undergoing radiotherapy and reported a significant reduction in acute radiation-induced diarrhea among patients receiving probiotic supplementation.[27] The similarity between these findings and our results further supports the clinical utility of probiotics as a supportive intervention during pelvic radiotherapy.

Demers et al. also evaluated the effect of probiotics in patients treated with pelvic radiation and demonstrated a beneficial effect on radiation-induced diarrhea, although variations were observed depending on probiotic formulation and patient characteristics.[28] Differences between studies may be explained by variations in probiotic strains, dose, duration of supplementation, radiation technique, irradiated volume, and toxicity assessment criteria.

In addition to diarrhea control, our study demonstrated a significant reduction in radiation-associated abdominal pain severity among patients receiving probiotics (0.33 ± 0.56 vs 0.84 ± 0.96; p=0.009). Although reductions in defecation urgency, fecal leakage, mucus discharge, and requirement for symptomatic medications were observed in the probiotic group, these differences did not reach statistical significance. The relatively small sample size and limited follow-up duration may explain the lack of statistical significance for these secondary outcomes.

The biological mechanisms underlying the beneficial effects of probiotics are multifactorial. Probiotic organisms contribute to intestinal homeostasis by enhancing epithelial barrier integrity, increasing mucin production, improving tight junction function, reducing bacterial translocation, and modulating inflammatory responses. Ouwehand highlighted that probiotic effects are strain-specific and dose-dependent, emphasizing the importance of appropriate

bacterial selection and adequate supplementation protocols.[29]

Radiotherapy can significantly alter intestinal microbial diversity, with greater dysbiosisobserved among patients experiencing severe gastrointestinal toxicity. Restoration of microbial balance through probiotic supplementation may reduce radiation-induced inflammation and improve mucosal recovery. Experimental studies have demonstrated that Lactobacillus species can enhance intestinal defense mechanisms and maintain epithelial integrity.[30–31]These observations provide a biological rationale for the clinical improvement observed in our study.

The safety profile of probiotics is another important consideration, particularly in cancer patients who may be receiving chemotherapy or immunosuppressive treatments. Previous studies have demonstrated the feasibility and tolerability of probiotic administration in oncology populations, although careful patient selection is recommended in severely immunocompromised individuals.[32]

The findings of our study have practical clinical implications. Probiotics are relatively inexpensive, easy to administer, and associated with minimal adverse effects. Incorporating probiotic supplementation as supportive therapy during pelvic radiotherapy may help reduce treatment-related gastrointestinal morbidity and improve patient comfort and quality of life.

However, this study has certain **Limitations:** The sample size was limited. Microbiological assessment of gut flora was not performed, which could have provided additional mechanistic insight. Furthermore, longer follow-up is required to determine whether reduction of acute toxicity translates into decreased late radiation-induced bowel complications.

In **CONCLUSION:** the present randomized prospective study demonstrates that probiotic supplementation significantly reduces the severity and duration of radiation-induced gastrointestinal symptoms, particularly diarrhea and abdominal pain, in patients undergoing pelvic radiotherapy. These findings support the use of probiotics as a potential supportive strategy during radiation treatment. Larger multicenter randomized trials incorporating microbiome analysis, quality-of-life assessment, and long-term follow-up are warranted to confirm these observations.

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