Section: General Surgery

Original Research Article

PERIOPERATIVE PROBIOTIC SUPPLEMENTATION FOR THE PREVENTION OF SURGICAL SITE INFECTIONS FOLLOWING ELECTIVE ABDOMINAL SURGERY: A RANDOMIZED CONTROLLED STUDY

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ABSTRACT

Background: Objectives: Surgical site infections (SSI) represent a major cause of postoperative morbidity, prolonged hospitalization, and healthcare costs. Probiotics have demonstrated potential to prevent SSI through modulation of gut microbiota, enhancement of intestinal barrier function, and immunomodulation. This study evaluated the efficacy of perioperative probiotic supplementation in preventing SSI following elective abdominal surgery.

Materials and Methods: This prospective, randomized, double-blind, placebo-controlled trial enrolled 80 patients undergoing elective abdominal surgery at a tertiary care center. Patients were randomly allocated to receive either multi-strain probiotics (n=40) or placebo (n=40) for 15 days perioperatively. The primary outcome was SSI incidence within 30 days postoperatively. Secondary outcomes included SSI type, hospital length of stay, and adverse events. Statistical analysis included chi-square tests, independent t-tests, and multivariate logistic regression.

Results: SSI incidence was significantly lower in the probiotic group compared to control (2.5% vs 55.0%, p<0.001), representing a 95.5% relative risk reduction with number needed to treat of 1.9. Hospital stay was significantly shorter in the probiotic group (8.93±1.88 vs 13.16±5.16 days, p<0.001). Multivariate analysis identified probiotic use as an independent protective factor (OR 0.018, 95% CI 0.002-0.143, p<0.001) and ASA III classification as a risk factor (OR 7.311, p=0.031). Compliance was 100% with minimal adverse events (2.5%).

Conclusion: Perioperative probiotic supplementation profoundly reduces surgical site infections and hospital stay in elective abdominal surgery with excellent safety profile, supporting integration into surgical infection prevention protocols.

Keywords: Probiotics, Surgical site infection, Perioperative care, Elective abdominal surgery, Infection prevention.

INTRODUCTION

Surgical site infections (SSIs) are among the most common and significant healthcare-associated infections worldwide, imposing a substantial burden on patients and healthcare systems. Despite advances in surgical techniques, antimicrobial prophylaxis, and infection-control practices, SSIs continue to complicate a considerable proportion of surgical procedures and account for approximately 20% of healthcare-associated infections.[1] The Centers for Disease Control and Prevention (CDC) defines an SSI as an infection related to an operative procedure occurring at or near the surgical incision

within 30 days of surgery, or within 90 days when prosthetic material is implanted. SSIs are associated with increased postoperative morbidity, prolonged hospital stays, higher healthcare costs, and increased mortality, particularly following abdominal surgical procedures.

Abdominal surgeries, especially those involving manipulation of the gastrointestinal tract, present unique challenges in infection prevention. The development of SSIs following these procedures is multifactorial, involving endogenous and exogenous sources of contamination. The gastrointestinal tract contains a complex and abundant microbial ecosystem, and surgical manipulation of the bowel may promote bacterial translocation, defined as the passage of viable microorganisms from the intestinal lumen to normally sterile tissues and organs. This process has been recognized as an important contributor to postoperative infectious complications, particularly in patients undergoing colorectal and other major abdominal surgeries.[2]

The intestinal barrier plays a crucial role in preventing microbial invasion and maintaining host homeostasis. Its integrity depends on the intestinal epithelium, mucus layer, gut-associated lymphoid tissue, and commensal microbiota.[3] During the perioperative period, factors such as anesthesia, surgical trauma, altered intestinal motility, changes in splanchnic blood flow, and antibiotic administration may disrupt this barrier. Such disruption can increase intestinal permeability and facilitate bacterial translocation, thereby contributing to postoperative infections and septic complications.[4]

The gut microbiome is also essential for maintaining intestinal homeostasis, regulating immune responses, and providing colonization resistance against pathogenic microorganisms. Surgical stress and perioperative antibiotics can alter the composition and function of the intestinal microbiota, resulting in dysbiosis.[5] This imbalance may impair immune function, compromise intestinal barrier integrity, and increase susceptibility to pathogenic organisms, potentially contributing to postoperative infectious complications.

Probiotics have therefore gained increasing attention as a potential strategy for improving postoperative outcomes. Probiotics are live microorganisms that, when administered in adequate amounts, confer health benefits on the host. Their proposed mechanisms include enhancement of intestinal barrier function, competitive inhibition of pathogenic bacteria, modulation of immune responses, reduction of bacterial translocation, and production of antimicrobial substances.[6]

The present study was therefore undertaken to evaluate the role of perioperative probiotic supplementation in preventing surgical site infections among patients undergoing abdominal surgery. By assessing SSI occurrence following probiotic administration during the perioperative period, this study aims to provide further evidence regarding the potential role of probiotics as an adjunctive strategy for SSI prevention and improved postoperative care.

MATERIALS AND METHODS

Study Design

This was an experimental study conducted to evaluate the role of perioperative probiotics in the prevention of surgical site infections in patients undergoing abdominal surgeries.

Study Setting and Duration

The study was conducted at Mysore Medical College and Research Institute, Irwin Road, Mysore. The study period was 18 months.

Inclusion Criteria

- Patients aged between 18 to 70 years who presented department with clinical diagnosis of any intestinal pathology were included in the study.
- Patient willing to give informed consent.

Exclusion Criteria

- Pediatric age group less than 18 years.
- Acute abdomen in pregnancy.
- Gynecological causes of acute abdomen.
- Traumatic cases of acute abdomen.
- Patients not giving valid informed consent for the surgery.

Data Collection Procedure

Approval was obtained from the Institutional Ethics Committee prior to the commencement of the study. Eligible patients were enrolled after obtaining informed consent. The intervention consisted of administering probiotics preoperatively from the time of admission and continuing for 10 days post-operatively. The probiotic preparation used contained a total daily dose of 2.6 $\times 10^{14}$ CFU administered at 2 grams per day. Any adverse events occurring during the 16-day intervention period were recorded. Patients were subsequently observed for a period of 1 month to monitor for the development of surgical site infections (SSI). The primary outcome measure was the incidence of surgical site infection.

Imaging Protocol

Not applicable for this study.

Data Analysis

Descriptive statistics including mean, standard deviation, and frequency distributions were calculated for the study variables. The Chi-square test was used as the non-parametric test for analyzing categorical variables. A p-value of less than 0.05 was considered statistically significant. Statistical analysis was performed using appropriate statistical software.

Sample Size and Calculation

The total sample size for this study was 80 patients. The sample size was calculated using the following formula:

$n = Z^2 \times p \times (1 - p) / e^2$

Where:

- n = sample size
- Z = Z value at 95% confidence level = 1.96
- p = prevalence = 0.033 (3.3%)
- e = margin of error = 0.1 (10%)

Using these parameters:

- P = 0.033
- Q = 1 - P = 0.967
- D = margin of error = 0.1

The calculated sample size was 80 patients.

Sampling Technique

Simple random sampling method was employed for patient selection.

RESULTS

Table 1: Baseline demographic and clinical characteristics of study participants

Variable	Probiotic (n=40)	Control (n=40)	Total (n=80)	p-value
Age, mean ± SD (years)	49.50 ± 11.71	49.92 ± 12.46	49.70 ± 12.00	0.877
Male gender	25 (62.5%)	16 (40.0%)	41 (51.2%)	0.183
Female gender	15 (37.5%)	24 (60.0%)	39 (48.8%)	
ASA I	15 (37.5%)	12 (30.0%)	27 (33.8%)	0.736
ASA II	16 (40.0%)	13 (32.5%)	29 (36.2%)	
ASA III	11 (27.5%)	13 (32.5%)	24 (30.0%)	
Clean wound	9 (22.5%)	9 (22.5%)	18 (22.5%)	1.000
Clean-contaminated wound	33 (82.5%)	29 (72.5%)	62 (77.5%)	
Duration of surgery, mean ± SD (min)	130.24 ± 47.30	139.47 ± 52.49	134.62 ± 49.73	0.410

The two groups were comparable with respect to age, gender, ASA physical status, wound classification, and operative duration (all p>0.05), indicating satisfactory baseline comparability. Most procedures involved clean-contaminated wounds (77.5%), and the majority of patients belonged to ASA I or II categories.

Table 2: Distribution of major abdominal pathologies

Pathology	Probiotic n (%)	Control n (%)	Total n (%)
Appendicitis	5 (12.5)	4 (10.0)	9 (11.2)
Carcinoma descending colon	3 (7.5)	4 (10.0)	7 (8.8)
Carcinoma sigmoid	4 (10.0)	5 (12.5)	9 (11.2)
Carcinoma stomach	2 (5.0)	5 (12.5)	7 (8.8)
Cholelithiasis	6 (15.0)	4 (10.0)	10 (12.5)
Ileocecal tuberculosis	4 (10.0)	4 (10.0)	8 (10.0)
Jejunal GIST	5 (12.5)	0	5 (6.2)
Large incisional hernia	4 (10.0)	4 (10.0)	8 (10.0)
Mesenteric GIST	1 (2.5)	2 (5.0)	3 (3.8)
Pancreatic pseudocyst	3 (7.5)	1 (2.5)	4 (5.0)
Ventral wall hernia	5 (12.5)	5 (12.5)	10 (12.5)

Chi-square = 8.205; p=0.609

A diverse range of elective abdominal pathologies was included. Cholelithiasis and ventral wall hernia were the most frequent diagnoses (12.5% each), followed by appendicitis and carcinoma sigmoid (11.2% each). The distribution of underlying pathologies was comparable between the two groups (p=0.609).

Table 3: Compliance and safety of probiotic therapy

Parameter	Probiotic Group (n=40)
Complete compliance	40 (100%)
Non-compliance	0 (0%)
Probiotic-related adverse event	1 (2.5%)
No adverse event	39 (97.5%)
Duration of therapy, mean ± SD	15.00 ± 0.80 days
Range of therapy	14–16 days

Compliance with the probiotic regimen was excellent, with complete adherence among all participants. Only one patient experienced a probiotic-related adverse event, and no serious complications were reported.

Table 4: Primary and major postoperative outcomes

Outcome	Probiotic (n=40)	Control (n=40)	p-value
SSI present	**1 (2.5%)**	**22 (55.0%)**	**<0.001**
SSI absent	39 (97.5%)	18 (45.0%)	
Mean hospital stay (days)	**8.93 ± 1.88**	**13.16 ± 5.16**	**<0.001**

Risk estimates for SSI

Measure	Value
Relative risk	0.045
Absolute risk reduction	52.5%
Relative risk reduction	95.5%
Number needed to treat	1.9

The incidence of SSI was markedly lower in the probiotic group than in the control group (2.5% vs 55.0%, p<0.001). Probiotic use was associated with a substantial reduction in both relative and absolute SSI risk. The probiotic group also had a significantly shorter hospital stay, with no patient requiring hospitalization for more than 14 days compared with 47.5% of controls.

Table 5: Characteristics of surgical site infections

Characteristic	Probiotic	Control	Total
Total SSI cases	1	22	23
Superficial incisional SSI	1 (100%)	8 (36.4%)	9 (39.1%)
Deep incisional SSI	0	14 (63.6%)	14 (60.9%)
Mean time to SSI diagnosis (days)	12.0	10.09 ± 1.95	10.17 ± 1.95

Deep incisional SSI constituted the majority of infections overall (60.9%). The single SSI in the probiotic group was superficial, whereas both superficial and deep infections occurred in the control group.

Table 6: Association of clinical factors with SSI

Factor	SSI rate/association	p-value
Clean wound	4/18 (22.2%)	0.690
Clean-contaminated wound	19/62 (30.6%)	
ASA I	0/27 (0%)	**<0.001**
ASA II	9/29 (31.0%)	
ASA III	14/24 (58.3%)	
Probiotic use	OR 0.018 (95% CI: 0.002–0.143)	**<0.001**
ASA III	OR 7.311 (95% CI: 2.482–21.536)	**0.031**
Clean-contaminated wound	OR 1.547 (95% CI: 0.450–5.320)	0.468
Age ≥60 years	OR 6.682 (95% CI: 2.206–20.237)	0.162
Male gender	OR 1.053 (95% CI: 0.400–2.776)	0.721

ASA classification showed a significant association with SSI, with infection rates increasing from 0% in ASA I to 58.3% in ASA III patients. Wound classification was not significantly associated with SSI. On multivariate analysis, probiotic use remained strongly protective against SSI, while ASA III status emerged as an independent risk factor.

Table 7: Effect of probiotic use according to wound classification

Wound classification	Probiotic SSI	Control SSI	p-value
Clean	0/9 (0%)	4/9 (44.4%)	0.089
Clean-contaminated	1/33 (3.0%)	18/29 (62.1%)	**<0.001**
Overall	**1/40 (2.5%)**	**22/40 (55.0%)**	**<0.001**

The protective effect of probiotics was particularly evident among patients with clean-contaminated wounds, where the SSI rate decreased from 62.1% in controls to 3.0% in the probiotic group. The overall reduction in SSI remained highly statistically significant.

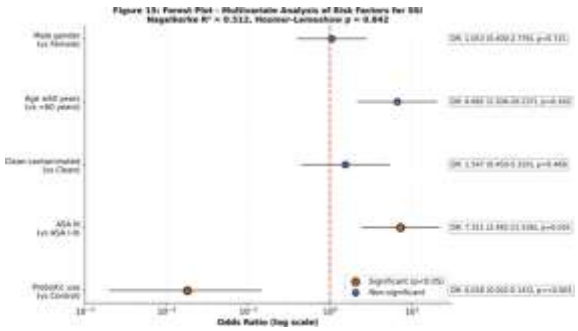

Figure 1: Forest Plot – Multivariate Analysis of Risk Factors

DISCUSSION

The present study evaluated the efficacy of perioperative probiotic supplementation in preventing surgical site infections (SSIs) following elective abdominal surgery. The principal finding was a marked reduction in SSI incidence among patients receiving probiotics, with only 1 of 40 patients (2.5%) developing an SSI compared with 22 of 40 patients (55.0%) in the control group (p<0.001). This corresponded to a relative risk reduction of 95.5%, an absolute risk reduction of 52.5%, and a number needed to treat of 1.9. The probiotic and control groups were comparable with respect to age, gender, ASA classification, wound classification, operative duration, and underlying pathology, supporting that the observed difference in SSI rates was associated with the intervention rather than major baseline imbalances.

The protective effect observed in this study is consistent with previous clinical trials reporting reduced postoperative infectious complications following perioperative probiotic or synbiotic administration.[7,8] Studies in patients undergoing colorectal and other major abdominal procedures have demonstrated lower rates of postoperative infections among probiotic-treated patients, although the magnitude of benefit has varied.[8,9,10] Differences in probiotic strains, dosage, duration of administration, patient characteristics, surgical complexity, and infection surveillance methods may explain this heterogeneity. The relatively high SSI rate in the present control group may also be related to the inclusion of a substantial proportion of higher-risk patients, including those classified as ASA III.[11]

Several mechanisms may explain the beneficial effect of probiotics. Surgical stress, intestinal manipulation, and perioperative antibiotic administration may disrupt the gut microbiota and intestinal barrier, promoting bacterial translocation and increasing susceptibility to postoperative infection. Probiotics may counter these effects by maintaining microbial balance, enhancing epithelial barrier integrity, competitively inhibiting pathogenic organisms, producing antimicrobial metabolites, and modulating host immune responses. These mechanisms may collectively reduce the movement of potentially pathogenic bacteria from the gastrointestinal tract to normally sterile tissues.[9,10,11]

The reduction in SSI was accompanied by a significantly shorter hospital stay in the probiotic group (8.93 ± 1.88 days) compared with the control group (13.16 ± 5.16 days; $p<0.001$). No patient in the probiotic group required hospitalization beyond 14 days, whereas nearly half of the control group had prolonged hospitalization. This finding suggests that the reduction in infectious morbidity may translate into faster postoperative recovery and reduced healthcare utilization. Similar reductions in hospital stay have been reported in previous studies of probiotic and synbiotic supplementation in abdominal surgery.[12,13]

The severity of SSI also differed between groups. The single infection in the probiotic group was superficial incisional, whereas the control group experienced both superficial and deep incisional infections, with deep infections accounting for the majority of cases. Although the number of infections in the probiotic group was too small for definitive conclusions regarding infection severity, this finding suggests a possible protective effect against more severe postoperative wound infections.

ASA physical status was significantly associated with SSI development. Infection rates increased progressively from 0% among ASA I patients to 31.0% among ASA II and 58.3% among ASA III patients ($p<0.001$). Multivariate analysis further identified ASA III status as an independent risk factor for SSI, whereas probiotic use remained a strong independent protective factor. In contrast, wound classification was not significantly associated with SSI in the overall cohort. Importantly, subgroup analysis demonstrated a marked reduction in SSI among patients with clean-contaminated wounds, from 62.1% in the control group to 3.0% in the probiotic group ($p<0.001$).

Compliance with probiotic therapy was excellent, with all participants completing the prescribed regimen. Only one patient experienced a mild adverse event, and no serious probiotic-related complications were reported. These findings indicate that perioperative probiotic supplementation was well tolerated in the selected surgical population.[14]

The study has certain limitations. The relatively small sample size and single-center design may limit the generalizability of the findings. The use of a multi-strain probiotic formulation also prevents identification of the specific strains responsible for the observed benefit. Furthermore, microbiome analysis and inflammatory biomarkers were not assessed, limiting direct evaluation of the underlying mechanisms. Larger multicenter studies are therefore required to confirm these findings and determine the optimal probiotic strains, dosage, timing, and duration of administration.

CONCLUSION

Perioperative probiotic supplementation represents a highly effective, safe, and well-tolerated intervention for preventing surgical site infections in patients undergoing elective abdominal surgery. This randomized controlled trial demonstrated a profound 95.5% relative risk reduction in SSI incidence, with the probiotic group achieving an infection rate of only 2.5% compared to 55.0% in controls. The intervention proved particularly beneficial in high-risk patients with elevated ASA classifications and clean-contaminated wounds, reducing infection rates from 62.1% to 3.0%. Beyond infection prevention, probiotics significantly shortened hospital stay by an average of 4.23 days, with substantial implications for healthcare resource utilization and patient quality of life. Multivariate analysis confirmed probiotic use as an independent protective factor (OR 0.018, $p<0.001$), superseding traditional risk determinants. The excellent compliance rate (100%) and minimal adverse events (2.5%) underscore the feasibility and safety of integrating probiotics into perioperative care protocols. With a number needed to treat of 1.9, perioperative probiotic prophylaxis offers exceptional clinical efficacy, representing a cost-effective, non-antibiotic strategy to enhance surgical outcomes. These findings support the integration of probiotics into enhanced recovery after surgery (ERAS) protocols and surgical infection prevention bundles. Further multicenter trials are warranted to validate these results across diverse surgical settings

and to optimize probiotic strain selection, dosing regimens, and treatment duration for maximal clinical benefit.

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