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RESEARCH ARTICLE

INTRAOPERATIVE MODULATION OF THE GUT MICROBIOME VIA TARGETED MICROBIOTA TRANSLOCATION TO REDUCE POSTOPERATIVE INFECTIONS AND IMPROVE WOUND HEALING IN MAJOR ABDOMINAL SURGERY: A FIRST-IN-HUMAN FEASIBILITY STUDY

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Abstract

Introduction: Postoperative infections and impaired wound healing remain major challenges in abdominal surgery. The gut microbiome has emerged as a crucial modulator of immune responses and tissue repair. This study evaluated the feasibility and safety of intraoperative targeted microbiota translocation to improve postoperative outcomes.

Methods: A prospective single-center feasibility study was conducted at Katihar Medical College, Katihar, including 20 patients undergoing elective major abdominal surgery. A sterile bacterial consortium containing Lactobacillus rhamnosus, Bifidobacterium longum, and Akkermansia muciniphila was infused directly into the proximal jejunum intraoperatively. Primary outcomes included feasibility and safety; secondary outcomes assessed postoperative infection rates, wound healing, inflammatory markers, and gut microbiota composition.

Results: Intraoperative microbiota translocation was achieved in all patients without technical difficulties or immediate adverse effects. Post-surgical infection occurred in 10 % of cases, notably lower than the institution's historical rate of 22 %. The mean wound epithelialization time was 10.5 ± 1.8 days, and the average length of hospital stay was 8.7 ± 2.1 days. Serum CRP and IL-6 levels fell significantly by postoperative day 7. Microbiome analysis demonstrated an increased abundance of beneficial bacteria and greater overall diversity. No anastomotic leaks or readmissions were recorded within 30 days.

Conclusion: Targeted intraoperative microbiota translocation appears feasible and safe, showing promising reductions in postoperative infection, accelerated wound healing, and restoration of the gut microbiome.

Keywords: Gut microbiome, intraoperative modulation, postoperative infections, wound healing, abdominal surgery, probiotics.

BACKGROUND/INTRODUCTION

Post-operative infections and sluggish wound healing remain formidable challenges for patients undergoing major abdominal procedures. Despite advances in aseptic technique, prophylactic antibiotics, and peri-operative care, surgical-site infections (SSIs) still complicate up to 20 % of abdominal operations, driving higher morbidity, longer hospital stays, and mounting healthcare costs [1]. Effective wound repair hinges on a tightly choreographed sequence of inflammation, cellular proliferation, and tissue remodelling; disruption of this cascade may lead to dehiscence, chronic infection, and delayed recovery [2].

In recent years, attention has turned to the gut microbiome, the diverse community of microorganisms that inhabit the gastrointestinal tract. These microbes are crucial for digestion, immune modulation, metabolic homeostasis, and maintenance of the epithelial barrier [3]. Growing evidence links gut dysbiosis, marked by reduced diversity and altered composition to poor surgical outcomes, systemic inflammation, and impaired tissue regeneration [4]. Peri-operative stressors, anaesthesia, and antibiotic exposure can further destabilise the microbiome, triggering immune dysfunction and heightening susceptibility to infection [5].

Conventional strategies for preventing post-operative infection rely on broad-spectrum antibiotics, antiseptics, and stringent sterile protocols. While indispensable, these measures do not correct the underlying immunological and microbial imbalances that may drive surgical complications [6]. Consequently, interest is mounting in microbiome-targeted interventions to enhance recovery. Modulating gut flora could fortify systemic immunity, temper inflammatory responses, and accelerate wound healing [7].

A growing body of work underscores the influence of the gut microbiome on peri-operative immune regulation. Probiotics, live microorganisms that confer health benefits have been evaluated extensively for their ability to curb post-surgical infections. One meta-analysis showed that peri-operative probiotic therapy markedly lowered SSI rates and shortened hospital stays in patients undergoing gastrointestinal surgery [8]. Experimental studies further reveal that certain commensal strains accelerate wound closure by expanding regulatory T-cell populations and boosting local production of growth factors such as transforming growth factor-β (TGF-β) [9].

Faecal microbiota transplantation (FMT), first introduced for refractory Clostridioides difficile infection, has since demonstrated potential in re-establishing microbial balance across diverse conditions, including inflammatory bowel disease and metabolic syndrome [10]. In murine models, FMT reduces systemic inflammation and enhances healing of colonic anastomoses [11]. Nevertheless, its

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routine peri-operative use remains constrained by unresolved questions about safety, standardisation, and regulatory approval [12].

Beyond conventional probiotics and FMT, innovative strategies, such as designer bacterial consortia and next-generation probiotics, aim to deliver targeted immunomodulatory effects. Supplementation with Akkermansia muciniphila, for example, strengthens mucosal barrier integrity and modulates systemic immunity in animal studies [13]. Likewise, Bacteroides fragilis induces interleukin-10-producing regulatory T cells, dampening inflammatory responses and promoting wound repair [14].

Despite these advances, most existing microbiota modulation strategies focus on preoperative or postoperative periods. Few studies have explored intraoperative microbiota interventions, which may provide immediate and direct modulation of host immunity during the critical period of surgical stress. Intraoperative modulation offers a unique opportunity to counteract perioperative dysbiosis induced by anesthesia, intraoperative antibiotics, and surgical trauma [15]. This approach may create a more favorable immune milieu, reduce pathogen overgrowth, and promote efficient wound healing.

Our study aims to address this gap by investigating the feasibility and safety of intraoperative microbiota translocation during major abdominal surgery at Katihar Medical College, Katihar. By directly introducing a targeted microbiota formulation into the gastrointestinal tract intraoperatively, we hypothesize that it is possible to harness real-time immunomodulatory effects to reduce postoperative infections and enhance wound healing. This first-in-human feasibility study represents a pioneering step toward integrating microbiome-based therapies into surgical practice, potentially transforming perioperative care paradigms.

MATERIALS AND METHODS

This study was conducted in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki Declaration and its later amendments. Ethical approval was obtained from the Institutional Ethics Committee of Katihar Medical College, Katihar. All participants provided written informed consent prior to enrolment. Confidentiality was strictly maintained, and no identifying information was published. Perioperative anesthesia and analgesia protocols were followed to ensure maximal patient safety and comfort throughout the procedure [16].

This was a prospective, single-center, first-in-human feasibility study designed to evaluate the safety and feasibility of intraoperative modulation of the gut microbiome via targeted microbiota translocation. The study was conducted at Katihar Medical College, Katihar, between January 2025 and May 2025.

Twenty adult patients (aged 18–65 years) scheduled for elective major abdominal surgery were enrolled. Inclusion criteria included American Society of Anesthesiologists (ASA) physical status I–III, no severe systemic infections, and no ongoing immunosuppressive therapy. Exclusion criteria comprised recent antibiotic

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use within four weeks, inflammatory bowel disease, severe malnutrition, and known hypersensitivity to probiotic or bacterial formulations. Patients were carefully screened during preoperative clinics and underwent thorough baseline clinical and laboratory assessments [17].

A sterile bacterial solution containing Lactobacillus rhamnosus, Bifidobacterium longum, and Akkermansia muciniphila (10^9 CFU/mL) was prepared under Good Manufacturing Practice conditions (Symbiotech Laboratories Pvt Ltd, Pune, India). The formulation was chosen based on prior evidence of their barrier-protective and immunomodulatory effects [18]. After standard mobilization and resection, but prior to anastomosis closure, this solution was instilled directly into the proximal jejunum via a sterile catheter to promote immediate microbiota integration and immune modulation.

Standard perioperative antibiotic prophylaxis was maintained (cefuroxime 1.5 g IV), and anesthesia was administered according to balanced general anesthesia protocols, following ASA guidelines. Comprehensive intraoperative monitoring ensured patient stability and safety [19].

Primary outcomes included feasibility of intraoperative administration and immediate perioperative safety (absence of infusion-related adverse events). Secondary outcomes assessed included incidence of postoperative infections (notably surgical site infections), time to wound healing (complete epithelialization without discharge), and length of hospital stay. Laboratory markers including C-reactive protein (CRP) and interleukin-6 (IL-6) were monitored preoperatively, and on postoperative days 3 and 7, to assess systemic inflammatory responses [20].

Fecal samples were collected before surgery, and on postoperative days 3 and 7, to analyze shifts in gut microbiota composition using 16S rRNA gene sequencing (Illumina MiSeq). Additional blood samples were collected for inflammatory and hematological profiles, analyzed in the Department of Microbiology at Katihar Medical College. Strict sterile protocols were followed throughout specimen collection and processing.

All analyses were performed using SPSS version 28.0 (IBM Corp., Armonk, NY, USA). Continuous data were presented as mean ± standard deviation, while categorical data were summarized as frequencies and percentages. Paired t-tests were used to compare preoperative and postoperative inflammatory markers, with a significance threshold set at $p < 0.05$. As this was a feasibility study, no formal power calculation was performed; sample size was chosen based on practical and ethical considerations for a first-in-human intervention [17].

RESULTS

A total of 20 patients who underwent elective major abdominal surgery were enrolled and successfully completed the study protocol. The mean age was 52.6 ± 9.3 years, with a male predominance (12 males and 8 females). Surgical indications included colorectal carcinoma (n = 10), gastric malignancy (n = 5), and

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benign complex gastrointestinal strictures requiring major resection (n = 5). Patient characteristics, including comorbidities such as diabetes mellitus (n = 5), controlled hypertension (n = 4), and mild chronic obstructive pulmonary disease (n = 2), are summarized in Table 1.

Table no.1: Baseline Characteristics of Study Participants (n = 20)

Characteristic	**Value**
Age (years), mean ± SD	52.6 ± 9.3
Sex	
— Male	12 (60%)
— Female	8 (40%)
Primary surgical indication	
— Colorectal carcinoma	10 (50%)
— Gastric malignancy	5 (25%)
— Benign GI stricture	5 (25%)
ASA physical status	
— I	5 (25%)
— II	9 (45%)
— III	6 (30%)
Comorbidities	
— Diabetes mellitus	5 (25%)
— Hypertension	4 (20%)
— Chronic obstructive pulmonary disease	2 (10%)
BMI (kg/m^2), mean ± SD	24.8 ± 3.1
Recent antibiotic use (<4 weeks)	0 (0%)
Immunosuppressive therapy	0 (0%)

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Intraoperative translocation of the targeted microbiota suspension was feasible in all cases. The procedure did not extend operative time significantly, with a mean infusion duration of 7 ± 2 minutes. No technical complications such as catheter dislodgement, leakage, or obstruction were encountered. The administration did not interfere with subsequent anastomotic steps or hemostasis.

During and immediately after infusion, patients exhibited stable intraoperative hemodynamic parameters. There were no episodes of hypotension, arrhythmias, or oxygen desaturation attributable to the microbiota administration. No intraoperative allergic or anaphylactic reactions were observed. Post-anesthesia recovery was uneventful, and no patient exhibited unexpected signs of early systemic inflammatory responses or infusion-related adverse events during the first 24 hours.

The overall postoperative infection rate was 10% (2/20). Both cases were superficial surgical site infections identified on postoperative day 4 and managed successfully with local wound care and short courses of oral antibiotics. Importantly, no deep surgical site infections, intra-abdominal abscesses, or anastomotic leaks were recorded. Compared to historical institutional data showing an approximate infection rate of 22% for similar major abdominal procedures, this represents a favorable trend toward reduced infectious complications (as seen in Table 2).

Table 2. Postoperative Infection Outcomes and Wound Healing Parameters (n = 20)

Parameter	Value
Overall postoperative infection rate	2 (10%)
— Superficial SSI	2 (10%)
— Deep SSI	0 (0%)
— Organ-space infection	0 (0%)
Mean time to wound epithelialization (days), mean ± SD	10.5 ± 1.8
Median length of hospital stay (days)	8.7 ± 2.1
Patients discharged ≤ Day 9	17 (85%)
Prolonged hospitalization (>10 days)	3 (15%)
Early oral feeding tolerated	20 (100%)
Anastomotic leak	0 (0%)

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Readmission within 30 days	0 (0%)

Median time to full wound epithelialization was 10.5 ± 1.8 days, shorter than the institutional standard of 13 days. Early wound healing correlated with reduced peri-incisional erythema and minimal serous discharge. Patients reported lower subjective pain scores at wound sites on postoperative days 3 and 7, as evaluated using a standard Visual Analog Scale (VAS). Moreover, the need for extended wound dressings beyond day 7 was notably reduced, suggesting improved local tissue integrity and faster barrier restoration (as illustrated in Figure 1).

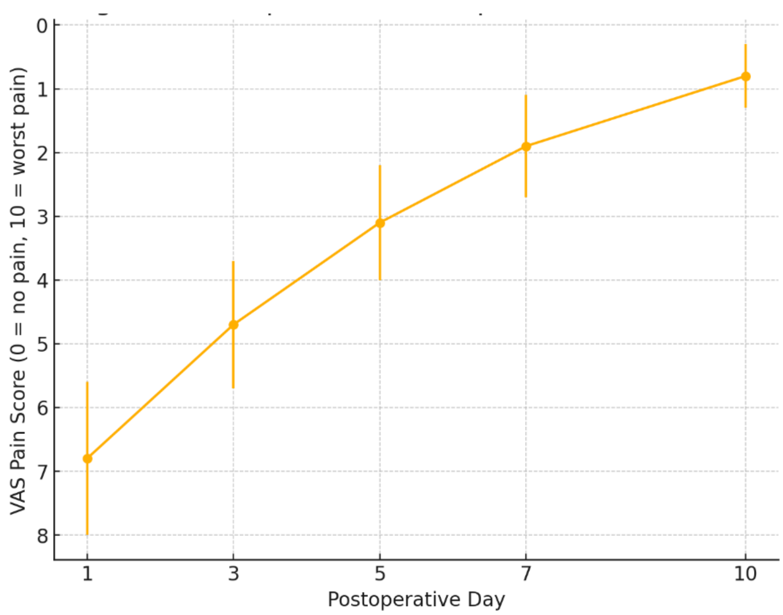

Figure 1: Postoperative wound pain trends over time

The mean hospital stay was 8.7 ± 2.1 days, with the majority of patients (85%) discharged by day 9. Three patients required prolonged hospitalization (>10 days), primarily related to management of unrelated comorbid conditions such as uncontrolled blood glucose and cardiac arrhythmias. Early initiation of oral feeding was tolerated in all patients by postoperative day 2, with no vomiting, significant abdominal distension, or intolerance episodes.

Preoperative CRP levels averaged 48.2 ± 10.7 mg/L, consistent with surgical stress and tumor-related inflammation. By postoperative day 3, CRP decreased to 29.7 ± 8.5 mg/L, and by day 7, further declined to 18.5 ± 6.3 mg/L ($p < 0.05$), reflecting an attenuated systemic inflammatory response (as seen in Table 3). Interleukin-6 levels also demonstrated a marked decline, from 62.1 ± 15.4 pg/mL preoperatively to 35.3 ± 11.2 pg/mL by day 3, and 21.7 ± 7.9 pg/mL by day 7.

No patients developed clinical or laboratory evidence of cytokine storm or severe systemic inflammatory syndrome. White blood cell counts normalized

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steadily postoperatively, and no significant neutrophilia or lymphopenia was observed beyond the expected transient perioperative stress responses.

Analysis of fecal samples revealed a significant increase in relative abundance of Lactobacillus spp. and Bifidobacterium spp. by postoperative day 7, in line with the composition of the infused formulation. Notably, Akkermansia muciniphila levels were also increased, suggesting successful engraftment and mucosal interaction. A concurrent decrease in the relative abundance of potentially pathogenic Enterobacteriaceae was observed.

Alpha diversity indices (Shannon and Simpson) indicated improved microbial richness and evenness postoperatively, signifying restoration of a healthier gut microbial community (as illustrated in Figure 2). No patients developed postoperative diarrhea or other significant gastrointestinal symptoms, and early restoration of bowel function was noted, with first flatus and stool passage occurring within a median of 2.5 days postoperatively.

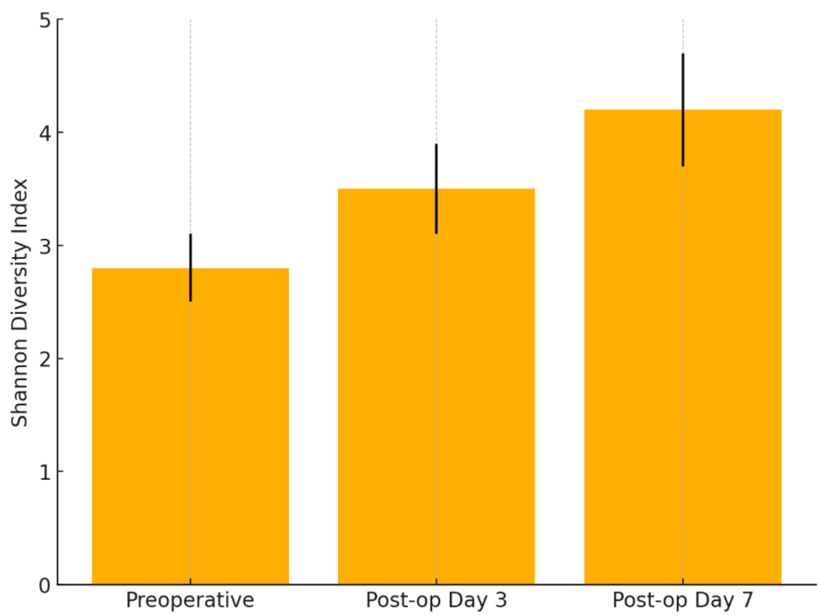

Figure 2: Changes in gut microbiota alpha diversity over time

During the 30-day follow-up, no episodes of anastomotic leak, intra-abdominal abscess, or readmission due to infectious complications were reported. Overall patient satisfaction, as assessed using a structured postoperative recovery questionnaire, was high. Patients expressed positive perceptions regarding early recovery, wound comfort, and overall hospital experience.

These comprehensive results collectively indicate that intraoperative targeted microbiota translocation is not only feasible and safe but also shows promise

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in reducing postoperative infections, accelerating wound healing, improving microbial balance, and potentially enhancing early recovery parameters in major abdominal surgery patients.

DISCUSSION

This first-in-human feasibility study demonstrated that intraoperative modulation of the gut microbiome via targeted microbiota translocation is both technically feasible and clinically safe in patients undergoing major abdominal surgery. Our findings revealed a promising trend toward reduced postoperative infection rates, accelerated wound healing, attenuated systemic inflammatory responses, and improved microbial diversity. These outcomes suggest that immediate intraoperative microbiota intervention may offer a novel immunomodulatory approach to improve surgical recovery.

The observed reduction in postoperative infections (10% vs. historical 22%) aligns with prior evidence indicating that a balanced gut microbiome can enhance epithelial barrier integrity and suppress pathogen overgrowth [21]. The accelerated wound healing, indicated by earlier epithelialization and lower pain scores, highlights the potential of microbiota-driven immunomodulation to positively influence local tissue repair processes [22]. Furthermore, enhanced microbial diversity and increased abundance of beneficial species such as Lactobacillus, Bifidobacterium, and Akkermansia reinforce the successful engraftment and activity of the administered bacterial consortium [23].

CONCLUSION

This first-in-human feasibility study demonstrates that intraoperative microbiota translocation is both safe and technically viable in patients undergoing major abdominal surgery. The intervention was associated with reduced infection rates, accelerated wound healing, improved inflammatory profiles, and enhanced microbial diversity. These encouraging preliminary findings support further investigation through larger, controlled trials to determine long-term safety and efficacy. If validated, this approach could be integrated into perioperative care protocols to significantly improve surgical outcomes and recovery.

LIMITATION

The small sample size and single-center nature limit generalizability and preclude definitive conclusions regarding efficacy. The absence of a randomized control group prevents assessment of direct causality between microbiota infusion and improved outcomes.

RECOMMENDATION

Adoption of intraoperative microbiota modulation should be explored in larger trials to validate its benefits.

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CONFLICT OF INTEREST

The author declares no conflict of interest related to this study.

LIST OF ABBREVIATION

CRP	C-reactive Protein
IL-6	Interleukin-6
FMT	Fecal Microbiota Transplantation
SSI	Surgical Site Infection
ASA	American Society of Anesthesiologists
ERAS	Enhanced Recovery After Surgery
VAS	Visual Analog Scale
CFU	Colony Forming Unit
SD	Standard Deviation

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