Frontiers on Healthcare Research

ISSN: 3032-7725
Journal homepage: frontiersonhealthcare.org

Publisher: Rumah Sakit dr. M. Djamil, Padang, West Sumatra, Indonesia

Effect of Preoperative Lactobacillus acidophilus Supplementation on Postoperative Gastric Residual Volume after Lower Digestive Laparotomy: A Randomized, Double-Blind, Controlled Trial

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Article information

Submitted
23-06-2026

Accepted
22-08-2026

Published
30-08-2026

Abstract

Background: Gastrointestinal dysmotility is among the most common complications after abdominal surgery and is reflected clinically by an elevated gastric residual volume (GRV), which increases the risk of aspiration and delays enteral feeding. Lactobacillus acidophilus is thought to improve gut motility through luminal acidification, competitive exclusion of pathogens, and direct stimulation of smooth-muscle contractility, but whether this translates into a lower GRV after digestive laparotomy has not been tested.
Objective: To determine whether preoperative Lactobacillus acidophilus supplementation reduces postoperative GRV after lower digestive laparotomy.

Methods: In this randomized, double-blind, placebo-controlled trial at Dr. Cipto Mangunkusumo National General Hospital, Indonesia, adults scheduled for elective laparotomy of the jejunum, ileum, colon, or rectum received oral Lactobacillus acidophilus 10^9 CFU or an identical placebo capsule three times daily for three days before surgery. A nasogastric tube inserted during surgery was aspirated every 6 hours after ICU admission; GRV was categorized as normal (<250 mL/24h) or increased (≥250 mL/24h) at 24 and 48 hours.
Results: Fifty-five participants were randomized (27 probiotic, 28 placebo); one placebo-group participant was withdrawn because of sepsis, leaving 54 participants analyzed per protocol. GRV was increased in 4/27 (14.8%) probiotic recipients versus 2/27 (7.4%) placebo recipients at 24 hours ($p = 0.669$; risk ratio for normal GRV 0.92, 95% CI 0.76–1.11) and in 1/27 versus 0/27 at 48 hours ($p = 1.000$). Stratified analysis identified age, neurological comorbidity, obesity, vasopressor use, opioid exposure, hypercapnia, and hyperglycemia as confounders that shifted the crude risk estimate by more than 10%; opioid and vasopressor exposure were also unevenly distributed between groups at baseline ($p = 0.006$ and $p = 0.026$, respectively).
Conclusion: A 3-day preoperative course of Lactobacillus acidophilus did not significantly reduce postoperative GRV after lower digestive laparotomy. The trial was underpowered relative to its planned sample size, and an uneven distribution of opioid and vasopressor exposure between groups may have obscured a true effect.

Keywords: *lactobacillus acidophilus, probiotics, gastric residual volume, laparotomy, intensive care unit*

Introduction

Laparotomy disrupts normal gastrointestinal motor activity, and gastrointestinal complications are among the most frequent problems seen after abdominal surgery. In a cohort of more than 1,100 emergency laparotomies, Tengberg et al. found that 12.5% of patients developed a gastrointestinal complication postoperatively, a rate exceeded only by pulmonary and abdominal infectious complications; most such events (nausea, vomiting, ileus,

anastomotic leak) became apparent within the first 72 hours[1]. A frequent but easily overlooked marker of this dysfunction is an elevated gastric residual volume (GRV), which signals delayed gastric emptying and carries a direct risk of pulmonary aspiration.

The mechanism behind postoperative gastric dysmotility remains incompletely understood, but current evidence points to disordered coordination of antral and pyloric contractions, that is, a failure of the propagating pressure wave that would otherwise clear gastric contents into the duodenum, rather than to a single anatomical or biochemical lesion[2]. Multiple perioperative factors compound this dysfunction, including opioid and vasopressor exposure, hyperglycemia, and advanced age, each of which independently slows gastric emptying in critically ill patients.

At our institution, a one-year audit of the adult intensive care unit (ICU) conducted between November 2020 and November 2021 found that 40% of 100 patients undergoing digestive laparotomy developed an increased GRV postoperatively, a proportion high enough to represent a recurring clinical problem, given its downstream implications for feeding tolerance, nutritional adequacy, and length of stay.

Current strategies to restore gastric motility (glycemic control, prokinetic agents such as metoclopramide, and erythromycin) carry recognized drawbacks, including tachyphylaxis with erythromycin and extrapyramidal effects with metoclopramide, and their efficacy in critically ill patients remains inconsistent[3]. This has prompted interest in gut-directed adjuncts with a more favorable safety profile.

Probiotic Lactobacillus species are among the candidates explored for this purpose. Lactobacillus strains lower luminal pH through lactate and acetate production, compete with pathogens for adhesion sites and nutrients, and, specific to Lactobacillus acidophilus, appear to enhance smooth-muscle contractility through a PKC/MLCK/MLC-dependent pathway[4,5]. In colorectal surgery, a short preoperative course of probiotics established measurable gut colonization within days and reduced postoperative infectious complications[6]. In infants, probiotic supplementation alongside partially hydrolyzed formula was associated with fewer regurgitation episodes and faster gastric emptying, consistent with a genuine prokinetic effect[7].

Whether this translates into a measurable reduction in GRV after digestive laparotomy in adults, however, has not been tested. We conducted this trial to determine whether a short preoperative course of Lactobacillus acidophilus reduces postoperative GRV in patients undergoing lower digestive laparotomy, hypothesizing that supplementation would lower the incidence of increased GRV relative to placebo.

Methods

Study Design and Setting

This randomized, double-blind, placebo-controlled trial was conducted in the adult intensive care unit of Dr. Cipto Mangunkusumo National General Hospital, Jakarta, Indonesia, in 2022, after approval from the Health Research Ethics Committee of the Faculty of Medicine, Universitas Indonesia (No. KET-680/UN2.F1/ETIK/PPM.00.02/2022) and institutional permission from the hospital director.

Participants and Eligibility Criteria

Eligible participants were men and women aged 18–60 years, ASA physical status I–III, scheduled for elective laparotomy of the lower digestive tract (jejunum, ileum, colon, or rectum) at the Central Surgical Installation, admitted to the ICU postoperatively, maintained on a clear-fluid diet, and without prior probiotic use. We excluded patients who declined participation or were uncooperative, those with a comorbidity likely to confound GRV assessment (anatomical gastric abnormality or prior gastric surgery, end-stage chronic kidney disease, acute respiratory distress syndrome, or a central nervous system lesion), and those whose clinical condition precluded continuing the assigned regimen. Participants who did not complete the assigned 3-day regimen were considered dropouts and excluded from the per-protocol analysis.

Sample Size

The sample size was calculated for comparison of two independent proportions (Zα 1.96, two-sided 95% confidence; power 80%), using a 10% proportion of GRV reduction in the probiotic arm versus 90% in the control arm, as reported in earlier probiotic trials in surgical patients[8,9], together with the 40% baseline incidence of increased GRV observed locally. This yielded a minimum requirement of 34 participants per group (68 total); the achieved sample fell short of this target because recruitment was constrained by the study's fixed enrollment window (see Limitations).

Randomization and Blinding

A research assistant with no other role in the study generated the allocation sequence by simple randomization (randomizer.org) and prepared 68 sequentially numbered, sealed envelopes, which were distributed as participants were enrolled. The hospital Pharmacy Installation compounded the probiotic and placebo capsules to be identical in appearance, taste, and packaging, keeping both the investigator performing the intervention and the participant blinded to allocation throughout the study.

Intervention

Participants assigned to the probiotic group received an oral capsule of Lactobacillus acidophilus 10^9 CFU (equivalent to 100 mg; Natrol Acidophilus Probiotic) three times daily for three days before surgery; the control group received an identical lactose-containing placebo capsule on the same schedule. Administration was recorded in the integrated patient progress notes. All participants then underwent elective lower digestive laparotomy; an 18F silicone nasogastric tube was placed intraoperatively, with its position confirmed by chest radiography after ICU admission. Intraoperative and postoperative management otherwise followed standard institutional protocols and was not altered by study participation.

Outcome Measures

Gastric aspirate was withdrawn via a 50-mL syringe every 6 hours for 48 hours and summed into cumulative 24-hour and 48-hour volumes, recorded jointly by the anesthesiology resident and ICU nursing staff. The primary outcome was GRV category at 24 and 48 hours, defined as normal (<250 mL/24h) or increased (≥250 mL/24h), consistent with previously validated thresholds for ICU gastric residual monitoring[10]. Prespecified candidate confounders (age, sex, obesity, comorbidity profile, enteral diet timing, opioid and vasopressor exposure, mechanical ventilation duration, hypoxia, hypercapnia, and blood glucose) were recorded concurrently from medical records.

Statistical Analysis

Data were analyzed using SPSS version 26. Normality of continuous variables was assessed with the Shapiro–Wilk test. Between-group comparison of the categorical primary outcome was performed using the chi-square test or Fisher's exact test, as appropriate. Candidate confounders were first compared between groups, then evaluated by Mantel–Haenszel stratified analysis against the primary outcome; a shift exceeding 10% between the crude and stratum-adjusted risk ratio was taken as evidence of confounding. A two-sided $p < 0.05$ was considered statistically significant.

Results

Participant Flow

The trial aimed to enroll 68 participants per the sample size calculation, but the fixed recruitment window yielded 55 randomized participants: 27 to the probiotic group and 28 to placebo (Figure 1). One participant in the placebo group was withdrawn after randomization and drug administration because of sepsis; no participant was lost to follow-up. The remaining 54 participants (27 per group) were analyzed per protocol.

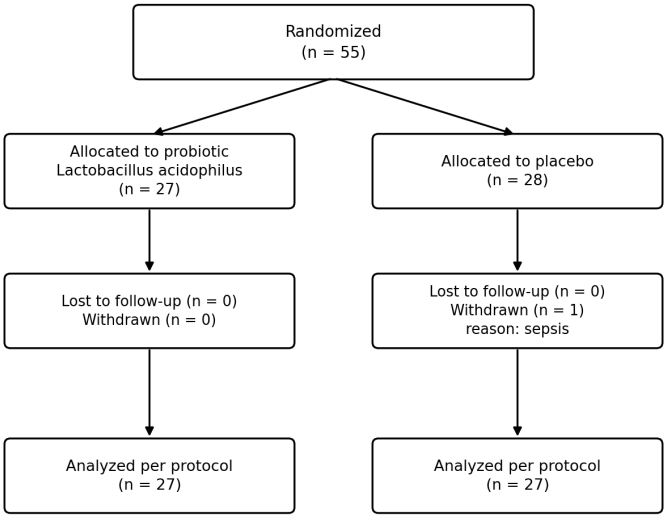

Figure 1. CONSORT flow diagram of participant randomization, allocation, follow-up, and analysis

Baseline Characteristics

Baseline characteristics were summarized in Table 1. Mean age was somewhat lower in the probiotic group than in the control group (48.0±12.8 vs 52.0±15.0 years), and the sex distribution differed numerically (59.3% female in the probiotic group vs 63.0% male in the control group). Pulmonary, cardiac, neurological, metabolic, and renal comorbidity profiles were broadly similar between groups; no participant in the probiotic group was obese, compared with 7.4% in the control group. Median length of ICU stay was marginally shorter with probiotic supplementation (1.4 vs 1.6 days).

Table 1. Baseline demographic and clinical characteristics

Characteristic	Probiotic (n = 27)	Placebo (n = 27)
Age (years), mean ± SD	48.0 ± 12.8	52.0 ± 15.0
ICU length of stay (days), mean ± SD	1.4 ± 0.8	1.6 ± 1.2
Male sex, n (%)	11 (40.7)	17 (63.0)
Female sex, n (%)	16 (59.3)	10 (37.0)
Obesity, n (%)	0 (0)	2 (7.4)
Pulmonary comorbidity, n (%)	2 (7.4)	2 (7.4)
Cardiac comorbidity, n (%)	6 (22.2)	6 (22.2)
Neurological comorbidity, n (%)	1 (3.7)	3 (11.1)
Metabolic comorbidity, n (%)	4 (14.8)	4 (14.8)
Renal comorbidity, n (%)	1 (3.7)	3 (11.1)

Data are descriptive; between-group comparisons were not formally tested for baseline characteristics.

Distribution of Candidate Confounders

Most candidate confounders (enteral diet timing, mechanical ventilation duration, hypoxia, hypercapnia, glycemic status, and patient positioning) were similarly distributed between groups (Table 2). Two exposures, however, differed significantly: a history of opioid use was less common in the probiotic group (25.9% vs 63.0%; p = 0.006), as was a history of vasopressor use (11.1% vs 37.0%; p = 0.026).

Table 2. Distribution of candidate confounding factors

Factor (n, % with exposure)	Probiotic (n = 27)	Placebo (n = 27)	p value
Age ≥ 60 years	20 (74.1)	17 (63.0)	0.379
Enteral diet initiated	24 (88.9)	22 (81.5)	0.704
History of opioid use	7 (25.9)	17 (63.0)	0.006
History of vasopressor use	3 (11.1)	10 (37.0)	0.026
Mechanical ventilation ≥ 48 h	0 (0)	2 (7.4)	0.491
Hypoxia	2 (7.4)	2 (7.4)	1.000
Hypercapnia	4 (14.8)	3 (11.1)	1.000
Blood glucose ≥ 200 mg/dL	4 (14.8)	4 (14.8)	0.311

Chi-square or Fisher's exact test as appropriate; the age distribution above reflects the categorical variable as recorded and should be read alongside the continuous age summary in Table 1.

Effect on Gastric Residual Volume

At 24 hours, GRV was increased in 4 of 27 participants (14.8%) receiving the probiotic versus 2 of 27 (7.4%) receiving the placebo, a numerically higher, not lower, incidence with probiotic supplementation, though the difference was not statistically significant (p = 0.669; risk ratio for a normal GRV, probiotic versus placebo, 0.92, 95% CI 0.76–1.11) (Table 3). At 48 hours, one probiotic-group participant and no placebo-group participant had an increased GRV (p = 1.000); the risk ratio could not be estimated because of an empty cell in the placebo arm. Univariable comparisons of the individual candidate confounders against 24- and 48-hour GRV likewise showed no statistically significant associations (all p > 0.05).

Table 3. Gastric residual volume at 24 and 48 postoperative hours

Timepoint	Probiotic, n (%)	Placebo, n (%)	p value	RR (95% CI)†
24 h – Normal	23 (85.2)	25 (92.6)	0.669	0.92 (0.76–1.11)
24 h – Increased	4 (14.8)	2 (7.4)		
48 h – Normal	26 (96.3)	27 (100)	1.000	not estimable
48 h – Increased	1 (3.7)	0 (0)		

†Risk ratio for a normal (non-elevated) GRV, probiotic versus placebo. The 48-hour risk ratio could not be estimated because of a zero cell in the placebo arm. Normal: <250 mL/24h; Increased: ≥250 mL/24h.

Stratified Analysis for Confounding

Because the probiotic and placebo groups differed at baseline in opioid and vasopressor exposure, we examined whether adjustment for candidate confounders altered the crude risk estimate for 24-hour GRV (Table 4). Age, neurological comorbidity, obesity, vasopressor use, opioid use, hypercapnia, and hyperglycemia (blood glucose ≥200 mg/dL) each shifted the stratum-adjusted risk ratio by more than 10% relative to the crude estimate, consistent with meaningful confounding; hypoxia did not (0% shift). The timing of enteral diet initiation showed the largest shift of all candidate factors, at 46.1%, although the corresponding stratum-specific risk ratios could not be fully reconstructed from the available data.

Table 4. Mantel–Haenszel stratified analysis for confounding of the 24-hour gastric residual volume outcome

Candidate confounder	Crude RR	Adjusted RR	ΔRR (%)	Confounding
Age ≥ 60 years	0.92	2.38	38.8	Present

Candidate confounder	Crude RR	Adjusted RR	ΔRR (%)	Confounding
Neurological comorbidity	0.92	1.85	15.4	Present
Obesity	0.92	1.85	14.8	Present
Vasopressor use	0.92	1.72	28.0	Present
Opioid use	0.92	1.28	71.1	Present
Hypoxia	0.92	2.00	0.0	Absent
Hypercapnia	3.43	3.60	17.1	Present
Blood glucose ≥ 200 mg/dL	0.92	1.79	26.1	Present

ΔRR = percentage difference between the crude and Mantel–Haenszel stratum-adjusted risk ratio; a shift exceeding 10% was taken as evidence of confounding.

Discussion

Effect of Probiotic Supplementation on Gastric Residual Volume

We found no evidence that a 3-day preoperative course of Lactobacillus acidophilus reduced postoperative GRV after lower digestive laparotomy; if anything, the incidence of increased GRV at 24 hours was numerically higher with probiotic supplementation, though well within the range expected by chance. This contrasts with smaller studies reporting a benefit: Orel found that Lactobacillus reuteri reduced GRV and accelerated gastric emptying in infants[11], and Mahmoodpoor et al. reported that a multi-strain probiotic preparation given for 14 days lowered GRV alongside a shorter ICU and hospital stay in critically ill adults[12]. Two differences may explain the discrepancy. First, both positive trials applied a longer exposure window than the 3 days used in the present trial; Zhang et al. demonstrated measurable Bifidobacterium colonization after a comparable 3-day preoperative course in colorectal surgery patients[6], but colonization density sufficient to alter motility may require longer exposure than colonization detectable by stool culture. Second, our sample of 54 fell well short of the 68 calculated as necessary to detect the assumed effect size, leaving the trial underpowered for a moderate difference in GRV incidence.

The biological rationale for a probiotic effect nonetheless remains plausible. Lactobacillus acidophilus normalized delayed gastric emptying and intestinal transit in a mouse model of chemotherapy-induced mucositis, an effect attributed partly to suppression of the inflammatory mediators that accompany gastric dysmotility[13]. Probiotics more broadly support gut barrier integrity and modulate enteric neural signaling in ways that could, in principle, restore coordinated antral contraction after surgery[14,15]. Whether a longer or higher-dose regimen would be sufficient to translate this mechanism into a measurable reduction in GRV is a question this trial was not designed, or powered, to answer.

Confounding Factors Influencing Gastric Residual Volume

Stratified analysis identified several factors (age, neurological comorbidity, obesity, vasopressor use, opioid exposure, hypercapnia, and hyperglycemia) that shifted the risk estimate for increased GRV by more than the conventional 10% threshold for confounding, and two of these (opioid and vasopressor exposure) were also unevenly distributed between the randomized groups. Each has an established physiological basis. Gastric emptying slows with age as part of a broader decline in gut motor reserve;[16] lesions or dysfunction affecting the vagally mediated gastric inhibitory and excitatory motor circuits can directly impair coordinated emptying;[17] and obesity is associated with increased gastric capacity, which independently raises measured residual volume[18]. Vasoactive drugs, by inducing splanchnic vasoconstriction, can impair gastrointestinal perfusion and motility regardless of the indication for their use[19], while opioids, acting on enteric mu receptors, slow antral and pyloric motility largely independent of the route of administration[20]. Hypercapnia and hyperglycemia act through distinct but convergent pathways: hypercapnia reduces gastric tone and motility via arterial chemoreceptor-mediated signaling[21], and hyperglycemia prolongs the lag phase of gastric emptying by reducing proximal gastric

tone and suppressing antral pressure waves[22]. Enteral diet timing also emerged as an influential factor, likely reflecting an interaction between feeding volume and the reduced emptying capacity already present in older or more physiologically compromised patients[23].

Because opioid and vasopressor exposure were both more common in the placebo group, any true probiotic effect on GRV could have been masked rather than absent altogether: the control group's higher pharmacological burden would tend to push its own GRV upward, narrowing the apparent between-group difference. This imbalance most likely arose from the trial's modest, underpowered sample rather than any flaw in the randomization procedure itself, and it underscores the value of either a larger sample or explicit adjustment for these exposures in future trials.

Strengths and Limitations

This trial's principal strength was its double-blind design, with a placebo capsule matched for appearance and taste by hospital pharmacy compounding, a feature that minimizes both performance and detection bias in a subjective, effort-dependent measurement such as nasogastric aspirate volume. Its principal limitation was recruitment: the achieved sample of 54 fell well short of the 68 required by the prespecified power calculation, leaving the trial underpowered to detect anything short of a large effect. The 3-day preoperative course, chosen for practical compatibility with typical preoperative admission windows, may also have been too brief for probiotic colonization to translate into a measurable motility effect. Single-center enrollment, a dichotomized rather than continuous GRV outcome, and an uneven distribution of opioid and vasopressor exposure between groups further limited the generalizability of these findings.

Conclusions

In this randomized, double-blind trial, a 3-day preoperative course of Lactobacillus acidophilus did not significantly reduce postoperative gastric residual volume after lower digestive laparotomy. Given the trial's underpowered sample and the uneven baseline distribution of opioid and vasopressor exposure, these findings should be read as inconclusive rather than as evidence against a genuine probiotic effect.

Recommendations for Future Research

An adequately powered, multicenter trial, enrolling to the originally calculated sample size, will allow a more definitive test of this hypothesis. Extending the preoperative course beyond three days, or using a multi-strain probiotic formulation, may better approximate the exposure duration associated with benefit in prior studies. Given the confounding identified here, future trials should consider stratified randomization or statistical adjustment for age, opioid and vasopressor exposure, and glycemic status, and might gain sensitivity by analyzing GRV as a continuous rather than a dichotomized outcome.

Funding

This study was conducted as part of the corresponding author's postgraduate thesis requirement at the Faculty of Medicine, Universitas Indonesia, and was funded entirely by the researchers, without support from any pharmaceutical or device sponsor.

Ethics approval and consent to participate

This study was approved by the Health Research Ethics Committee of the Faculty of Medicine, Universitas Indonesia – Dr. Cipto Mangunkusumo National General Hospital (protocol 22-06-0657, approved 4 July 2022) and conducted with institutional permission from the hospital director. Written informed consent was obtained from all participants before enrollment.

Conflict of interest

The authors declare no conflict of interest.

Author contributions

CS conceived and designed the study, performed data collection and the intervention, analyzed the data, and drafted the manuscript. RS, SKM, and WSJ supervised the study design and conduct, and critically revised the manuscript for important intellectual content. All authors read and approved the final manuscript.

Data availability

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Declaration concerning generative AI and AI-augmented technologies in the compositional process

In the course of preparing this paper, the authors utilized ChatGPT to enhance readability and linguistic quality. Subsequent to utilizing this tool/service, the writers assessed and amended the information as necessary and assume complete accountability for the publication's content.

Declarations of competing interest

This study does not involve any personal, financial, or other conflicts of interest.

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