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Meta-analyses

Effects of perioperative supplementation with pro-/synbiotics on clinical outcomes in surgical patients: A meta-analysis with trial sequential analysis of randomized controlled trials

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SUMMARY

Background & aims: The Potential benefits and possible risks of perioperative supplementation with probiotics/synbiotics in surgical patients are not fully understood. Recent evidence has rapidly evolved and conveys conflicting results. Thus, we undertook a meta-analysis of randomized controlled trials (RCTs) to valuate the effectiveness, safety, cost-effectiveness and quality of life of perioperative supplementation with pro-/synbiotics.

Methods: We systematically searched PubMed, Embase and the Cochrane Library through October 2015 to identify RCTs that assessed the effects of perioperative supplementation with pro-/synbiotics in surgical patients. The predefined primary efficacy outcome was surgical site infection (SSI). Random-effects model was applied to pool outcome data accounting for clinical heterogeneity.

Results: Our meta-analysis included data from 34 trials comprising 2634 participants, of whom 1300 received perioperative pro-/synbiotics intervention and 1334 received valid control treatment. Compared with the control group, patients in the pro-/synbiotics group had a lower risk of SSI (relative risk: 0.65; 95% confidence interval: 0.51, 0.84; $P = 0.0007$). Trial sequential analysis confirmed the evidence was sufficient and conclusive. Subgroup analyses indicated the findings were consistent in all subgroup analyses except for the probiotics, enteral feeding, pre-/postoperative and live transplantation subgroups. Pro-/synbiotics also reduced the incidence of other infectious complications (including any infection, pneumonia, urinary tract infection, wound infection and sepsis); shortened antibiotic therapy, intensive care unit stay and hospital stay; and promoted earlier first defecation and first bowel movement. Pro-/synbiotics further reduced the incidence of abdominal side effects, lowered hospital costs and improved the Gastro-Intestinal Quality of Life.

Conclusions: For surgical patients, perioperative supplementation with pro-/synbiotics is effective in preventing or controlling SSI and other infectious complications. Perioperative pro-/synbiotics might also be associated with fewer side effects, lower hospital cost and better quality of life. Current evidence indicated that perioperative synbiotics supplementation is preferred and recommended as an adjunct in surgical patients.

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1. Introduction

It has been estimated that the annual number of major surgical procedures has exceeded 234.2 million worldwide [1]. However, perioperative infections continue to plague modern healthcare systems and induce considerable harm to patients [2]. More than 5% of patients undergoing a surgical procedure develop a surgical site infection (SSI) [3]. Postoperative infectious complications including SSI, pneumonia and urinary tract infection, are common causes of postoperative morbidity and mortality and represent a major threat to patient safety and have become a serious public concern [1,2,4]. Postoperative infections further increase antibiotic consumption and prolong intensive care unit (ICU) stay and hospital stay, substantially increasing medical expenses [2,4,5]. Therefore, prevention of infectious complications and other morbidities has become a high priority of perioperative care.

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Abbreviations

CFU	colony forming unit
CI	confidence interval
GIQoL	Gastro-Intestinal Quality of Life
GRADE	Grading of Recommendations Assessment, Development, and Evaluation
ICU	intensive care unit
MD	mean difference
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT	randomized controlled trial
RR	relative risk
SMD	standard mean difference
SSI	surgical site infection
TSA	trial sequential analysis

Probiotics are living microorganisms believed to convey health benefits to the host when sufficiently consumed [6]. Synbiotics are nutritional supplementations combining probiotics with prebiotics (selectively fermented ingredient that stimulate the growth and/or function of beneficial intestinal microorganisms) in a form of synergism [7]. Previously published studies have validated the beneficial effects of pro-/synbiotics in various clinical settings [8–11]. However, previous reviews about the effects of perioperative pro-/synbiotics in surgical patients have been non-systematic [12–16], focusing on specific patient populations or incomplete outcomes, and have not included the latest clinical trials. Recently, several randomized controlled trials (RCTs) on the topic have been published and conveyed conflicting results [17–50]. We therefore undertook a meta-analysis to evaluate broadly the latest and most convincing evidence on perioperative supplementation with pro-/synbiotics on clinical outcomes in surgical patients.

2. Methods

The present meta-analysis was performed according to the recommendations of the *Cochrane Handbook for Systematic Reviews of Interventions* [51] and was reported in compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement guidelines [52]. There was no registered protocol for this review.

2.1. Literature search strategy

We carried out a systematic electronic search in PubMed, Embase, and the Cochrane Central Register of Controlled Trials from inception to October 20, 2015. Details of the search strategy are available in Table S1. No language restriction was imposed. We repeated the searches on December 10, 2015, to ensure literature saturation. We also searched the ClinicalTrials.gov registry (www.clinicaltrials.gov) and manually checked the bibliography lists of included studies, systematic reviews and meta-analyses, or narrative reviews identified through the initial search.

2.2. Study selection

Two investigators (X.-D. W. and M.-M. L.) independently screened the titles and abstracts to remove duplicate records and to exclude records that did not fulfill the inclusion criteria. If the titles and abstracts appeared to meet the inclusion criteria or any uncertainty existed, we obtained the full text of the records to decide eligibility. We also recorded the reasons for excluding trials. Discrepancies were resolved through discussion. We included published RCTs that met the following criteria: (i) Population: patients undergoing surgical procedures; (ii) Intervention: received any kind of probiotics or synbiotics as prophylaxis administrated preoperative and/or postoperative; (iii) Comparison: received proper controls such as placebo or other agents; and (iv) Outcomes: with one or more of the outcomes in the following description.

2.3. Data abstraction

Two authors (X.-D. W. and M.-M. L.) independently extracted the data. Data abstracted from each trial included: authors, publication year, geographical area, number of participants, demographic characteristics, clinical setting, type and dosage of pro-/synbiotics used, pro-/synbiotics source, route and duration of administration, control treatment and follow-up. Abstracted data were entered into a pre-generated standardized data extraction forms. We also sought supplementary appendices of included trials or contacted authors whenever additional information was required. We resolved disagreements by discussion, and one arbitrator (W. H.) adjudicated unresolved disagreements.

2.4. Outcome measurements and definitions

The predefined primary efficacy outcome was SSI (including wound infections or superficial incisional infections, deep incisional infections, and organ space infections) at the final follow-up; secondary efficacy outcomes were other infectious complications (including any infection, pneumonia, urinary tract infection, wound infection, sepsis, intra-abdominal infection, cholangitis and central line infection), non-infectious complications, anastomotic leakage, acute transplant rejection, mortality, length of antibiotic therapy, length of ICU stay, and length of hospital stay (defined as the number of inpatient days from surgery until discharge). The safety outcomes were side effects, including diarrhea, abdominal cramps and abdominal distension. We also extracted hospital cost data and Gastro-Intestinal Quality of Life (GIQoL) index scores to evaluate cost-effectiveness and quality of life.

2.5. Risk of bias assessment

We used the Cochrane risk of bias tool to appraise risk of bias [53]. Two authors (X.-D. W. and X. L.) respectively reviewed each study and labeled a value of high, low, unclear to each of the following categories: random sequence generation (selection bias), allocation concealment (selection bias), blinding of participants and personnel (performance bias), blinding of outcome assessment (detection bias), incomplete outcome data (attrition bias), selective reporting (reporting bias), and other bias. Trials with a high risk of bias for any one or more key domains were considered at high risk of bias; whereas trials with a low risk of bias for all key domains were considered at low risk of bias; otherwise, they were considered at unclear risk of bias. We also assessed bias in the financial support.

2.6. Grading quality of evidence

Two experienced authors (X.-D. W. and N. H.) applied the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) approach to assess the quality of evidence [54,55]. Quality of evidence was categorized into 4 levels: very low, low, moderate, or high. Summary tables were constructed using the GRADE profiler (GRADEpro, version 3.6).

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