

Systematic review of the effectiveness of the Lactinex probiotic against all-cause diarrhea

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Background & Review

Probiotics are a growing industry worth an estimated \$54.21 billion, though little research exists to recommend which formulations are most effective.

- Probiotic usage has long been sought to treat a wide range of ailments including Celiac's disease, diarrhea, bacterial infections, autism, vaginal dysbiosis, and a host of other medical conditions.

The second most commonly stocked probiotic found in hospitals nationwide is Lactinex.

- Lactinex is a combination probiotic containing *Lactobacillus acidophilus* and *Lactobacillus bulgaricus* (*helveticus*). It is often used in the treatment of diarrhea.
- Many probiotics do not contain their specific probiotic strains on the label.

This review seeks to evaluate the effectiveness of Lactinex in the treatment of all-cause diarrhea.

- A growing body of data is shedding light on probiotic efficacy, especially with symptomatic relief of gastrointestinal diseases.
- The absence of strain specific research impairs physicians' abilities to optimize therapeutic use of probiotics.



Methodology

Literature Review

- A systematic review was performed of over 2000 papers with a blinded consensus of the available studies via Rayyan QCRI. In areas of disagreement, three authors would convene to make a unanimous decision upon full text review.
- Four papers were found to meet inclusion criteria.

	Inclusion criteria	Exclusion criteria
Population	Any	
Interventions	Lactinex or Floranex (Lactobacillus acidophilus & Lactobacillus bulgaricus (L. Helveticus))	Any probiotic that was not a 50/50 mix of L. acidophilus and L. bulgaricus (L. Helveticus)
Outcomes	Diarrhea	
Study design	RCTs Placebo-controlled trials Studies with a clear sample size calculation	Meta-analysis Systematic review
Date restrictions	None	
Language restrictions	English language	
Country	Not restricted by country	

Data Collection & Quality Assessment

- Randomized, placebo-controlled, trials evaluating the effectiveness of a combination of Lactobacillus acidophilus and Lactobacillus bulgaricus by any name including Lactinex and Floranex in the treatment of diarrhea by any cause were identified by literature review.
- Data items were collected as in the original systematic review, including patient demographics, sample size, strain of probiotic, setting, primary and secondary endpoints, and results.

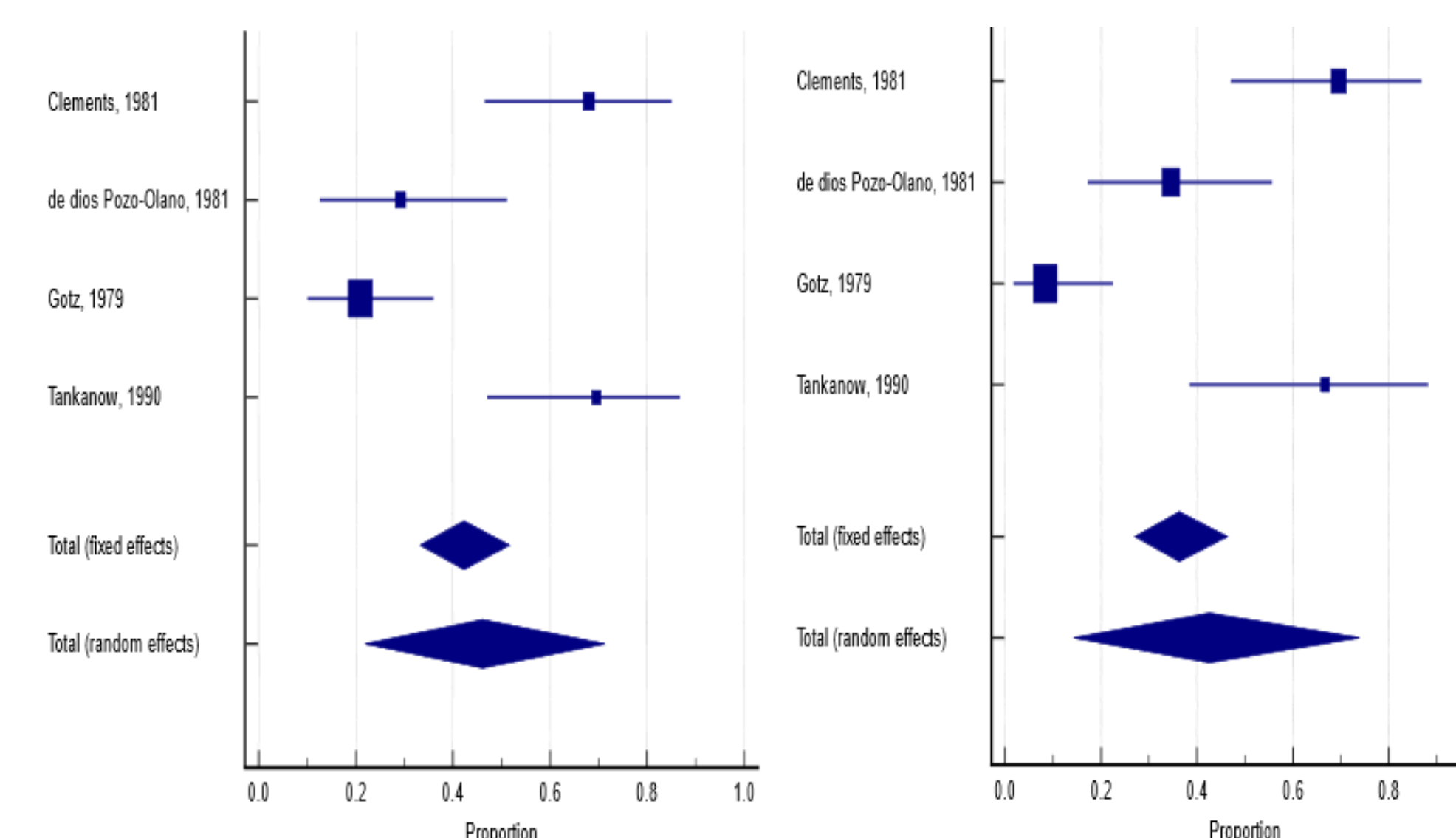
Statistical Analysis

- The following data were collected from each article
 - The number of control cases who developed diarrhea.
 - The total number of control cases.
 - The number of Lactinex cases who developed diarrhea.
 - The total number of Lactinex cases.

Results

Upon Completion of the review, no clinically significant difference in relief of diarrhea was noted between Lactinex and Placebo-treated groups.

Relative effectiveness of Lactinex vs Control.



Graph 1 - Shows the effectiveness of Lactinex vs Placebo at preventing all cause diarrhea. From the graphs, there is little to no statistical or clinical difference between the two at treating all-cause diarrhea.

Power Analysis

- A power analysis was performed (sample-size calculation). Above, we present the rounded overall proportions for Control and Lactinex. The nonrounded values are 31.286% for Control and 31.177% for Lactinex. With alpha set at 0.05, a 2-tailed test (which means that an effect in either direction is interpreted), plus sample sizes of 4 for Control and Lactinex, an assessment of the difference in proportions (46.100% versus 42.583%) would have a power of 5.1%. For a power of 80.0%, sample sizes of 3,133 articles would be required for Control and for Lactinex.

Discussion

Summary of Findings

- Although the meta-analyses indicated slight publication bias for Control and for Lactinex articles, the overall proportion of cases with diarrhea for the four Lactinex articles was only 3.5% lower than the overall proportion for the four Control articles ($P = 0.5081$), with our considering that the 3.5% lower percentage to be of no clinical importance. To demonstrate that this lower percentage was statistically significant (at an alpha level of 0.05 with a power of 80.0%) would require thousands of Control and Lactinex articles.

- This systematic review evaluated the available evidence for the use of Lactinex and was not able to justify its continued use considering this evidence.

Implications for the Future

- Of the available research articles on Lactinex as a treatment for all- cause diarrhea, there was not a significant statistical or clinical difference between Lactinex and Placebo.

Value based-care

- It is then important to evaluate the worth of Lactinex when considering the nationwide push to value-based care [VBC]. While relatively inexpensive, there is not enough available evidence to support continued usage of Lactinex for diarrhea.
- More current, large-scale studies to assess the efficacy of Lactinex and other probiotics in general are warranted. In the absence of this data, Lactinex should be used judiciously, if at all.

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