

future challenge on probiotics

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Future challenge on probiotics uses from fermented milk on the endocrine disorder in human

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Abstract. More than fifty different probiotics have been identified with different structures and modes of action. This study aimed to offer an overview of the evidence on the clinical microbiology activity of the probiotics group derived from fermented milk. We conducted a framework for reporting probiotics activity using the MICRO (Microbiology Investigation Criteria for Reporting Objectively) checklist. Two electronic databases (Pubmed and EMBASE) were used to conduct this study. The initial search discovered 22 references (Pubmed 8 and EMBASE 16). We included human study, clinical trial study, English written, and full articles in this review. Of all these original articles, only six articles were included in the review. These included articles reported the testing phase on the pre-analytical and analytical phases. This review found that probiotics such as *Lactobacillus acidophilus* La-5 and *Bifidobacterium animalis* subsp *lactis* BB-12 are beneficial in humans' endocrine disorder therapy. This activity includes maintaining serum insulin levels in pregnant women and reducing weight in healthy obese men and women. Thus, probiotics, with their several features, may advance their candidacy as therapeutic agents. However, there is more effort to do. For example, finishing the analytical phase, especially on quality assurance and avoiding bias.

Keywords: Probiotics, fermented milk, endocrine disorders

1. Introduction

Endocrine disorders are often quite complex. They involve hyposecretion and hypersecretion due to the feedback mechanisms involved in the endocrine system. Many diseases can be caused by this endocrine disorder, including glucose homeostasis disorders, thyroid disorders, calcium homeostasis disorders, metabolic bone disorders, pituitary gland disorders, sex hormones disorders, and tumors of the endocrine glands(1–4). This study focused on glucose homeostasis related to the diabetes mellitus group and body weight abnormalities.

Probiotics themselves have been known to have more than 50 forms of structure and modes of action (5–7). Some probiotic products such as fermented milk containing lactic acid bacteria regulate blood sugar balance positively. Supplementation with probiotics reduces the risk of newborn hyperbilirubinemia and improves glycemic control, blood lipid profile, body inflammation, and



oxidative stress in pregnant women diagnosed with GDM (8–10). Also, in pregnant women with hyperglycemia, probiotic supplementation for six to eight weeks resulted in a significant decrease in insulin resistance (11,12). So, the use of probiotic supplements seems promising and will be hopeful as a potential therapy to manage hyperglycemia metabolism. However, given the heterogeneity in the existing studies. Further studies are assured to address the limitations of current evidence and better information on the management of hyperglycemia in pregnancy. Additional high-quality studies with a longer duration are needed to determine the safety, optimal dosage, and quintessential bacterial composition of prebiotics before their routine use can be recommended in this group of patients.

Furthermore, we need to select the structure and activity of these probiotics related to blood glucose regulation in humans. One way to collect evidence by avoiding bias is to conduct a systematic literature review (13). This present study aims to provide an overview, utilizing a literature review of the evidence on the clinical microbiology activity of the probiotics group derived from fermented milk.

2. Methods

2.1. Study design and search strategy

We conducted a literature review of the probiotics use in fermented milk related to endocrine disorders published between 2000-2020, taking into account reporting guidelines of Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram (13). We accessed three electronic databases (PubMed and EMBASE) in March 2021. Figure 1 shows details of the search terms. We only included studies that were performed in humans and that were written in English. We combine Medical subject heading and text word using “OR” for each keyword and next to compile them with “AND” using Boolean logic.

2.2. Study selection and data extraction

The search results were downloaded into *Mendeley citation manager*. From the initial search results, duplicates were removed, and the title and abstract were screened. In addition, articles that were not probiotics studies in humans and not full papers (e.g., conference proceedings) were excluded.

2.3. Quality of reporting

The MICRO (Microbiology Investigation Criteria for Reporting Objectively) checklist was used as a checklist to rate the quality of reporting and interpretation of clinical microbiology data in the included papers (14). These criteria were first developed by an international working group of clinical and laboratory microbiologists, infectious disease physicians, epidemiologists, and mathematical modelers.

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(((("probiotics"[MeSH Terms] OR probiotics[Text Word]) AND
"Probiotics"[Mesh]) AND ("cultured milk products"[MeSH Terms] OR
fermented milk product[Text Word])) AND ("endocrine system diseases"[MeSH
```

Figure 1. Search strategy using Medical Subject Heading (MeSH)

3. Results

3.1. Systematic search strategy

The database search discovered 368 references (PubMed 254, EMBASE 114), of which 274 were left after deduplication (see fig.2 for a flow chart diagram). The process of screening of the title and the abstract found that 56 articles had a topic other than a clinical trial in humans, By this screening, eight articles met the inclusion criteria. Therefore, a final set of these eight publications was included in the study.

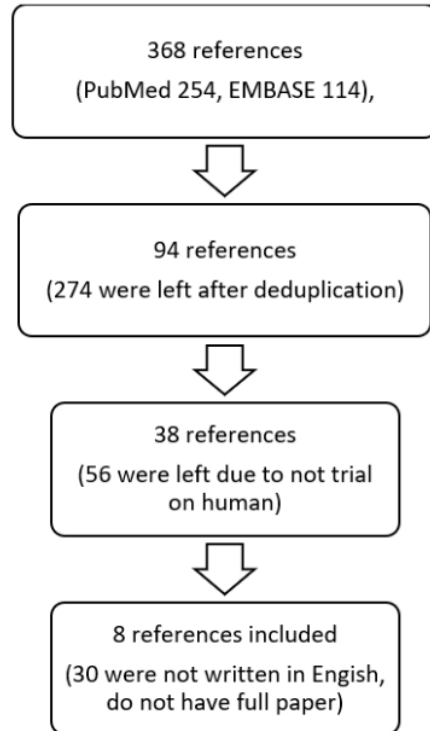


Figure 2. Flow of search strategy in systematic review.

3.2. Data Extraction

An overview of the main study features of the included probiotics use in endocrine disorders studies is provided in Table 1. Table 2 shows information on categories of included studies regarding MICRO checklist.

Table 1. Characteristic of included study.

Study	Year of publication	Participants	Length of study	Control	Intervention probiotic	Milk product	Conclusion of endocrine disorders
Tonucci et al. (15)	2015	50 Type 2 Diabetes Mellitus	6 weeks	Conventional fermented milk	Lactobacillus acidophilus La-5, Bifidobacterium animalis subsp lactis BB-12 (10 ⁹ colony-forming units/d, each)	Fermented milk	Probiotic consumption enhanced the glycaemic control in T2DM
Ejtahed et al. (16)	2011	64 Type 2 Diabetes Mellitus	6 weeks	300 g/d of conventional yogurt	Lactobacillus acidophilus La5 and Bifidobacterium lactis Bb12 in 300 g/d probiotic yogurt.	Yogurt	Probiotic yogurt could significantly decreased fasting blood glucose (P < 0.01), hemoglobin A1c (P < 0.05) and increased in T2DM.
Ejtahed et al. (9)	2011	60 Type 2 Diabetes Mellitus	6 weeks	300 g/d of conventional yogurt	Lactobacillus acidophilus La5 and Bifidobacterium lactis Bb12 in 300 g/d probiotic yogurt.	Yogurt	4.54% decrease in total cholesterol, a 7.45% decrease in LDL-C in T2DM
Asgharian et al. (11)	2019	65 Pregnant women	16 weeks	100g/d conventional yogurt	100g/d Lactobacillus acidophilus La5 and Bifidobacterium lactis Bb12	Yogurt	Increases the effects on glucose metabolism of overweight and obese pregnant women
Tazakori et al. (17)	2017	60 Type 2 Diabetes Mellitus	Not mention	200g/d conventional yogurt	200 g/d Lactobacilli acidofilus and bifidobacterium	Yogurt	Improved diabetic patients lipid profile, no lowering effect on blood glucose
Madjd et al. (8)	205	89 Healthy obese	12 weeks	Standard low-fat yogurt (LF) contains <i>S. thermophiles</i> and <i>L. bulgaricus</i>	<i>Streptococcus thermophiles</i> , <i>Lactobacillus bulgaricus</i> , enriched with the probiotic culture (<i>Lactobacillus acidophilus</i> LA5) and bifidobacteria (<i>Bifidobacterium lactis</i> BB12) with a total minimum of 1 × 10 ⁷ colony-forming units.	Yogurt	Positive effects on lipid profiles and insulin level in diet program
Asemi et al. (12)	2012	70 primigravida-singleton pregnant women at 3 rd trimester	9 weeks	200g/ d conventional yoghurt	<i>Streptococcus thermophilus</i> , <i>Lactobacillus bulgaricus</i> , fortified with <i>Lactobacillus acidophilus</i> LA5 and <i>Bifidobacterium animalis</i> BB12	Yogurt	Maintains serum insulin levels for 9 weeks.
Ivey et al (18)	2014	156 healthy overweight	6 weeks	Milk plus placebo capsules	Milk plus <i>L. acidophilus</i> La5, <i>B. animalis subsp lactis</i> Bb12 in capsules	Milk and capsules	No significant results on short-term glycaemic control

Table 2. MICRO reporting checklist.

No	Item	Tonucci et al. (15)	Ejtahed et al. (16)	Ejtahed et al. (9)	Asgharian et al. (11)	Tazakori et al. (17)	Madjd et al. (8)	Asemi et al. (12)	Ivey et al. (18)
1	Specimen types	Y	Y	Y	Y	Y	Y	Y	Y
2	Sampling period	Y	Y	Y	Y	N	Y	Y	Y
3	Sampling strategy	Y	Y	Y	Y	Y	Y	Y	Y
4	Target organism	Y	Y	Y	Y	Y	Y	Y	Y
5	Geographical	N	N	N	N	N	N	N	N
6	Clinical setting	Y	Y	Y	Y	Y	Y	Y	Y
7	Specimen processing	Y	Y	Y	Y	N	Y	Y	Y
8	Target organism identification	Y	Y	Y	Y	Y	Y	Y	Y
9	Antimicrobial susceptibility	NA	NA	NA	NA	NA	NA	NA	NA
10	Resistance test	NA	NA	NA	NA	NA	NA	NA	NA
11	Antimicrobial resistance	NA	NA	NA	NA	NA	NA	NA	NA
12	External quality assurance	N	N	N	N	N	N	N	N
13	Accreditation	N	N	N	N	N	N	N	N
14	Duplicate isolates	N	N	N	N	N	N	N	N
15	Population	Y	Y	Y	Y	Y	Y	Y	Y
16	Denominators	N	N	N	N	N	N	N	N
17	Site of acquisition	Y	Y	Y	Y	Y	Y	Y	Y
18	Reporting resistance	NA	NA	NA	NA	NA	NA	NA	NA
19	Reporting drug resistance	NA	NA	NA	NA	NA	NA	NA	NA
20	Limitation	Y	Y	Y	Y	Y	Y	Y	Y

N: No; Y: Yes; NA: Not Applicable;

--- Pre-Analytical Phase; --- Analytical Phase --- Post-Analytical Phase

All of the included studies were clinical trials. Clinical trials that use intention-to-treat analysis may be reliable sources for an evaluation, as they approximate real-world clinical practice better than per-protocol analyses or any other laboratory experiments. In addition, all trial-based studies included reported various outcome measures, as seen in Table 1.

1 Quality of reporting assessment

For each study, reporting on all 20 items in the MICRO checklist is provided in Table 2. Most of the studies were not reported comprehensively in the sense that they did not provide information on several items on the checklist. Almost all studies have completed reporting checklist that should be reported in the pre-analytical phase. The Pre-analytical phase includes specimen types, sampling periods, sampling strategy, target organism, and geographical setting. What much goes unreported is the geographic setting. Most papers report laboratory conditions and locations but not the area where the study was conducted. For example, the study of Madjd et al. did not report the sampling period and how long participants received intervention from probiotic products.

Meanwhile, for the analytic phase, many things are not reported and not applicable to be reported. For example, the effects caused by probiotics themselves but do not use biological samples containing bacterial metabolites, such as the glycemic index and lipid profile. In the glycemic index data, there will be no bacterial isolates or the results of bacterial metabolism. On the contrary, what was found was the body's response to changes in homeostasis.

What the included articles did not report at all was quality assurance. Accreditation of the laboratory where the research was conducted was also very important. Accreditation here can be defined as a statement of whether the laboratory has been recognized through a national or international body (for example, International Organization Standards, ISO) and which tests are included in the accreditation statement.

4. Discussion

Initially, the proposed Microbiological Investigation Criteria for The Objective Reporting Framework (MICRO) is a list of items included in the report studies. The study involved human clinical,

microbiological data originating from any region of the world, with various income levels. It provides a concise and comprehensive explanation for physicians, researchers, reviewers, and journals who work on, critique, and publish clinical microbiology data set (14). Researchers realized that numerous aspects must be considered in reporting a study. Sometimes researchers think of this as trivial but very calculated in assessing a research result, starting from the common ones in the pre-analytic phase. Sometimes researchers forget to write down the criteria for the test subject and the test sample. Subject and sample are two different things that should be explained in the article.

Another thing to note here is timing; when the study was conducted, how long it took the research, and how long each participant received treatment.

Some of the essential criteria that must be explained in this MICRO reporting most are in the analytical phase. They are reporting of antimicrobials tested on a subset of isolates, multi-drug resistance definition, and reporting, changes to published antimicrobial susceptibility breakpoints over time, classification of infections by location, selection of appropriate isolates to include in analysis and testing, and reporting clinically inappropriate bug-drug combinations. Henceforth, user comments will be searched after publication and implementation of the checklist. In particular, feedback from users in non-Asian environments will be invaluable as expected revisions will be needed in due course.

Strength and limitation

The MICRO checklist provides a concise, consistent and comprehensive reporting framework to ensure that interpretation and meta-analysis of the data set are meaningful. Unfortunately, while the limitation of the study was the detailed microbiological data sets from South and Southeast Asia were not included in the review. Even though the number and types of probiotic bacteria vary widely from this area, most countries in this region are still developing countries. Therefore, it is still challenging to fulfill each of the criteria in the MICRO checklist.

5. Conclusion

From the included articles collected, it can be concluded that the probiotics that provide positive results for endocrine health are *Lactobacillus acidophilus* La5 and *Bifidobacterium lactis* Bb12. In short, given the global threat to human health, there is an urgent need to capture and model existing infection data while surveillance initiatives are relatively recent. Probiotics, with their several features, may advance their candidacy as therapeutic agents. However, there is more effort to do. Finishing the analytical phase, especially on quality assurance and avoiding bias.

6. Competing Interest

All authors in this article declared that they have no competing interests related to this study.

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