Review

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Review

The Role of Lactoferrin and Lactoferrin Supplementation in The Prevention of Lactational Mastitis and Other Breast Inflammations: A Literature Review and Future Perspectives

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Abstract

Background/Objectives: Lactoferrin has been studied for its antimicrobial, anti-inflammatory, and immunomodulatory properties. While the presence and role of lactoferrin in breast milk have been relatively well described, its potential as a dietary supplement to prevent inflammatory breast conditions has not been adequately addressed in the literature. Animal models—particularly in bovine mastitis—have also suggested a possible protective role for lactoferrin in mammary inflammation. The aim of this review is to critically evaluate existing evidence on the role of lactoferrin in inflammation and immunity, with a particular focus on its potential preventive role in lactational breast conditions. **Methods**: A comprehensive literature search was performed across PubMed, Embase, and CINAHL. The search was carried out without any temporal restrictions, and studies published in English or Italian were included. **Results**: Lactoferrin has well-documented properties and evidence from animal models and studies on other inflammatory conditions supports its potential role in reducing inflammation and preventing infections. There is a clear lack of clinical trials specifically evaluating lactoferrin supplementation in the prevention of lactational mastitis. Most studies have been conducted in non-human models, and there is a need for more human-specific research. **Conclusions**: future studies should be focused on understanding the role of lactoferrin supplementation, its security and efficacy and also its potential use as a diagnostic marker. It is essential to move beyond theoretical and indirect evidence, and to conduct rigorous clinical research to fully understand its potential role in obstetric care, particularly in the prevention of lactational mastitis.

Keywords: lactoferrin; mastitis; mammary inflammation; mastitis prevention; immune defense; lactoferrin supplementation

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1. Introduction

Lactational mastitis and other breast inflammatory conditions are common complications during breastfeeding, affecting up to one-third of lactating women worldwide [1]. Mastitis and other inflammatory conditions of the mammary gland, such as lactational breast abscesses, are commonly associated with pain, infection, and inflammation. These conditions often result in swelling, erythema, and fever, which can lead to early cessation of breastfeeding. The pain and discomfort

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caused by mastitis may discourage mothers from continuing breastfeeding, thereby potentially impacting maternal-infant bonding, milk production, and overall breastfeeding success. Early weaning, in turn, can increase the risk of both maternal and infant health complications, including the mother's increased susceptibility to further infections and the infant's reduced access to essential nutrients and immune protection provided by breast milk. According to the Academy of Breastfeeding Medicine protocol, timely diagnosis, appropriate management, and support for continued breastfeeding are critical in minimizing these negative outcomes for both the mother and child. The Academy of Breastfeeding Medicine guidelines recommend standard treatment for mastitis, including antibiotics for moderate to severe cases, particularly those with systemic symptoms such as fever. In addition, management strategies emphasize non-pharmacological approaches, including frequent breastfeeding or milk expression, proper breast drainage, warm compresses, and supportive care. However, there is growing interest in complementary and alternative medicine (CAM) approaches to support immune function and prevent the recurrence of mastitis. [2,3].

Lactoferrin, a multifunctional iron-binding glycoprotein naturally present in human milk, has been studied for its antimicrobial, anti-inflammatory, and immunomodulatory properties [4–6]. It plays a vital role in innate immune defense by limiting bacterial growth through iron sequestration and by modulating the host's inflammatory response [7]. While the presence and role of lactoferrin in breast milk have been relatively well described, its potential as a dietary supplement to prevent inflammatory breast conditions has not been adequately addressed in the literature. Clinical studies have explored oral lactoferrin supplementation in other inflammatory conditions, including neonatal infections, gastrointestinal diseases, and systemic inflammation [8,9].

Animal models—particularly in bovine mastitis—have also suggested a possible protective role for lactoferrin in mammary inflammation. However, to date, no human clinical trials have directly assessed the effect of lactoferrin supplementation on the prevention of lactational mastitis or related breast inflammations, representing a clear gap in the current research landscape. The goal of this review is to critically evaluate existing evidence on the role of lactoferrin in inflammation and immunity, with a particular focus on its potential preventive role in lactational breast conditions. By synthesizing current knowledge and highlighting missing links, we propose a framework for future clinical investigations.

2. Materials and Methods

A comprehensive literature search was conducted to identify relevant studies examining the role of lactoferrin and lactoferrin supplementation in the prevention of lactational mastitis and other inflammatory breast conditions during breastfeeding.

To guide the literature search and ensure a focused review, the PIO framework (Population, Intervention, Outcome) was used to define the research question. This approach allowed for the identification of relevant studies addressing the preventive role of lactoferrin in breast inflammation during breastfeeding. The components of the PIO are defined as follows:

- Population (P): Women during breastfeeding
- Intervention (I): Lactoferrin supplementation
- Outcome (O): Prevention of lactational mastitis and other inflammatory breast conditions

This framework served as the basis for the development of the search strategy and selection criteria.

2.1. Search Strategy

A comprehensive literature search was performed across the following databases: PubMed, Embase, and CINAHL. The search was carried out without any temporal restrictions, and studies published in English or Italian were included. The search strings used in each database are outlined below:

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- PubMed: "lactoferrin"[Title/Abstract] AND ("breastfeeding"[MeSH] OR "lactation"[MeSH]) AND ("mastitis"[MeSH] OR "breast inflammation"[MeSH] OR "mammary inflammation"[Title/Abstract])
- Embase: "lactoferrin"/exp AND ("breastfeeding"/exp OR "lactation"/exp) AND ("mastitis"/exp OR "breast inflammation"/exp OR "mammary inflammation"/exp)
- CINAHL: "lactoferrin" AND ("breastfeeding" OR "lactation") AND ("mastitis" OR "breast inflammation" OR "mammary inflammation")

Boolean operators were used to combine the terms. Filters applied included language restriction (English or Italian), and only full-text articles were considered for inclusion.

2.2. Eligibility Criteria and Study Selection

Studies were included if they met the following criteria:

- Focused on lactoferrin supplementation in the context of breastfeeding women, or explored its biological role in human milk, anti-inflammatory properties, and immune-modulating effects;
- Investigated lactational mastitis, mammary inflammation, or related breast conditions, or examined analogous inflammatory conditions (such as bovine mastitis);
- Published in peer-reviewed journals with no restrictions on publication date;
- Written in English or Italian;
- Designed as clinical studies, observational studies, preclinical studies (in vitro/in vivo), or narrative/systematic reviews exploring mechanisms of action or clinical outcomes related to lactoferrin and inflammation.

2.3. Exclusion Criteria

- Studies not directly involving lactoferrin or not related to breastfeeding-associated breast conditions or inflammatory properties;
- Conference abstracts, letters to the editor, opinion papers, and articles without full text available;
- Articles not published in English or Italian.

3. Results

3.1. Role of Lactoferrin in Human Breast Milk

Human breast milk contains a balanced composition of nutrients, growth factors, hormones and enzymes. This wide variety of bioactive factors plays a crucial role not only in infants' growth and development, but also in their protection from infections, allergies and other diseases [10].

Adapted T cells populations identified in human breast milk have a role in the mammary gland local immune defense and an additional role in neonatal immune support [11]. Breast adapted T cells are characterized by the expression of immune signaling genes, high proliferation and high cytokine production capacities [11].

Nonspecific antimicrobial proteins are also important for the host defense system and probably act together with the specific antibodies. The most important of these are lysozyme, lactoperoxidase, and lactoferrin [12].

Peptides derived from lactoferrin are breast milk antibacterial peptides that have attracted the most attention during the last decade. An antimicrobial domain, named lactoferricin, was found in the N-terminal region of human and bovine lactoferrin molecule. Lactoferricin has revealed a broad spectrum of activity against Gram-positive and -negative bacteria and parasites. Furthermore, lactoferricin has been shown to have antiviral, antitumor and anti-inflammatory properties [12].

In this context, some systematic reviews showed a significant concentration of lactoferrin in breast milk and its correlation with IgA secretory levels, that underlines its antimicrobial and anti-inflammatory effects [13]. There is also an inter-individual variability in these factors' concentration which suggest a unique composition of breast milk and its importance in influencing neonatal immune system [14].

The maternal and infant factors that may affect lactoferrin concentration in human breast milk are still not clear but a correlation was identified between lactoferrin levels and lactation stage: colostrum has the highest quantity of lactoferrin, but it decreases with days postpartum [15]. No other maternal or neonatal factors investigated showed a constant link with lactoferrin levels [15].

Lactoferrin concentration in human breast milk is subject to change even during pathological and inflammatory processes. In fact, it was shown that lactoferrin and other breast milk protein concentrations significantly increase in women with subclinical mastitis, suggesting a protective and adaptive role of breast milk itself [13].

These results underline the importance of investigate the physiological regulation of this glycoprotein in human breast milk, in accordance to its crucial role.

3.2. Anti-Inflammatory and Immunomodulatory Properties of Lactoferrin

Lactoferrin is an immune-related component that plays its role in a complex immunological and regulatory network consisting of white blood cells, antibodies, secretory molecules and also specific miRNAs, which could be an ideal biomarker for diagnosis and prognosis of various disease [16].

Lactoferrin is an iron-binding protein, present in large amount in colostrum and breast milk. It has shown several protective activities [17]:

- Antimicrobial activity, which has been presumed due to iron deprivation, but more recently attributed also to a specific interaction with the bacterial cell wall and extended to viruses and parasites;
- Immunomodulatory activity with a direct effect on the development of the immune system in the newborn. Lactoferrin along with breast milk leukocytes, immunoglobulins and cytokines promotes the infant immunocompetence and play a role in the protection of mammal gland from infection, emphasizing its importance for both mother and infant [18,19];
- Anti-inflammatory activity;
- Anticancer activity, recently discovered. Lactoferrin and others breast milk components such as alpha-lactalbumin promote cancer cell apoptosis and inhibit tumor growth, resulting in a reduced cancer risk in mothers who breastfeed [20]. This finding points out the regulation role of lactoferrin which provides not only immunological advantages for infants but also in the mammal gland tissues itself.

All these protective activities can be also found, sometimes to a greater extent, in peptides derived from limited proteolysis of lactoferrin that could be generated after lactoferrin ingestion [12,17].

Lactoferrin could therefore be considered an ideal nutraceutical product thanks to its relatively cheap production from bovine milk and to its widely recognized tolerance after ingestion, along with its well demonstrated protective activities [17].

3.3. Evidence from Other Inflammatory Conditions

Breast milk provides access to a large volume of breast tissue, in the form of exfoliated epithelial cells, and to the local breast environment, in the form of molecules in the milk. Thus, Aslebagh et al. (2018) analyzed human breast milk by mass spectrometry to build a biomarker signature for early detection of breast cancer in young women. The study identified dysregulated levels of lactoferrin and other molecules in the breast milk of women who later developed breast cancer [21].

A study in premenopausal nonlactating women conducted by Vizoso et al. (1994) showed instead a relationship between serum PRL levels and protein composition of breast secretion [22]. After a TRH stimulation test, the maximum PRL response was significant higher in woman whose mammary fluids contain lactoferrin than in those with fluids lack of this protein [22]. It suggests that lactoferrin is regulated not only by inflammatory or infective stimuli but also by endocrine signaling with potential implications in mammal physiology and pathology.

These data are supportive of the idea that lactoferrin and breast milk proteins have a role in cancer and inflammatory mammary gland diseases, and their analysis should be considered in further research as a simple and noninvasive procedure for studies.

3.4. Bovine Mastitis Models and Their Relevance

Genetically modified animal models for the mammary gland expression of recombinant human lysozyme (rhLZ) and lactoferrin (rhLF) have been studied over the past 20 years. Lines of transgenic mice, goat and more recently cows with genetically altered milk for expression of rhLZ and rhLF were created and the milk used for in vitro and in vivo studies. These studies demonstrated that milk from rhLF and rhLZ transgenic animals possesses enhanced antimicrobial activity, slowing the growth of pathogenic bacteria in vitro, and has a lower somatic cells count, a measure commonly used to monitor the state of infection of the mammary gland from lactation, thereby indicating modulation by rhLZ and rhLF resulting in a healthier udder [23]. These data suggest a possible lactoferrin application in preventing mastitis and other mammary gland infective disease in the livestock sector and, by analogy, in the human being [24]. Therefore, lactoferrin could be a therapeutical option in preventing bovine and human mastitis, improving breast health and reducing antibiotics use.

In this context, a research on chronic bovine mastitis caused by a clinical isolate of S. aureus highly resistant to beta-lactam antibiotics examined the efficacy of lactoferrin in increasing the inhibitory activity of penicillin. It was shown that bovine lactoferrin added to penicillin is an effective combination for the treatment of stable S. aureus infections, suggesting the potential use of lactoferrin even in antibiotic resistant mammary infections [25].

Needless to say, there are limitations in direct transferring these results from bovine models to human beings due to biological differences. So, clinical studies on human mastitis should be promoted to confirm the efficacy of lactoferrin even in human models.

3.5. Clinical Studies on Lactoferrin and Lactational Mastitis

Subclinical mastitis is an asymptomatic inflammatory condition of the lactating mammary gland associated with early lactation failure and poor infant weight gain. Occasionally, subclinical mastitis may progress to clinical mastitis, presenting with symptoms such as fever, mammary gland pain and reddening, combined with breast engorgement.

Mastitis is caused by milk stasis, infections and/or micronutrient deficiency. Literature shows that women undergoing C-sections have a greater likelihood of developing mastitis due to the delay in breastfeeding consequently leading to breast engorgement, milk statis and inadequate breast emptying [26]. Furthermore mothers with mastitis had significantly shorter gestational age at delivery [26].

Subclinical and clinical mastitis are significantly associated with alteration of micro- and macronutrient composition of human milk, probably due to an increased permeability of the mammary epithelium as a mechanism to combat inflammation [26,27]. Mastitis milk has the same anti-inflammatory components and characteristics of normal milk, with elevations in selected components/activities that may help to protect the nursing infant from developing clinical illness due to feeding on mastitis milk [28]. Higher levels of sodium, iron and total and specific milk proteins, such as lactoferrin, were observed in breast milk of mothers with mastitis [26,29,30], while lactose concentration, fatty acids, calcium and phosphorus turned out to be decreased [26].

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Lactoferrin increment during mastitis was shown by several studies which underline the crucial role of this protein in the local immunological response and its involvement in the immunological network. In 96 Malawian women with mastitis, elevated sodium concentrations in breast milk, resulting to be an indicator of mastitis, are associated with a significantly increase of lactoferrin and some other immunological and inflammatory factors such as IL-8 (Interleukin-8), SLPI (Secretory Leukocyte Protease Inhibitor) and RANTES [31]. Another research conducted by Demianchuck et al. in 2024 revealed that in lactational mastitis the level of lactoferrin can exceed the control values 3.1 times while IL-8 can be up to 7 times higher than the control group [32]. These are new tools that can be potentially used to facilitate rapid diagnosis and treatment of conditions of the lactating breast.

Furthermore, a study conducted on Gambian mothers showed a predisposition to mastitis in lactating women with deficiency in IgA, C3 and lactoferrin [29], suggesting an immunological vulnerability and opening a way to preventing strategies based on lactoferrin and other immunological factors supplementation. For example, anti-secretory factor (AF), which can be induced in milk by maternal consumption of a low-cost cereal product, has been associated with decreased mastitis [33]. So, consumption of cereals which induce AF should be investigated as a potential intervention in less-developed countries where the consequences of mastitis for infants are most severe.

3.6. Future Perspective

COVID-19 pandemic introduced new challenges and questions about breastfeeding with special attention to the potential viral vertical transmission by breastfeeding. Although the absence of SARS-CoV-2 active virus in human milk, latest data suggest the presence of SARS-CoV-2 specific antibodies in breastmilk of infected and vaccinated mothers, providing immunological support to the infant [34]. Investigating human breast milk antiviral mechanism and its antiviral molecules, such as lactoferrin, could be a new focus for future researches and could open the way to new strategies to better deal with pandemic events.

3.7. Summary of Findings

This section synthesizes the evidence regarding lactoferrin's potential role in preventing lactational mastitis:

- Strengths:
  - Lactoferrin is present in breast milk and has well-documented antimicrobial and immunomodulatory properties.
  - Evidence from animal models and studies on other inflammatory conditions supports its potential role in reducing inflammation and preventing infections.
- Weaknesses:
  - There is a clear lack of clinical trials specifically evaluating lactoferrin supplementation in the prevention of lactational mastitis.
  - Most studies have been conducted in non-human models, and there is a need for more human-specific research.

4. Discussion

Analyzed data confirm lactoferrin immunomodulating, anti-inflammatory and antimicrobial properties [studio8]. Its characteristics and its natural presence in human breast milk make lactoferrin a biological appropriate supplement for preventing mammary gland diseases.

Despite all the evidences on lactoferrin immunological role and its elevation in mammary gland inflammatory states [35][36], no studies on lactoferrin supplementation in preventing mastitis or other inflammatory diseases were already led. In this context, data on mastitis among humans are

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scarce and inconsistent and this may be attributed to the fact that most of our knowledge is extrapolated from preclinical studies and the limited number of clinical observations offer several limitations.

Mastitis is one of the most frequent cause of early breastfeeding interruption and the demand of natural and safe prevention strategies is getting increasingly higher. Lactoferrin supplementation could be a complementary option to the traditional management, especially in women experiencing recurrent mastitis episodes [35]. Although, the absence of data on the efficacy and security of lactoferrin supplementation limits its use in the present clinical practice. Researches on bovine mastitis suggest a potential efficacy, but their applicability in a human context is limited.

Trials on other mammary inflammatory conditions provide indirect evidences which underline the necessity of more studies focused on mastitis.

Human breast milk remains an important source of protection against infections, inflammations, allergies and long-term metabolic disorders and future studies should be focused on understanding the role of lactoferrin supplementation, its security and efficacy and also its potential use as a diagnostic marker. Identifying the profile of women with an increased risk for mammary inflammatory diseases or supporting breast local immunity during early post-partum could be ideas for future researches.

5. Conclusions

In conclusion, lactoferrin is a promising biomolecule with significant antimicrobial, anti-inflammatory and immunomodulatory properties that could play a vital role in the prevention of lactational mastitis and other inflammatory breast conditions. Although its presence in human breast milk its potential protective functions are well-established, there is a clear gap in the literature regarding its specific effectiveness in preventing or treating lactational mastitis. Current evidence from animal studies, particularly in bovine mastitis, and from clinical trials in other inflammatory conditions suggests that lactoferrin supplementation could offer benefits in reducing inflammation and improving immune responses. However, no human clinical trials have directly addressed the use of lactoferrin for lactational mastitis prevention, indicating a crucial area for future research.

Given the increasing interest in complementary and alternative medicine (CAM) approaches for mastitis management, further well-designed, large scale, randomized controlled trials are necessary to evaluate the safety, efficacy and optimal dosing of lactoferrin supplementation in lactating women. Additionally, studies should focus on identifying specific populations of women who might benefit most from lactoferrin supplementation, such as those with recurrent mastitis or other risk factors.

In summary, while lactoferrin shows substantial promise, it is essential to move beyond theoretical and indirect evidence, and to conduct rigorous clinical research to fully understand its potential role in obstetric care, particularly in the prevention of lactational mastitis.

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Abbreviations

The following abbreviations are used in this manuscript:

CAM	Complementary and alternative medicine
rhLZ	Recombinant human lysozyme
rhLF	Recombinant human lactoferrin

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IL-8	Interleukin- 8
SLPI	Secretory Leukocyte Protease Inhibitor

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