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A Review of Current Evidence and Future Directions on Galactogogues in Lactogenic Insufficiency

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Abstract: Lactogenic insufficiency is a multifactorial condition of inadequate breast milk production that challenges successful breastfeeding and infant nutrition. Galactogogues include pharmaceutical agents, herbal medicines, nutritional supplements, and other natural bioactives, which are widely used to enhance lactation; however, their clinical utility varies. This review summarizes the pathophysiology of lactogenic insufficiency, the classification of galactogogues, and their proposed mechanisms. Dopamine antagonists enhance lactation through prolactin, but raise safety and tolerability concerns. Herbal and dietary galactogogues show promise through hormonal modulation, mammary stimulation, and antioxidant activity; however, clinical evidence is heterogeneous. Marine-derived bioactives and functional foods are novel but insufficiently explored. Standardized formulations, well-designed clinical trials, and mechanistic studies are needed to establish safe and effective galactogogue-based interventions.

Keywords: *Lactogenic Insufficiency; Galactogogues; Domperidone; Fenugreek; Marine Bioactive Peptides; Breastfeeding.*

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I. INTRODUCTION

Breastfeeding provides nutrients and bioactive components that support infant development, immunity, and maternal health [1]. Lactogenic insufficiency can cause maternal stress, inadequate infant growth, and early cessation of breastfeeding. Lactation is regulated by prolactin, oxytocin, and effective milk removal, and insufficient glandular tissue, endocrine disorders, and maternal illness may impair supply [2]. Galactogogues, from domperidone to fenugreek, shatavari, and milk thistle, are considered when breastfeeding support alone is insufficient, but their effectiveness and safety vary, and the evidence is limited by methodological inconsistency and non-standardized formulations [3]. Use is also shaped by culture, perceived benefit, and access to care [4]. Perceived insufficient milk supply is a common reason for premature cessation and has been systematically studied [5] with maternal perceptions and causes explored in qualitative and cohort studies [6,7] and self-efficacy interventions assessed for their effect on them [8]. Distinguishing perceived from actual insufficiency is therefore essential before galactogogues are used. This review evaluates pharmaceutical, herbal, nutritional, and emerging marine-derived galactogogues, focusing on efficacy, mechanisms, safety, evidence gaps, and future directions.

II. PHYSIOLOGY OF LACTATION

During pregnancy, estrogen and progesterone drive ductal and alveolar development; after delivery, progesterone withdrawal lets prolactin stimulate synthesis of milk proteins, lactose and lipids [9,10]. Suckling reduces dopaminergic inhibition of prolactin and stimulates oxytocin, which contracts myoepithelial cells to eject milk. Frequent, effective milk removal sustains supply by relieving local feedback inhibition, whereas poor removal reduces it [9,10]. Neuroendocrine regulation has been reviewed comprehensively [11], prolactin modulates oxytocin neuronal activity in pregnancy and lactation [12], and maternal oxytocin responses during breastfeeding have been systematically examined [13].

III. LACTOGENIC INSUFFIECIENCY (LI)

LI is inadequate milk synthesis or secretion, potentially causing poor infant growth and early weaning [14]. It is *primary* when due to intrinsic limits, such as insufficient glandular tissue or endocrine deficiency, and *secondary* when linked to modifiable factors — ineffective latch, infrequent feeding, maternal illness, stress, or medication. Diabetes mellitus and polycystic ovary syndrome may add metabolic

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and hormonal disturbance [14,23]. Cesarean delivery, postpartum haemorrhage, retained placenta and anaemia can delay lactogenesis [15], and infant factors such as prematurity, poor suck–swallow coordination and oral abnormalities compromise stimulation [16]. Assessment should rely on infant weight gain, urine and stool output, feeding pattern, maternal health, breast anatomy and milk transfer, not expressed volume alone [14]. Delayed lactogenesis II is an important contributor to early LI, and its recognition and management have been described [17]; its incidence and risk factors have been reviewed systematically [18,19] and linked to maternal obesity [20], metabolic and obstetric parameters [21] and primiparity in a baby-friendly hospital [22].

Table 1 Classification of Galactogogues by Origin, Mechanism and Level of Evidence

Category	Galactogogue	Proposed mechanism	Evidence level	Main adverse effects
Pharmaceutical	Domperidone	D2 receptor antagonism → ↑ prolactin	Moderate–High (RCTs)	Cardiac risk (QT) at high doses
	Metoclopramide	Central dopamine inhibition → ↑ prolactin	Moderate	CNS effects, depression
	Sulpiride	Dopaminergic blockade	Limited–Moderate	Sedation, extrapyramidal effects
Herbal	Fenugreek (*Trigonella foenum-graecum*)	Prolactin modulation; phytoestrogenic	Low–Moderate	GI discomfort, hypoglycaemia
	Shatavari (*Asparagus racemosus*)	Estrogen-like; mammary stimulation	Low	Limited safety data
	Moringa (*Moringa oleifera*)	Nutritional support; antioxidant; ↑ prolactin	Low–Moderate	Generally safe
	Fennel (*Foeniculum vulgare*)	Phytoestrogenic; smooth-muscle relaxation	Low	Possible estrogenic effects
Nutritional	Omega-3 fatty acids	Improve milk composition, mammary cell function	Moderate	Generally safe
	Proteins, amino acids; oats, barley; garlic, brewer's yeast	Milk synthesis support; β-glucan (hypothesised); indirect metabolic	Weak / anecdotal	Safe
Functional food	Probiotics	Gut–hormonal axis modulation	Emerging	Safe
Marine-derived (emerging)	Marine peptides; squalene	Mammary stimulation, antioxidant, hormonal modulation	Preclinical	Limited data
Experimental	Recombinant prolactin; plant polyphenols/flavonoids	Direct prolactin supplementation; antioxidant, gene-expression modulation	Experimental / preclinical	Not established

IV. CURRENT MANAGAEMENT STRATEGIES

Management begins by identifying reversible causes, improving breastfeeding practice, and providing clinical and emotional support. Early assessment separates primary from secondary insufficiency, with hormonal tests when indicated [24]. Early initiation, frequent feeding, correct latch, skin-to-skin contact and adequate milk removal are essential,[24] and lactation counselling addresses technical difficulty and stress-related impairment of milk ejection [25]. When direct breastfeeding is inadequate, regular pumping or hand expression maintains supply, particularly in delayed lactogenesis [24].

Pharmacological galactogogues are considered only when these measures fail to work. Domperidone has increased milk volume in some mothers of preterm infants [26] and in pump-dependent mothers early pumping behaviour and volume relate to timing of secretory activation [27], for which milk biomarkers have been proposed as predictors [28,29]. Manual expression has been compared with pumping in the first postpartum week [30]. Placebo-controlled domperidone trials exist in mothers of premature newborns[31] and sick neonates [32]. alongside comparisons with metoclopramide [33] and a trial after lower-segment caesarean section [34] Meta-analytic work has evaluated milk expression after domperidone [35] and compared domperidone and metoclopramide by Bayesian network meta-analysis [36].

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➢ *Safety and Toxicity of Galactogogues*

Table 2 Doses Used in Studies, Adverse Effects and Safety Notes

Galactogogue	Dose used in studies	Reported adverse effects	Safety notes	Ref.
Domperidone	10–20 mg, 3×/day	Headache, dry mouth, cramps, QT prolongation	Caution in cardiac risk	[57]
Metoclopramide	10 mg, 2–3×/day	Fatigue, depression, anxiety, extrapyramidal symptoms	Not for long-term use	[57]
Fenugreek	1–6 g/day	GI discomfort, allergy, maple-like body odour	May lower blood glucose	[37]
Fennel	1–3 g/day	Mild digestive upset, hormonal effects	Contains phytoestrogens	[37]
Moringa	250–500 mg extract/day	Rare GI upset	Safe at moderate doses	[37]
Shatavari	500–1000 mg extract/day	Rare allergic reactions	Widely used in Ayurveda	[37]

➢ *Galactogogues: Concept and Classification*

Galactogogues (Greek *galacto*, milk; *agogue*, to lead) promote the initiation, maintenance, or augmentation of milk production. They act mainly by raising prolactin, improving mammary responsiveness, or supporting lactation through metabolic or hormonal modulation [37], and span traditional medicine, modern pharmacotherapy, and nutraceutical research. They remain adjunctive, because effective milk removal is the principal driver of lactation [38]. Milk production is regulated by the prolactin–dopamine axis: hypothalamic dopamine inhibits pituitary prolactin, so dopamine-receptor blockers raise prolactin and stimulate synthesis, while oxytocin-mediated ejection and local autocrine control influence total output [39]. Table 1 classifies the main agents by origin, mechanism, evidence, and adverse effects.

The safety and efficacy of these substances have been reviewed [40,41], and the Academy of Breastfeeding Medicine has issued successive protocols on galactogogue use [42,43]. A Cochrane review assessed oral galactagogues, natural and drug, in mothers of non-hospitalised term infants,[44] and botanicals and phytochemicals for women's health have also been reviewed [45].

➢ *Clinical Evidence for Selective Herbal and Nutritional Galactogogues*

Fenugreek is the most widely studied botanical galactagogue, evaluated by network meta-analysis [46] and in trials of fenugreek-containing teas on signs of milk sufficiency [47] and on milk production and birth weight recovery.[48] Randomized trials have tested *Moringa oleifera* capsules in early postpartum women [49], Wang Nam Yen herbal tea[50] and shatavari in lactational inadequacy [51], and a systematic review appraised moringa for milk volume and prolactin [52]. By contrast, banana blossom did not increase milk volume in mothers of preterm newborns in a placebo-controlled trial [53]. Among nutritional interventions, maternal DHA supplementation alters the fatty acid composition of milk [54], as summarized in reviews of omega-3 and other polyunsaturated fatty acids in pregnancy and lactation;[55,56] these effects concern composition, not volume, and should not be equated with lactogenic efficacy.

Product-level safety information is compiled in the LactMed database for metoclopramide [58], fenugreek [59], fennel [60], moringa [61], milk thistle [62] and marine oils [63], and toxicity data for silymarin, the principal constituent of milk thistle, have been summarised in an updated review [64].

V. LIMITATION OF CURRENT EVIDENCE

Evidence on efficacy and safety remains inconsistent [37]. Small samples reduce power and risk of overestimating effects [57]; designs, doses, durations, participants, and breastfeeding practices are heterogeneous [37]; and outcome measures (milk volume, perceived supply, infant weight gain, and breastfeeding duration) are inconsistent [38]. Herbal products vary in plant material, extraction, and phytochemical composition, limiting reproducibility.3 Short follow-up and poor adverse-event reporting obscure long-term maternal and infant safety, drug transfer into milk, and developmental effects [57]; and incomplete reporting and missing-data handling add bias [65]. Research is geographically and culturally concentrated [37]; and evidence for emerging agents–marine bioactives, functional foods, probiotics, and peptides–rests largely on in vitro and animal studies [57]. Publication bias and the scarcity of large multicenter RCTs add uncertainty [37]. Systematic reviews of herbal galactogogues66 and their use in mothers of preterm infants [67] show continued interest alongside limited controlled evidence. Future work needs adequately powered RCTs, standardized outcomes, product characterization, comprehensive safety monitoring, and longer follow-up.

VI. FUTURE PERSPECTIVES AND RESEARCH DIRECTIONS

Future studies should establish reproducible clinical benefit, acceptable safety, and sustained breastfeeding outcomes through well-designed trials with standardized assessments [57]. Trials should distinguish delayed lactogenesis, impaired synthesis, and inadequate milk transfer, with appropriate controls, standardized support, and long-term follow-up. Herbal and nutritional products require authenticated materials, validated analytics, consistent formulations, and evidence-based dosing [3]. Marine-derived bioactive peptides offer promise but require identification, structural characterization, dose–response, bioavailability, and toxicological studies. Mechanistic work should address prolactin signalling, oxytocin-mediated ejection, mammary epithelial function, and molecular pathways, and integrating

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cellular, molecular, and proteomic findings with functional measures of milk production may aid translation [68]. Safety assessment should cover maternal adverse effects, interactions, infant outcomes, contamination, and long-term risks,[3] and studies should test whether maternal health, lactation stage, infant characteristics, and cause of insufficiency modify response [57]. Standardized outcomes milk volume, infant growth, breastfeeding continuation, maternal satisfaction, and adverse events are essential, and translation needs collaboration across pharmacology, nutrition, lactation science, toxicology, and regulation. Traditional medicine supplies further candidates: Ayurvedic herbal medicines in female reproductive health [69] and moringa in pregnancy and breastfeeding [70] offer foundations for hypothesis-driven research.

VII. CONCLUSION

Lactogenic insufficiency is multifactorial and can compromise breastfeeding outcomes and maternal confidence. Management requires early identification of physiological, hormonal, metabolic, psychological, and breastfeeding-related factors, sound technique, and professional lactation support. Pharmaceutical and natural galactogogues are potential adjuncts, but their variable efficacy and safety demand cautious use and clinical assessment. Rigorous trials, standardized formulations, reliable milk production measurement, and systematic safety evaluation are needed. Plant-derived compounds and marine bioactive peptides are promising but require reproducible laboratory work, toxicity testing, and controlled clinical validation; marine-derived peptides, in particular, warrant study of active components, mechanisms, bioavailability, and safety.

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