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Systematic Review of Breastfeeding and Herbs

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Abstract

Objectives: Despite popular and historical use, there has been little modern research conducted to determine the safety and efficacy of herb use during breastfeeding. The purpose of this study was to systematically review the clinical literature on herbal medicine and lactation.
Methods: The databases PubMed, CAB Abstracts, Cochrane Central Register of Controlled Trials, HealthSTAR, Cumulative Index to Nursing and Allied Health Literature, and Reprotox were systematically searched for human trials from 1970 until 2010. Reference lists from relevant articles were hand-searched.
Results: Thirty-two studies met the inclusion criteria. Clinical studies were divided into three categories: survey studies ($n=11$), safety studies ($n=8$), and efficacy studies ($n=13$). Six studies were randomized controlled trials. The most common herbs studied were St. John's wort (*Hypericum perforatum* L.) ($n=3$), garlic (*Allium sativum* L.) extract ($n=2$), and senna (*Cassia senna* L.) ($n=2$). Studies were very heterogeneous with regard to study design, herbal intervention, and outcome measures. Overall, poor methodological quality predominated among the studies.
Conclusions: Our review concludes that further research is needed to assess the prevalence, efficacy, and safety of commonly used herbs during breastfeeding.

Introduction

According to the National Institutes of Health's Office of Dietary Supplements, products made from botanicals that are used to maintain or improve health may be called herbal products, botanical products, or phytomedicines.[1] In the United States, these products are regulated as dietary supplements, a category that includes botanical products, vitamins, minerals, amino acids, and other substances. A 2008 report of complementary and alternative medicine use in the United States indicated that approximately 22% of American women use natural products, including herbal medicine.[2] According to Nordeng and Havnen,[3] women report using complementary and alternative medicine, such as herbal medicine, to have personal control over their own health and because of concerns about medication side effects. This may be particularly true for many breastfeeding women. Some women might use an herbal product, instead of a pharmaceutical, for postpartum conditions such as postpartum depression (St. John's wort), constipation (*Senna*), and colds and flu (garlic and *Echinacea*) and for lactation-related issues.

The World Health Organization recommends exclusive breastfeeding for the first 6 months of life as the best nutrition for the infant.[4] In many cultures, the knowledge of herbal galactagogues (herbs that increase milk production) is passed down from generation to generation. Examples of herbal galactagogues include fenugreek, blessed thistle, milk thistle, fennel, anise, nettle, and others; however, there are very few modern data on their safety and efficacy.[5,6]

Under the 1994 Dietary Supplement Health and Education Act, herbal medicines are held to different regulatory standards than prescription medications. At present, there are concerns about the quality and safety of herbal products during pregnancy and lactation.[7] The primary purpose of this study was to systematically review the existing clinical studies on herbal dietary supplement use among breastfeeding women. The secondary purpose was to assess the methodological quality of existing clinical trials.

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Methods

Type of studies, participants, and outcome

Only human trials were included. The studies were divided into three categories: survey studies, safety studies, and efficacy studies.

Search methods for identification of studies

The databases PubMed, CAB Abstracts, Cochrane Central Register of Controlled Trials, HealthSTAR, the Cumulative Index to Nursing and Allied Health Literature, and Reprotox were systematically searched from 1970 to November 2010. Additionally, we hand-searched the bibliographies of obtained articles for additional publications that would meet our criteria. The articles were identified from databases using MeSH terms such as "lactation" or "breastfeeding" or "galactogogue" and were combined with MeSH terms such as "plant extract" or "herb" or "medicinal herb" or "dietary supplement" or "phytotherapy." Only articles written in English, human trials, published studies (no dissertations), and studies with abstracts were included in the review. We included articles that were published between 1970 and 2010.

Data collections

The initial database searches identified 1,575 articles (Fig. 1). After duplicate articles were removed, 942 abstracts were reviewed by two independent reviewers (K.B. and P.G.) for eligibility criteria. Exclusion criteria were as follows: (1) studies without abstracts, (2) dissertations, (3) vitamins/minerals/non–plant-based products, (4) review articles, (5) animal studies, and (6) in vitro studies. Only 62 clinical studies met the eligibility criteria. After the full text was reviewed, 32 studies were included in the final analysis. The abstraction tool assessed the studies in three parts: (1) aim of the study, study design, study population, and study characteristics; (2) modified Herbal Consort checklist; and (3) modified Jadad criteria.[8,9]

The Herbal Consort score looks for inclusion of certain information about the herb in question, as well as the quality of adverse event reporting. The Jadad scale looks at various

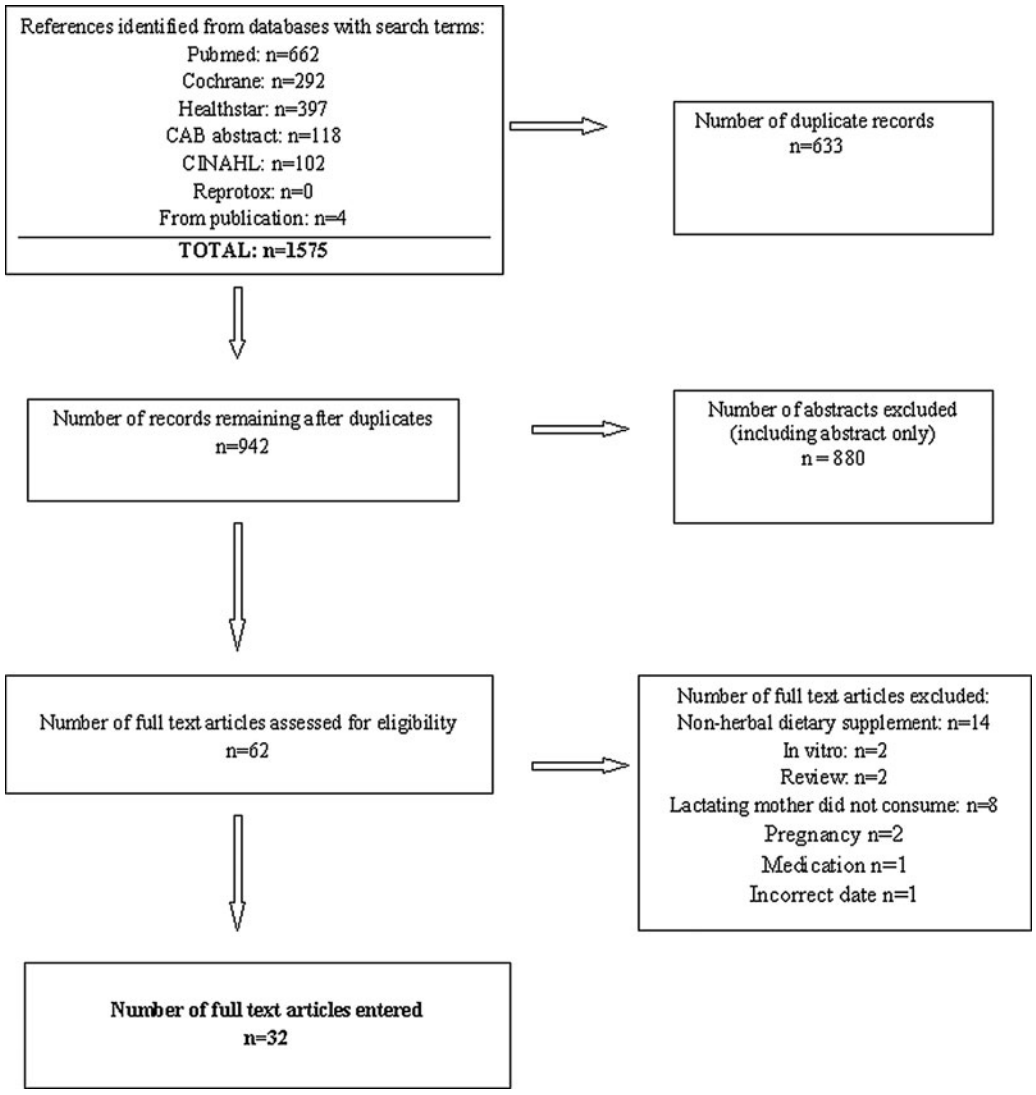

FIG. 1. Search flow to obtain studies examined in this article.

Table 1. Characteristics, Aims, and Quality of the Studies

Study type, reference (year)	*Name of plant/dietary supplement, Latin plant name, dose, type of product*[a]	*Total sample, type of study*	*Aim of the study*	*Modified Consort and Modified Jaded scores*
Survey				
Sinha and Hema[24] (1998)	N: *shatavari* herb/turmeric soup/papaya L: — D: — T: —	*n* = 200 S: NRCT, survey	To know about maternal practices of the "HO" tribe residing in Bihar, India	14 –1
Barennes et al.[6] (2009)	N: traditional herbal tea L: — D: — T: herbal tea	*n* = 300 S: NRCT, survey	To assess traditional postpartum practices, mother and child nutritional status	14 0
Damanik[5] (2009)	N: *torbangun* L: *Coleus amboinicus* Lour D: 120–150 g of leaves T: soup	*n* = 60 S: NRCT, survey	To assess practice and cultural beliefs related to consumption of *torbangun* as a galactagogue during the early lactation period	11 –2
Finley et al.[25] (1985)	N: herbal tea L: — D: — T: tea	*n* = 60 S: NRCT, survey	To assess changes in food consumption patterns during pregnancy and lactation	13 –2
Kulakac et al.[26] (2006)	N: herbal tea (fennel) L: — D: — T: —	*n* = 135 S: NRCT, survey	To identify the changes used by mothers in their nutrition to increase their milk production and extend the breastfeeding period	14 –1
Lockett and Grivetti[27] (2000)	N: local names L: *Adina microcephala/Annona senegalensis/Balanites aegyptiaca/Borassus aethiopum/Dereium microcarpum/Ficus thonningii/Gardenia aqualla/Grewia mollis/Lannea schimperi/Moringa oleifera/Parinari curatellifolia/Parkia biglobosa/Prosopos africana/Strychnos spinosa/Tamarindus indica/Veronia colorata/Ximenia americana/Ziziphus mauritiana* D: — T: Various preparations, primarily aqueous extracts	*n* = 100 S: NRCT, survey	To determine dietary patterns for pregnant and lactating mothers among two groups of rural Fulani agropastoralists of eastern Nigeria	13 0
Raven et al.[28] (2007)	N: warm or cold food, ginger, wine, dates, mother wort (bath) L: — D: — T: —	*n* = 44 S: NRCT, survey + qualitative interview	To explore current status of *zuo yuezi* in Fujian province, China, from social, cultural, and western medical perspectives[b]	14 NA

(*continued*)

Table 1. (Continued)

Study type, reference (year)	*Name of plant/dietary supplement, Latin plant name, dose, type of product*[a]	*Total sample, type of study*	*Aim of the study*	*Modified Consort and Modified Jaded scores*
Sayed et al.[29] (2007)	N: *satvin/lasun/math/shatavari/tivar/punar-nava/rui/papai/takla/dhania/shweta kawali/jira/kali musli/haldi/nagar motha/ranmethi/dudhi/kala umbar/badi shep/anatamool/kurchi/bhui-kohala/patheri/ahliva/moha/karela/kalonji/nagaphana/darni/erand/meetha patii/til/—/methi/nirgudi* L: *Alstonia scholaris/Allium sativum/Amaranthus spinosus/Asparagus racemosus/Barringtonia actunguala/Boerhaavia diffusa/Calotropis procera/Carica papaya/Cassia tora/Coriandrum sativum/Cryptolepis buchanani/Cuminum cyminum/Curculigo orchioides/Curcuma longa/Cyperus rotundus/Desmodium triflorum/Euphorbia hirta/Ficus hispida/Ficus racemosa/Foeniculum vulgare/Hemidesmus indicus/Holarrhena antidysentrica/Ipomoea digitata/Launea obtusus/Lepidium sativum/Madhuca indica/Momordica charantia/Nigella sativa/Opuntia elatior/Pueraria tuberosa/Ricinus communis/Scoparia dulcis/Sesamum indicum/Solena amplexicaulis/Trigonella foenum-graecum/Vitex negundo* D: — T: various preparations including powders, pastes, and as fruits or vegetables	*n* = — S: NRCT, surveys	To investigate various plants used as galactagogues by the Warlis tribe of Dahanu, India	12 –2
Singh and Singh[30] (2003)	N: Banana/black gram/pea/aroid L: *Musa paradisiaca/Vigna mungo/Pisum sativum/Alocasi macrorrhiza* D: — T: —	*n* = — S: NRCT, survey	To summarize what traditional healers used for poor lactation	11 NA
Zhang et al.[31] (2008)	N: — L: — D: — T: —	*n* = 433 S: NRCT, survey	To determine the use of herbs in Australia	14 –2
Parveen[32] (2009)	N: garlic bulb/*ponnugantikura* young stem/*pillitegalu* root/*chanaupala vittulu* seed/*donda* fruit/*chengalva* rhizome/*jilakara* (cumin) fruit/*matikkayalu* pod/*tungamushti* root/*brahmamedi* fruit/*somph* (fennel) fruit/*gambhari* root/*palajilledu* root/*nuvvulu* seed/*menthulu* seed/*munagaaku* leaf L: *A. sativum/Alternanthera sessilis/A. racemosus/Chamaecrista absus/Coccinia grandis/Costus speciosus/C. cyminum/Cyamospsis tetragonoloba/C. rotundus/Ficus hispida/F. vulgare/Gmelina arborea/Holostemma ada-kodien/Sesamum orientale/T. foenun-graecum/M. oleifera* D: — T: various preparations including powders, pastes, and as fruits or vegetables	*n* = — S: NRCT, survey	To obtain knowledge about galactagogue plants used by nursing mothers of tribal groups	11 –2

(*continued*)

Table 1. (Continued)

Study type, reference (year)	*Name of plant/dietary supplement, Latin plant name, dose, type of product*[a]	*Total sample, type of study*	*Aim of the study*	*Modified Consort and Modified Jaded scores*
Safety				
Faber and Strenge-Hesse[33] (1988)	N: senna and psyllium laxative (Agiolax®)[c] L: *Senna* spp., *Plantago ovata* D: 5 g of the standardized senna preparation (=15 mg of sennosides A+B) with psyllium T: granules	*n*=20 S: NRCT, open label	To carry out 24-hour monitoring after repeated doses of senna pods for investigation of the laxative metabolite rhein in breastmilk	11 −2
Shelton[16] (1980)	N: senna tablets (Senokot®)[d] L: *Senna* spp. D: 7 mg of sennosides A+B T: tablets	*n*=471 S: RCT	To determine successful treatment of constipation by Senokot and its effect on breastfed babies	10 4
Kristiansson et al.[34] (1987)	N: khat leaves L: *Catha edulis* D: — T: leaves chewed	*n*=11 S: NRCT, open label	To investigate if active substances of khat leaves are excreted in human breastmilk and whether these substances are absorbed by infant	12 −2
Klier et al.[17] (2002)	N: St. John's wort L: — D: 300 mg TID (Jarsin) T: —	*n*=1 S: NRCT, case report	To examine the effect of St. John's wort on an infant	9 NA
Lee et al.[19] (2003)	N: St. John's wort L: *H. perforatum* D: — T: —	*n*=167 S: NRCT, cohort	To examine safety of St. John's wort on a breastfeeding mother and infant	11 0
Klier et al.[18] (2006)	N: St. John's wort L: *H. perforatum* D: 300 mg TID (Jarsin) T: tablets	*n*=7 S: NRCT, open label	To add information about safety of St. John's wort during breastfeeding	11 −2
Pansatiankul et al.[10] (2008)	N: herb liqueur extract L: — D: — T: tincture (alcohol extract)	*n*=80 S: NRCT, case-control	To determine the risk factors of APCD in early infantile period	12 NA
Chien et al.[35] 2006)	N: traditional Chinese herbs—*Dong qua*i root, *Lycium* fruit, jujube fruit, *shy wuh tang* (formula of rehmannia tuber, *dong quai* root, Sichuan lovage root, and Chinese peony root) L: *Angelica sinensis*, *Lycium* spp., *Ziziphua jujuba*, *shy wuh tang* (Rehmannia glutinosa, *A. sinensis*, *Ligusticum sinense*, *Paeonia lactiflora*) D: 1 g of herb, analyzed T: —	*n*=72 S: NRCT, survey+lead analysis	To assess the relationship between consumption of traditional Chinese herbs and lead concentration in breastmilk	11 −2
Efficacy				
Damanik et al.[36] (2006)	N: torbangun vs. reference group and fengugreek group L: *Coleus amboinicus* Lour vs. *T. foenum-graecum* Lour D: 150 g of leaves vs. 600-mg capsule T: leaves vs. seeds	*n*=75 S:RCT	To report the effects of consumption of torbangun leaves for 1 month after birth on the quantity and quality of breastmilk	10 1

(*continued*)

Table 1. (Continued)

Study type, reference (year)	*Name of plant/dietary supplement, Latin plant name, dose, type of product*[a]	*Total sample, type of study*	*Aim of the study*	*Modified Consort and Modified Jaded scores*
Sharma et al.[37] (1996)	N: *shatavari* (68% of herbal formula), *sowa* (4.5%), *bidarikand* (4.5%), *mulethi* (4.5%), *palak* (12%), *safed jeera* (2%), *panchatrinamol* (4.5%) L: *A. racemosus*, *Anethum sowa*, *I. digitata*, *Glycyrrhiza glabra*, *Spinacia oleracea*, *C. cyminum*, "panchatrinamol" D: 2 teaspoons twice daily for 4 weeks T: —	*n* = 64 S: RCT	To study the effect on prolactin and clinical galactogogic	9 4
Ushiroyama et al.[38] (2007)	N: *Xiong-gui-tiao-xue-yin* (an herbal formula) vs. ergotamine L: *A. sinensis/Cnidium monnieri/Rehmannia glutinosa/Atractylodes macrocephala/Wolfiporia cocos/Citrus unshiu/C. rotundus/Paeonia suffruticosa/Lindera aggregata/Z. jujuba/Leonurus sibiricus/ Zingiber officinale/Glycyrrhiza* spp. D: 6.0 g/day T: freeze-dried aqueous extract dissolved in water	*n* = 82 S: RCT	To evaluate the clinical efficacy of a traditional Japanese drug in puerperal women by evaluating enhancement of lactation and changes in plasma concentrations of prolactin and oxytocin	9 2
Shrivastav et al.[39] (1988)	N: jasmine flowers L: *Jasminum sambac* D: 50 cm of stringed flowers T: flowers	*n* = 60 S: RCT	To evaluate the efficacy of jasmine in the suppression of puerperal lactation in comparison with bromocriptine	10 –1
Mennella and Beauchamp[40] (1991)	N: garlic extract L: — D: 1.5 g of garlic extract (from General Nutrition) T: capsule	*n* = 8 S: NRCT, before-after	To assess if odor of human milk is altered because certain flavors in the mother's diet are transmitted to her milk	10 –1
Menella and Beauchamp[41] (1993)	N: garlic extract L: — D: 1.5 g of garlic extract (from General Nutrition) T: capsule	*n* = 30 S: NRCT?, case-crossover	To evaluate the infants' behavior after garlic ingestion	11 0
Vinoy et al.[42] (2002)	N: betel nut quid (betel nut chewed with or without tobacco and slaked lime) L: *Areca catechu/Piper betel/Nicotiana* spp. D: — T: —	*n* = 47 S: NRCT, survey + lab test	To assess the effect of energy expenditure during the postpartum period	13 –2
Girija et al.[43] (1984)	N: dietary supplement (sesame cake /jaggery/oil) L: — D: 50 g of sesame cake + 40 g of jiggery + 10 g of oil T: —	*n* = 48 S: NRCT, survey + analysis of food composition	To assess supplementation of diet to improve nutrition and milk production	13 –2
Gupta et al.[44] (2003)	N: (*Ajwain*) omum seeds/Italian millet (*kangni*)/*gond* L: — D: — T: —	*n* = — S: NRCT, survey + analysis of food composition	To examine nutritional composition of traditional supplements for lactating women in India	12 NA

(*continued*)

Table 1. (Continued)

Study type, reference (year)	*Name of plant/dietary supplement, Latin plant name, dose, type of product*[a]	*Total sample, type of study*	*Aim of the study*	*Modified Consort and Modified Jaded scores*
Cruz et al.[45] (1981)	N: soybeans L: — D: — T: —	*n* = 30 S: NRCT, SIgA analysis	To study milk samples from Guatemalan women for the presence of antibodies against food products	13 –2
Mennella and Beauchamp[46] (1993)	N: beer L: — D: 0.3 g/kg dose (4.5%) T: tincture (alcohol extract)	*n* = 12 S: NRCT, before–after	To evaluate the effects of the consumption of a single serving of beer by lactating mothers	11 1
Di Pierro et al.[47] (2008)	N: Silymarin L: *Silybum marianum* D: 240 mg/day T: sachet	*n* = 55 RCT	To evaluate role of silymarin as a safe and effective galactagogue for human species	8 2
Westfall[48] (2003)	N: blessed thistle, fennel, fenugreek, raspberry leaf, stinging nettle L: *Cnicus benedictus*, *Foeniculum vulgare*, *T. foenicum-graecum*, *Rubus idaeus*, *Urtica dioica* D: — T: tea from seeds, capsule, oil	*n* = 23 NRCT, qualitative	To discuss the potential value of herbs in breastfeeding women and provide direction for future research	11 NA

[a]N, name of plant/dietary supplement; L, Latin name (genus species); D, dose; T, type of product.
[b]*Zuo yuezi* is the month postpartum in China associated with a variety of traditional beliefs and practices. *Zuo yuezi* included: dietary changes, such as eating more food and avoiding "cold food," behavioral changes, hygiene changes, and practices associated with infant feeding, including supplementary feeding and giving honeysuckle herb to the infant.
[c]Trademark of Madaus Pharmaceuticals (Pty) Ltd.
[d]Trademark of Purdue Products L.P.
APCD, acquired prothrombin complex deficiency; NA, not available; NRCT, non-randomized controlled trial; RCT, randomized controlled trial; S, study type; sIgA, secretory immunoglobulin A; TID, three times a day.

characteristics of randomized controlled trial (RCT) and non-RCT study design. We modified the "Consort Items for Randomized Controlled Trials of Herbal Medicine Interventions" to create a quality score to access the methodological value of each study.[8] Our modified scale contains seven items (best score = 7; worst score = 14). If an item had multiple criteria listed, we assigned the lower (better) score if one of them was met (see Appendix 1). To assess the quality of the RCTs, a Jadad criterion was used; to assess the quality of non-RCTs, a modified Jadad criterion was created (see Appendix 2).[9]

Results

In total, 32 studies were included in this review (see Fig. 1). Thirty full text articles did not meet our eligibility criteria: 14 discussed non-herbal dietary supplements, two were in vitro studies, two were reviews, eight were studies where the lactating mother did not use herbs, and four studies did not meet inclusion criteria (see Fig. 1).

Table 1 provides summaries of the study characteristics, aims of studies, and the quality of the studies. In Table 1, the studies are divided into three main categories: survey studies ($n = 11$), safety studies ($n = 8$), and efficacy studies ($n = 13$). Six studies were RCTs.

The 32 studies were very heterogeneous with regard to the specific herbs studied. The most common were St. John's wort (*Hypericum perforatum*) ($n = 3$), garlic (*Allium sativum*) extract ($n = 2$), and senna (*Cassia senna*) ($n = 2$). Fourteen studies did not include genus species (Latin) names. Five studies did not mention common herbal names. Fifteen studies did not include dose. The dosage form (i.e., tea, capsule, powdered herb) was not described in 13 articles. Among the other 16 articles, the most common types of product were modified extract ($n = 6$), tea ($n = 3$), capsule ($n = 3$), concentrated extract ($n = 3$), and tincture ($n = 2$). Many studies used multi-ingredient herbal preparations ranging from one to 35 single herbs.

The sample size of the studies ranged from one to 471 subjects. Four published studies did not document sample size. In terms of subject characteristics, 72% did not document subject's education, 75% did not document income, 84% did not report subject's ethnicity, and 28% did not document patient's age.

The quality of study methodology, using the modified Herbal Consort criteria, ranged from 8 ($n = 1$) to 14 ($n = 5$) on a scale of 7–14, with 7 indicating the highest quality study (Fig. 2). Figure 2 shows the distribution of the modified Herbal Consort scores. In terms of quality scores, the modified Jadad scores ranged from −1 to 4 for RCTs (scale of −2 to 5) and 1 to −2 for non-RCTs (scale of −2 to 3). The lowest quality score is represented by −2.

Table 2 presents the survey studies. As shown in Table 2, the main outcomes are qualitative, describing the list of plants commonly used by postpartum women or herbal dietary modifications that were done to help increase milk production. Most of these studies did not discuss safety of the herbal intervention in the women or newborns.

There were a total of eight published safety studies, which included *Senna* spp. (*Cassia* spp.) ($n = 2$), St. John's wort (*H. perforatum*) ($n = 3$), herbal liqueur ($n = 1$), and a traditional Chinese herb ($n = 1$) (Table 3). One case-control study reported a potential serious side effect, acquired prothrombin complex deficiency syndrome, among Thai infants consuming an herbal liquor.[10] The herbal ingredients were not disclosed in the article.

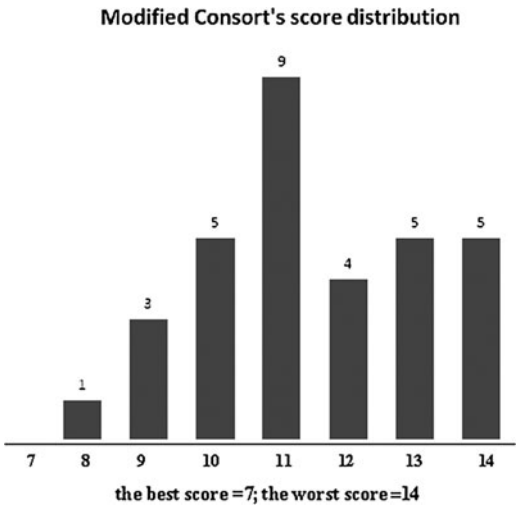

FIG. 2. Distribution of quality scores.

There were 13 efficacy studies: seven had outcomes in the mother, two in the infant, and four in both mother and infant (Table 4). Outcomes were measured in numerous ways, including milk intake by infant, biomarkers such as prolactin and oxytocin levels in the mother, weight of infant, duration of the infant attached to the mother, decrease of duration of illness, or levels of antibodies in milk.

Discussion

This systematic review of herb use in breastfeeding women identified 32 studies in the last 40 years: survey studies ($n = 11$), safety studies ($n = 8$), and efficacy studies ($n = 13$). These studies have heterogeneous interventions, study designs, and outcomes measured. Many studies on safety or efficacy were of poor methodological quality. In considering the scores from the modified Jadad and modified Herbal Consort assessment tools, it should be noted that the modifications to these tools were not validated but provide a basic assessment of the quality of the research.

Although other reviews, such as those of Anderson and Valdes,[11] Conover and Buehler,[12] Belew,[13] Low Dog,[14] and Dugoua et al.,[15] have focused on the use of single herbs or pharmaceutical agents during breastfeeding or preconception, this review included multiple herbs and herbal formulas only during breastfeeding. One of the major highlights of this review is reporting the deficit in published data on herb use among breastfeeding women in the United States.

In our review, we documented eight clinical safety studies, only one of which was an RCT[16] (Table 3). In Thailand, one case-control study of 20 infants with acquired prothrombin complex deficiency syndrome reported higher rates of postpartum mothers using an herbal liquor extract compared with controls ($n = 60$).[10] The authors did not report the ingredients used in the herbal liquor. The two studies of senna and two studies of St. John's wort reported no adverse events.[17,18] One study of St. John's wort did note change in infant behavior that did not require intervention by the primary care provider.[19]

Table 2. Outcome for Survey Studies

Reference (year), name of herbal medicine cited in article	*Adverse events*		*Outcome*	
	Mother	*Infant*	*Mother*	*Infant*
Sinha and Hema[24] (1998) *Shatavari* herb/turmeric soup/papaya	Not reported	Not reported	List of food that help milk production	Not reported
Barennes et al.[6] (2009) Traditional herbal tea	Not reported	Not reported	Herbal tea was considered to be beneficial for lactation	Not reported
Damanik[5] (2009) *Torbangun*	Not reported	Not reported	Knowledge of the Bataknese women about *torbangun* soup and belief that it increases milk production and restores balance after delivery	Not reported
Finley et al.[25] (1985) Herbal tea	Not reported	Not reported	Women were well nourished with the exception of energy requirement; mean nutrient intake exceeded the respective Recommended Dietary Allowance for lactating women.	Not reported
Kulakac et al.[26] (2006) Herbal tea (fennel)	Not reported	Not reported	To increase milk production mothers increased fluid intake (38.6%) and increased sweets consumption (25.3%).	Not reported
Lockett and Grivetti[27] (2000) Various preparations, primarily aqueous extracts of local names	Not reported	Not reported	The list of wild plants that is used for local group members to increase milk production	Not reported
Raven et al.[28] (2007) Warm or cold food Ginger, wine, dates Mother wort (bath)	Not reported	Babies fed powdered milk to supplement breastmilk had increased diarrhea.	Provides adequate nutrition during *zuo yuezi* and avoid cold foods	Not reported
Sayed et al.[29] (2007) Various preparations including powders, pastes, and as fruits or vegetables	Not reported	Not reported	List of plants that were used as galactogogues	Not reported
Singh and Singh[30] (2003) Banana/black gram/pea/ aroid	Not reported	Not reported	Any plants from the four mentioned were used to help with poor lactation.	Not reported
Zhang et al.[31] (2008) Did not report name of herb	Not reported	Not reported	10% of women indicated that they used herbs during breastfeeding.	Not reported
Parveen[32] (2009) Various preparations of plants	Not reported	Not reported	List of 16 plants that are believed to increase milk production	Not reported

The four efficacy studies were RCTs and reported diverse outcomes such as using biomarkers, weight gain or loss, or time attached to the mother's breast. Only one study showed that breastmilk intake was higher than in the placebo group.

Many women consume herbal teas during breastfeeding, and there are many breastfeeding teas in the marketplace. (Note that tea technically refers to water extracts made from the tea plant [*Camellia sinensis*], but herbal tea is part of the common vernacular and is used in this article.) It is surprising that there are few data on the safety or effectiveness of fenugreek, one of most common herbal dietary supplements used by breastfeeding women. A 2011 study published by Turkyilmaz et al.[20] found an herbal tea with fenugreek significantly increased milk production in breastfeeding women. However, it was not included in this review because the inclusion criteria specified articles published between 1970 and 2010.

According to Herbal Consort guidelines, good quality studies should include randomization, blinding, and placebo control.[8,11] Most of the herbal studies did not meet Herbal Consort guidelines; for example, the studies were not RCT but open-label, case-control, or before–after studies. Additionally, none of these studies met full criteria for the Herbal Consort criteria that provide guidelines for the reporting of herbal interventions, particularly for RCTs.[8] For example, most studies did not report the Latin (botanical) name of the herb being studied, and some did not include the common name of the herb

This systematic review has limitations, including not reviewing non-English studies, animal studies, and in vitro studies. We chose to focus on human data because of the prevalence of the use of herbs by nursing women and the relevance of human studies to nursing women. Although animal studies can provide useful information on the safety and efficacy of herbs, the results may not be directly applicable to human clinical use. The exclusion of non-English articles was due to a lack of resources to translate articles written in other languages.

Table 3. Outcome for Safety Studies

Reference (year), name of plant/ herb/dietary supplement	*Adverse events*		*Efficacy*	
	Mother	*Infant*	*Mother*	*Infant*
Faber and Strenge-Hesse[33] (1988) Senna and psyllium laxative (Agiolax)	Not reported	None of the breastfed infants showed any changes in stool consistency. 0.007% of the sennoside intake (as rhein) was excreted in breastmilk. Post-dose varied between 0 and 27 ng/mL with values below 10 ng/mL in 94% in milk samples	Not reported	Not reported
Shelton[16] (1980) Senna tablets (Senokot)	Mild abdominal cramps in mothers	No diarrhea or loose stool seen in infant	Successful treatment of constipation in the immediate postpartum period in an average of 94% of patients	Not reported
Kristiansson et al.[34] (1987) Khat leaves	Not reported	Norpseudoephedrine found in breastmilk and in one infant urine specimen	Not reported	Not reported
Klier et al.[17] (2002) St. John's wort	No side effects observed in mother	No side effects observed in infants Hyperiacin was not excreted to breastmilk, but hyperforin was detected in fore- and hindmilk in very low concentration.	Not reported	Not reported
Lee et al.[19] (2003) St. John's wort	No maternal adverse events	In Group 2 and 3 each there was 1 colicky infant, and in Group 1 there were 2 cases of colic, 2 of drowsiness, and 1 of lethargy.	No change in milk production.	Not reported
Klier et al.[18] (2006) St. John's wort	No adverse effects	No adverse effects or unusual behavior such as lethargy, rashes, photosensitivity, and sleep pattern. The hyperforin concentration was analyzed and varied from 2.1 to 5.6 ng/mL in foremilk.	Not reported	Not reported
Pansatiankul et al.[10] (2008) Herb liqueur extract	Not reported	Vitamin K level was lower in breastmilk of cases versus controls.	Not reported	Not reported
Chien et al.[35] (2006) Traditional Chinese herbs	Not reported	The concentration of lead in breastmilk was higher in the consumption group of traditional Chinese herbs compared with the control group ($p < 0.05$).	Not reported	Not reported

Currently, in the United States, herbal products are regulated as dietary supplements, and supplement manufacturers are responsible for generating or compiling evidence of safety and efficacy for their products.[21] As pre-market approval for supplements is not required by the Food and Drug Administration, there are no existing regulatory guidelines in the United States that propose a risk assessment or protocol to determine the safety and efficacy of herb use during breastfeeding. In the European Union, where herbal products are regulated as medicines and require pre-market approval from the government, a risk assessment protocol for medicinal plant safety during breastfeeding has been developed.[22] The risk assessment integrates evaluation of nonclinical and clinical data and includes consideration of nonclinical pharmacological and pharmacokinetic properties of the medicinal product, as well as results from nonclinical toxicity studies and clinical experience.[22] Similarly, in Canada, herbal products are regulated as Natural Health Products and require pre-market approval from the government.[23] Evidence of safety and efficacy must be provided for a product to be granted a Natural Health Products license, and higher levels of safety evidence must be provided for products intended for use by vulnerable populations (i.e., pregnant or nursing women).

Therefore, there are international models that can be used to assess the safety or efficacy of herbal products during pregnancy and lactation, and further research agendas should take into account high-quality basic science and clinical research on newborns and their mothers.

Conclusions

In conclusion, based on the limitations of the available literature, it is difficult to develop accurate information on the

Table 4. Outcome for Efficacy Studies

Reference (year), name of plant/herb/dietary supplement	*Adverse events*		*Efficacy*	
	Mother	*Infant*	*Mother*	*Infant*
Damanik et al.[36] (2006) *Torbangun* vs. reference group and fengugreek group	Not reported	Not reported	Milk intake significantly increased from 361 to 479 mL, on average a 65% increase ($p < 0.05$).	Not reported
Sharma et al.[37] (1996) *Shatavari* (68% of herbal formula), *sowa* (4.5%), *bidarikand* (4.5%), *mulethi* (4.5%), *palak* (12%), *safed jeera* (2%), *panchatrinamol* (4.5%)	No liver abnormalities seen in mothers	Not reported	In both groups the prolactin level declined after therapy, and there was no difference between placebo and intervention.	There is no difference between placebo and intervention in infant weight gain rate.
Ushiroyama et al.[38] (2007) *Xiong-gui-tiao-xue-yin* (an herbal formula) vs. ergotamine	No adverse events seen in mothers	Not reported	Plasma prolactin levels on Day 1 ($p = 0.037$) and Day 6 ($p = 0.0042$) were different between the ergotamine group and the traditional Japanese group. Plasma oxytocin levels on Day 1 ($p = 0.024$) and Day 6 ($p =$ NS) were different between ergotamine group and the traditional Japanese group.	Daily milk volume differed significantly between the two groups.
Shrivastav et al.[39] (1988) Jasmine flowers	No side effects seen in mothers	No applicable	After 72 hours the fall in serum prolactin ($p < 0.001$) was significant for both groups, but the fall was significantly greater in women treated with bromocriptine compared with those treated with jasmine ($p < 0.01$).	Not applicable
Mennella and Beauchamp[40] (1991) Garlic extract	Not reported	Not reported	Not reported	Infants were longer attached ($p < 0.05$) to mothers and sucked more when the milk ($p = 0.007$) smelled like garlic.
Menella and Beauchamp[41] (1993) Garlic extract	Not reported	4 of 10 infants from the placebo group were colicky, and 4 from the garlic group	Not reported	More breastfeeding time in infants whose mother ingested garlic but no difference in amount of milk
Vinoy et al.[42] (2002) Betel nut quid (betel nut chewed with or without tobacco and slaked lime)	Not reported	Not reported	Moderate users on average have significantly lower heart rates than low users ($p = 0.001$).	Not reported
Girija et al.[43] (1984) Dietary supplement (sesame cake/jaggery/oil)	Not reported regarding supplement	Not reported	Decrease of duration of illness among groups ($p < 0.01$)	Increase the velocity of the weight of the infants
Gupta et al.[44] (2003) (*Ajwain*) omum seeds/ Italian millet (Kangni)/ Gond	Not reported	Not reported	Sample recipes (*Ajwain*) when consumed during lactation were high in energy and low in essential nutrients	Not reported
Cruz et al.[45] (1981) Soybeans	Not reported	Not reported	No differences ($p > 0.1$) in levels of anti-soybean antibodies among the groups	Not reported
Mennella and Beauchamp[46] (1993) Beer	Not reported	The dose of alcohol ingested by the infants ranged from 18.6 to 66.7 mg.	Infants consumed less milk in 4 hours after the mother drank alcoholic beer ($p = 0.03$).	No change in time that infant was attached to mother ($p =$ NS)

(*continued*)

Table 4. (Continued)

Reference (year), name of plant/herb/dietary supplement	Adverse events		Efficacy	
	Mother	Infant	Mother	Infant
Di Pierro et al.[47] (2008) Silymarin	No side effects seen in mothers	No side effects seen in infants	On Days 30 and 63 increase in milk production ($p = 0.01$)	Not reported
Westfall[48] (2003) Blessed thistle, fennel, fenugreek, raspberry leaf, stinging nettle	Not reported	Not reported	14 of the 23 women used some form of galactagogue, and 11 of these women used herb: blessed thistle, 2 users; fennel, 4 users; fenugreek, 4 users; raspberry leaf, 2 users; stinging nettle, 2 users. Women received herbal advice from midwives, friends, a doula, or family member.	Not reported

NS, not significant.

safety and efficacy of specific herbs during breastfeeding. It is critical that more research is conducted in this area, including national prevalence, safety, and efficacy studies. Furthermore, careful thought must be put into appropriate outcome measures and methods needed to address the ethics of doing such studies in such a vulnerable population. It may be that novel research methods will be needed to address such a large research agenda.

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(Appendices follow →)

Appendix 1

Modified Consort items scale for RCTs of herbal medicine interventions

1. HERBAL MEDICINAL PRODUCT NAME **[ ] Yes [ ] No**
   a. The **Latin binominal** name together with botanical authority and family name for each herbal ingredient
   b. The **proprietary product name** (i.e., brand name) or the extract name and the name of manufacturers of the products
2. CHARACTERISTICS OF THE HERBAL PRODUCT **[ ] Yes [ ] No**
   a. Part of plant used to produce product extract
   b. The type of product used
   c. The type and concentration of extraction solvent used and the ratio of herbal drug to extract
   d. The method of authentication of raw material and lot number of the raw material. State if a voucher specimen was retained and, if so, where it is kept or deposited and the reference number.
3. DOSAGE REGIMEN & QUANTITATIVE DESCRIPTION **[ ] Yes [ ] No**
   a. The dosage of the product, the duration of administration, and how it was determined
   b. The content (weight, concentration) of all quantified herbal products constituents, both native and added, per dosage unit
   c. For standardized products, the quantity of active/marker constituents per dosage unit
4. QUALITATIVE TESTING **[ ] Yes [ ] No**
   a. Product's chemical fingerprints and method used and who performed the chemical analysis; whether a sample of the product was retained and, if so, where it is kept or deposited
   b. Description of any special testing/purity testing undertaken, which unwanted components were removed, and how
   c. Standardization: what to standardize and how
5. PLACEBO/CONTROL GROUP **[ ] Yes [ ] No**
   a. rationale for the type of control/placebo used _____
6. PRACTITIONER **[ ] Yes [ ] No**
   a. Description of the practitioners _____
7. ADVERSE EVENTS **[ ] Yes [ ] No**
   a. type of the adverse events_____

Appendix 2

Jadad scale—RCTs (yes = 1 or − 1, no = 0)

1. Was the study described as randomized (this includes the use of words such as randomly, random, and randomization)?
   yes = 1, no = 0
2. Was the study described as single-blinded?
   yes = 1, no = 0
3. Was there a description of withdrawals and drop-outs?
   yes = 1, no = 0
4. Method to generate the sequence of randomization was described and was appropriate (e.g., table of random numbers, computer-generated, coin tossing, etc.)
   yes = 1, no = 0
5. Method of double-blinding described and appropriate (identical placebo, active placebo, or dummy)?
   yes = 1, no = 0
6. Method of randomization described but it was inappropriate (allocated alternately, according to date of birth, hospital number, etc.)?
   yes = −1, no = 0
7. Method of double-blinding described but it was inappropriate (comparison of tablet vs. injection with no double dummy)?
   yes = −1, no = 0

Total Score: /5

Jadad Scale (modified)—non-RCTs

1. Was the study described as double-blind?
   yes = 1, no = 0
2. Was there a description of withdrawals and drop-outs?
   yes = 1, no = 0
3. Method of double-blinding described and appropriate (identical placebo, active placebo, dummy)?
   yes = 1, no = 0

4. Method of randomization described but it was inappropriate (allocated alternately, according to date of birth, hospital number, etc.)?
   yes = −1, no = 0
5. Method of double-blinding described but it was inappropriate (comparison of tablet vs. injection with no double dummy)?
   yes = −1, no = 0

Total Score: /3