

The Use of Herbal Products during Breastfeeding: A Study from a Public Italian Hospital

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Abstract

Background: The use of herbal products is steadily increasing worldwide, especially by women, also during pregnancy and breastfeeding, even if safety data are lacking. Aim of this study was to estimate the prevalence of use and the attitude toward herbal remedies among women during breastfeeding, by an interview-based survey.

Methods: Participants were interviewed after receiving the informed consent, by a structured and validated questionnaire.

Results: Two hundred forty-four breastfeeding women completed the questionnaire. The majority of them were non-smokers and non-drinkers, whereas they were regular consumers of herbal products during breastfeeding (97%). Medicinal plants most commonly used were sweet almond oil (68%) and fennel (37%). Herbal products were often associated with other prescription drugs (89%). Five percent of women have experienced dermatological and gastrointestinal adverse reactions, potentially due to herbal products.

Conclusions: This study reports that nursing mothers are generally no smokers, avoid alcohol consumption, and they reduce the use of drugs to those really needed. At the main time, this study highlights that breastfeeding mothers have limited knowledge on the risk/benefit profile of plant-derived products. As data on the excretion of chemical components of herbal products and their metabolites in breast milk are lacking, it is generally better to avoid during breastfeeding the use "natural remedies" whose safety has not been well established.

Keywords: Herbal products; Breastfeeding women; Safety; Plant-derived products

Introduction

Natural products, particularly plant-derived ones, are generally used to improve the sense of well-being as well as to treat minor illnesses, and their use is steadily increasing worldwide [1,2]. In particular, women of 25-34 years of age seem to be the major users of plant-derived products, also and especially during pregnancy and breastfeeding [3,4], because these products are perceived as risk-free and helpful for various physiopathological conditions [1]. Even if in the recent years the scientific interest for herbal products during pregnancy is increasing all over the world, the information available on their use by breastfeeding women is still lacking and almost missing. This lack of scientific data goes along with a lack of knowledge of pharmacokinetic data on most plant-derived products, so that the amount of them that diffuses into mother's milk is unforeseeable. In this perspective, various parameters (absorption, distribution, metabolism and excretion) should be cautiously evaluated. For example, the metabolic and excretory capacities of the babies increase in a directly manner with their age [5], whereas the absorption and distribution of a xenobiotic into the breast milk depends on its chemical and physical characteristics (acid or basic nature, lipophilicity, etc.), and on many other factors (e.g., milk composition, proteins binding) [5,6]. Therefore, the exposure to herbal products should be probably avoided, in absence of correct information. Hence, the aim of the present study is to evaluate the prevalence of use and the knowledge of the safety and efficacy of herbal products by breastfeeding women.

In our survey, herbal products are considered as all products (herbal dietary supplements, cosmetics, homeopathic remedies, and medicinal herbal-based products) containing an herbal substance. The latter is

defined by the European Parliament as "all mainly whole, fragmented or cut plants, plant parts, algae, fungi, lichen in an unprocessed, usually dried form, but sometimes fresh". Moreover, from an **herbal substance** different herbal preparations (powdered herbal substances, tinctures, extracts, essential oils, etc.) can be made [7].

Methods

A mono-centric cross-sectional study was carried out at the Umberto I-Policlinico di Roma (an Italian public hospital in the centre of Italy). The interviews were carried out twice a week, from June 2012-June 2013.

Breastfeeding women were recruited for participation during their staying in the hospital, in the first few days after childbirth, and were random interviewed.

This study did not require ethical approval as it was an observational study. However, all study participants provided their informed consent, and the survey was also approved by the superintendent of

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gynecology's ward of the Department of Obstetrics, Gynecology, and Urology, Sapienza University of Rome.

A structured questionnaire, that included descriptive (age, country of birth, level of study, work experience, etc.) and analytical (e.g., product used and reason of use, participant's knowledge and primary source of information on herbal products, use of other therapies, perspective of safety and efficacy) questions on herbal products, was utilized. The survey was planned and validated according to other language questionnaire [8,9]. The validation procedure was carried out by a panel of experts as reported by Lapi et al. [9]. The survey was administered in Italian language; a detailed sample of its translation is reported in Table 1.

What we intended for "herbal products", as previously stated, was explained to the interviewees before the administration of the questionnaire. All data were anonymously collected in a specific database, using Office Excel software. Skilled health personnel carried out each interview.

Statistical analysis included simple descriptive statistics such as mean and standard error for normally distributed data, and medians and ranges for non-normally distributed data.

Results

All breastfeeding women (n=244), that were contacted during their staying in the Umberto I - Policlinico hospital, gave their consent to the interview. In our study, as the breast milk is the first natural food for babies immediately after delivery [10,11], we have considered as nursing women each woman who has mammary secretion of colostrum, transitional or mature milk [12]. Where specified (90.6%; n=221), they were 32 (\pm 0.4) years old, Italian (82.4%; n=182) and foreign (17.6%; n=39) women. Italian women were mainly from the central Italy (89%; n=162), whereas the North (1.7%; n=3) and the South (9.4%; 17) of Italy were less represented. Among immigrant women, the most representative geographical areas were East of Europe (74.5%; n=29), Latin-American (15.4%; n=6), and Asia (10.2%; n=4). Nursing women had a medium level of education (53.7%; n=131), and occupation (24.2%; n=59) and 24.2% declared to be clerk. The majority of nursing women (54.1%; n=132) were non-smokers, or they stopped smoking during pregnancy (35.2%; n=86). They were also no (79.1%; n=186) or lightly (19.1%; n=45) consumers of alcoholic beverages. Only few breastfeeding women were smokers (10.7%, n= 26) or heavy drinkers (1.7%, n=4). A summary of the characteristics (e.g. life style, work experience) of the nursing women is presented in Table 2.

Among women surveyed, 79.8% (n=190) had taken herbal products during their life and 97.3% (n=214) started to take these products also during pregnancy and breastfeeding. Only 20.2% (n=48) of women have never used herbal products in their life, and they did not use natural products neither during pregnancy, nor during breastfeeding (2.7%, n=6).

The products most commonly used, their frequency of consumption and the duration of treatment are reported in Table 3. Breastfeeding women that used only multivitamin supplements were 1.4% (n=3).

Ninety-six percent (n=235) of nursing women responded to the next part of the questionnaire, among them was also included one puerpera who could not breastfeed, but was taking various plant-derived products (i.e., fennel and sweet almond oil).

Herbal remedies were often used in association between them (95.3%, n=224) and with drugs (89%; n=208), including steroids and

thyroid hormones (55%, n=114), antianemic (45%, n=94), and other gynecological medications (43%, n=90). The average number of herbal products taken in association by women (n=235) was about 2.47 ± 0.07 (ranging from 1 to 7 products), whereas drugs were 1.96 ± 0.06 (ranging from 1 to 5 medicines) (n=213).

The most common reasons for using herbal products during lactation were considered as due to (76.4%, n=178) or partially dependent (14.6%, n=34) on pregnancy or breastfeeding. Referring the aforementioned issues, in the multiple answers possibility, the following conditions were reported: breast milk stimulation and maintenance of lactation (2.8%; n=6), dermatological conditions (85.8%; n=193), gastrointestinal problems (9.8%; n=22), psychological ailments (20.0%; n=45), and vascular troubles (11.3%; n=24). In particular, among dermatological problems, stretch marks (85.8%; n=182) and "preparation of nipples" for breastfeeding (3.8%, n=8) were the most recorded. Regarding psychological conditions, anxiety (13.7%; n=29) and insomnia (1.9%, n=4) were the most common. As regards discomforts related to gastrointestinal conditions, constipation (3.3%, n=7) and dyspepsia (4.2%, n=9) were frequently reported. Finally, among vascular troubles, conditions as varices (7.5%, n=16) and heavy legs sensation (2.4%, n=5) were recurrent.

The interviewed women (responders=235) learned about herbal products from the advices of variety of sources that included the following: gynecologist (44%; n=103), herbalist (40%; n=94), pharmacist (29%; n=68), general practitioner (23%; n=55), friends (15%; n=34), pediatrician (13%; n=30), personal experience (10%; n=24), and Internet websites (9%; n=21). Purchase of various plant-derived products occurred primarily in pharmacy (66%; n=154), herbalist's shops (39%; n=90), supermarket (20%; n=47), perfumery (13.7%, n=32), Internet (0.9%; n=2) and catalogues (0.9%; n=2).

Breastfeeding women considered as the unsafe period in taking herbal products during pregnancy the following: first trimester 15% (n=35), all over the pregnancy period 3% (n=7), never 75% (n=175), don't know 7% (n=17). On the other hand, drugs were considered as dangerous during the first trimester by 36% (n=83), all over the pregnancy period by 53% (n=123), never by 2% (n=5), and don't know by 9% (n=21) of the interviewed.

The opinion of breastfeeding women on the safety and efficacy of herbal remedies versus pharmaceutical products is reported in Figures 1A and 1B, respectively.

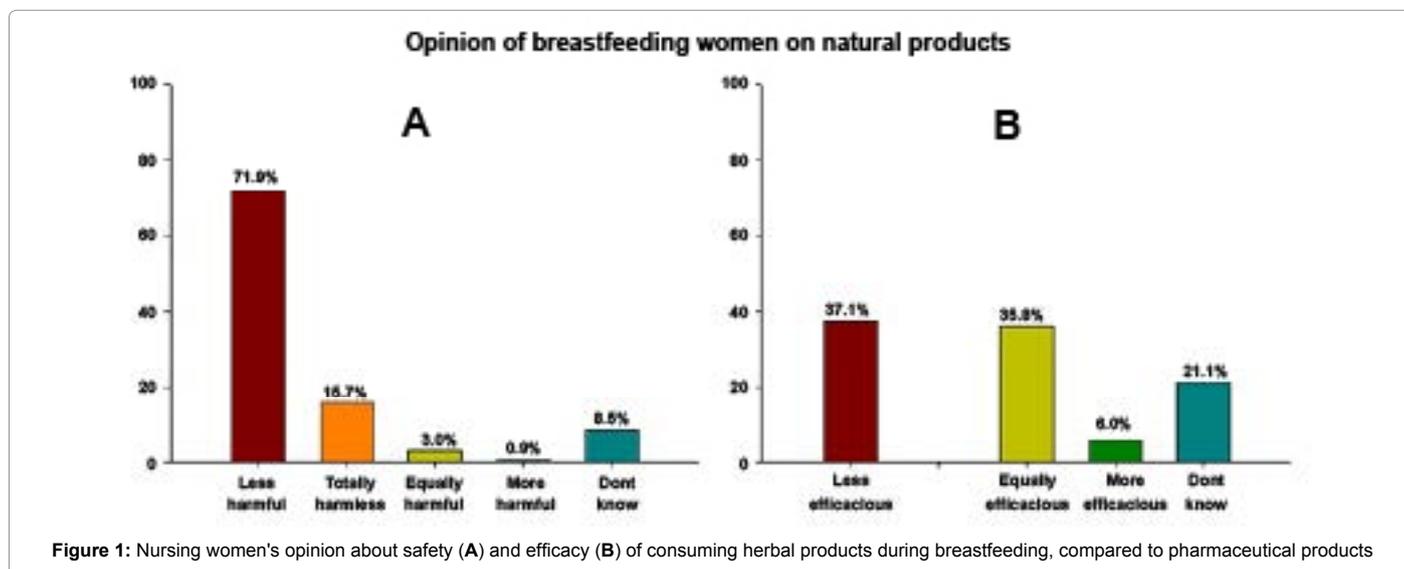
Finally, 5.1% (n=12) of breastfeeding women experienced adverse dermatological reactions (n=8) such as erythema, dermatitis, itching, and burning sensation, generally associated to the use of sweet almond oil (n=5), vanilla cream (n=1), and cosmetics containing various associations of herbal ingredients, including rice oil (*Oryza sativa*), pea extract (*Pisum sativum*), sunflower oil (*Helianthus annuus*), castor oil, etc. (n=2). Gastrointestinal reactions (i.e. heartburn, vomit, constipation; n=4), after using multivitamin supplements (n=3) and herbal derived product (n=1) were also reported. In particular, a case of constipation was reported in an infant of 10 weeks, whose mother had been taking a product containing numerous medicinal plants, including coriander (*Coriandrum sativum*), ginger (*Zingiber officinalis*), cumin (*Cuminum cyminum*), chicory (*Cichorium intybus*), fennel (*Foeniculum vulgare*), althaea (*Althaea officinalis*).

Discussion

To the best of our knowledge and according to a search on PubMed website-terms that were searched on January 2014, without any

<p>Personal data</p>	<p>Age: _____ Nationality: _____ Level of education: _____ Profession: _____ Week of lactation: _____ Previous pregnancies: <ul style="list-style-type: none"> • Yes • If yes, how many? _____ • No </p>
<p>Lifestyle</p>	<p>Do you smoke? o Yes o Never smoked o Former smoker Do you drink alcohol beverages during lactation? o No o Yes, occasionally (less than three glasses per week) o Yes, quite frequently (3-14 glasses per week) o Yes, usually (more than 14 glasses per week) What foods do you consume most frequently? o Carbohydrates (pasta, bread, cakes): _____ o Meat: _____ o Vegetable: _____ o Fish: _____ o Fruit: _____</p>
<p>Use of herbal products during life</p>	<p>Have you ever used herbal products? o Yes o No</p>
<p>Use of herbal products during pregnancy/lactation</p>	<p>Have you ever used herbal products during pregnancy/lactation? o Yes o No (specify) _____ If yes, which kind of product? 1. Homeopathic 2. Cosmetics 3. Medicinal herbal-based products 4. Herbal dietary supplements 5. Other food supplements (e.g. vitamins, minerals) If possible, please, specify the name of the product/s that has been used? 1. _____ 4. _____ 2. _____ 5. _____ 3. _____ 6. _____ Why do you use herbal products (specify the reason)? o Independent reasons of the lactation _____ o Because of the lactation _____ o Both _____ What is/was the frequency and the duration of your herbal treatment/s? Please, specify: _____</p>

Table 1: Sample of questionnaire, administered to breastfeeding women by health professionals



Characteristics	% (n)
Nationality	Italian: 82.4% (182)
	• Northern 1.7% (3)
	• Central 89.0% (162)
	• Southern 9.4% (17)
Parity	• Foreigners: 17.6% (39)
	Primiparous: 50.4% (123/244)
	• previous pregnancy: 61.2% (74/121)
	• previous pregnancies 26.4% (32/121)
Level of education	• previous pregnancies 5.8% (7/121)
	• >3 previous pregnancies: 6.6% (8/121)
	Primary/secondary school: 18.4% (45)
Occupation	High school: 53.7% (131)
	Degree: 27.9% (68)
	Clerk: 24.2% (59)
	Housewife: 19.7% (48)
	Teacher: 7.0% (17)
	Worker: 4.5% (11)
	Saleswoman: 4.5% (11)
	Beautician: 2.9% (7)
	Shopkeeper: 2.5% (6)
	Nurse: 2.5% (6)
Social worker: 2.0% (5)	
Student: 2.0% (5)	
Favorite food	Carbohydrates (pasta, bread, etc.): 34.1% (79)
	Meat (beef, white meat, etc.): 22.8% (53)
	Vegetable (salad, spinach, etc.): 22.0% (51)
	Fruit (orange, apple, etc.): 15.9% (37)
	Fish (shrimp, tuna, etc.): 3.4% (8)
	Other (milk, dairy products, etc.): 1.7% (4)
Smoking	Current smoker: 10.7% (26)
	Never smoker: 54.1% (132)
	Previous smoker: 35.2% (86)
Alcohol use	No, never: 79.1% (186)
	Yes, occasionally (less than three glasses per week) : 19.1% (45)
	Yes, quite frequently (3-14 glasses of alcohol /week): 1.7% (4)

Table 2: Descriptive characteristics of breastfeeding women (n=244)

limit of language, were the following: “botanicals and breastfeeding” “herbal products and breastfeeding”-this is one of the few studies that examined personal use, knowledge of safety and efficacy of herbal products among breastfeeding women.

Limitation of the study is that this a mono-centric study that involved breastfeeding women from one geographic location (Rome, Italy), however data were obtained from the Umberto I-Policlinico of Rome, which is the biggest public hospital in Italy, and even one of the largest in Europe [13].

The analyzed population, despite their medium sociocultural level, appeared to be conscious to use drugs only when necessary and aware of the importance of a proper diet, during breastfeeding. This fact is important, because of the recent evidence indicating that breastfed infants, as exposed to a variety of flavors by mother’s milk, have a greater acceptability of new food during their weaning period, and are less inclined to develop chronic diseases [14]. Of note is that nursing women were regular users of a variety of plant-derived products; even those who had never used herbal products during their life, began to take them (almost every day) during pregnancy and continued throughout breastfeeding. Moreover, breastfeeding women often associated herbal remedies between them, and/or with drugs. This should be avoided, considering the possibility of pharmacological interactions between different therapies that makes the final effect of the association totally unforeseeable [15,16].

Breastfeeding women considered plant-derived supplements as useful, without taking into account the possibility of adverse outcome for them and/or their baby, and considered herbal products as less dangerous than drugs, so having a poor knowledge of the risk/benefit profile of botanicals. These beliefs have also been reported in other studies carried out in pregnant and breastfeeding women [3,17,18]. Paradoxically, interviewed women used herbal products, even if considered them less efficacious than pharmaceutical products. Compared to what happens in other countries, where family and friends are the most cited source of information about botanicals [19], in our study, participant’s primary source of advice was gynecologists. However, while herbalists and pharmacists receive academic training courses on botanicals, other health practitioners (including

Product used % (n)	Frequency of use % (n)	Duration of use (days ± SE)	Most representative ingredients
Cosmetics containing plants 93.6 (218)	Daily 95.0 (191) Twice a week 2.5 (5) Once a week 2.5 (5)	199.0 ± 5.4	- Almond oil (68.3%; n=149); - Multi-herbal ingredients, including rice oil in association with peas extract, sunflower, castor oil (29.8%; n=65); - Calendula (2.3%; n=5); - Aloe gel (1.4%; n=3); - Others (5.1%; n=11)
Food supplements 91.4 (213)	Daily 98.1 (154) Twice a week 1.9 (3)	184.6 ± 80.7	- Multivitamin supplements (54.9%; n=117) - Others (folic acid, iron, etc. - 80.8, n=172)
Herbal dietary supplements 36.9 (86)	Daily 81.9 (59) Twice a week 11.1 (8) Once a week 6.9 (5)	198.2 ± 12.6	- Fennel (37.2%; n=32); - Licorice (5.8%; n=5); - Fenugreek (3.5%; n=3) - Green tea (3.5%; n=3); - Others (unspecified multiple-ingredients herbal teas - 31.4%; n=27; propolis 41.3%; n=19,)
Homeopathic medicines 10.3 (24)	Daily 100 (9)	82.8 ± 38.0	- Arnica (17%; n=4) - Multi-ingredient syrup (8.3%; n=2)
Herbal derived drugs 11.7 (14)	Daily 60.0 (3) Twice a week 20.0 (1) Once a week 20.0 (1)	122.8 ± 58.4	- Valerian (28.6%, n=4); - Aloe juice (7.1%; n=1); - Silymarin (from milk thistle) (14.3%; n=2)

Table 3: Characteristics of plant-derived products used by breastfeeding women. Data are reported as percentage (%) and number of respondents (n), taking into account that the interviewed women had a multiple answer possibility

gynecologists) usually do not receive any professional education on herbal remedies, at least in Italy. The comforting aspect, despite the e-trade of botanicals is widespread, is that the nursing Italian women appeared to prefer pharmacies, as their favorite source of purchasing.

In our study, most of women reported no side effects, with the exception of dermatological and gastrointestinal reactions associated with cosmetics and herbal supplements. The first category is considered as safe, even if few adverse reactions due to their herbal composition are reported [3,15,20]. Some concerns raised from the daily application of almond oil to the abdomen of pregnant women, because it was associated with preterm birth [3]. The authors have hypothesized that the association between almond oil and shortening of gestation could be due to a premature contractions by a chronic mechanical stimulation of myometrium and/or to an uterotonic effect of some almond oil compounds (e.g., fatty acids), which could target the myometrium [3]. This event, although unusual and not related with lactation, should be kept in mind because if almond oil can reach the myometrium, may also be delivered to the infant through breast milk.

The use of other herbal-based cosmetics has been reported, including those containing calendula and aloe. Even if both plants appear as safe in the common practice, eczema and ocular irritations are reported [15,21], as well as contact dermatitis and oral mucositis after the topical application of aloe [22]. Consequently, they should be contraindicated in hypersensitive patients [16].

Regarding herbal supplements, safety data were not discussed in the clinical studies identified for lactation [23]. However, several reactions have been recently reported, making some medicinal plants unsuitable for their use during lactation and other specific conditions [19,23,24]. In our survey, breastfeeding women reported the use of milk thistle and fenugreek (usually in association), as galactogogues, although their effects and the dose necessary to obtain an increase of breast milk production should be further evaluated [23,25]. Both herbs have been suspected to increase the risk of bleeding, and it is suggested that they should be discontinued at least two weeks before any surgical procedure [26]. Then, their use shortly before the childbirth is not safe. In addition, fenugreek could induce hypoglycemia and gastrointestinal upsets and should be used cautiously in patients taking medications that may interfere at the same pharmacological levels [21,27].

In our study, additional concerns arise from other medicinal plants used by nursing women (e.g. fennel, licorice, aloe). *Foeniculum vulgare* and *Glycyrrhiza glabra* have been used as herbal dietary supplements, whereas *Aloe vera* has been taken as non-prescription medicine. For these plant-derived products, several adverse reactions have been reported. In particular, fennel may cause contact dermatitis, and an increase of estrogen levels [16]. Its long term use has been associated with the onset of premature thelarche in one female infant and three female children, where an increase of 15-20 fold of serum estradiol levels, and a case of vaginal discharge were found [28]. This estrogenic effect (ascribed to the anethole content) could also induce a suppression of lactation in breastfeeding mothers [28]. Noteworthy is that, in our survey, one of the fennel consumers could not breastfeed; however a definitive conclusion cannot be drawn from this case. As regards licorice, some evidences suggest that its regular intake is associated with adverse manifestation, including cardiovascular reactions [20], abortion and preterm labour [3]. In some cases, however, other drugs (e.g., antiinflammatory, antihypertensives) taken in association with licorice could be involved in the adverse outcome [20]. Moreover, of concern are association of licorice and fennel with other medicinal

plants, that have been reported to induce lethargy, hypotonia, and emesis in two neonates of breastfeeding women consuming a large volumes of this herbal tea mixture [29]. With regard to the use of aloe as a laxative medicine, it should be kept in mind that its use is not recommended in children under 12 years of age and, according to European Medicine Agency, during breastfeeding, "as there are insufficient data on the excretion of metabolites in breast milk", but it is hypothesized that some its metabolites pass in small amounts [30]. Finally, the constipation reported in an infant of 10 weeks, whose mother had been taking a mixture of medicinal plants is not scientifically explainable, because of the complexity of the product [20]. Moreover, as it is unknown if plant ingredients are excreted in human breast milk, their use during lactation is not recommended [31-33]. Noteworthy is that for all of the mentioned products in our study, no information is available on their quality and this it should be taken in mind before drawing definitive conclusions on the safety of "natural" products.

In this study, taking into consideration the widespread use of botanical agents, in relation to the relatively small number of adverse reactions due to them, it seems that the incidence of adverse effects is low. However, it is clear that the implementation of the Phytovigilance system can further improve our knowledge on the safety of botanicals. In accordance to the Motherisk Program, to achieve a conclusion on this topic there is a need for future research [34]. Till then, these products should be probably contraindicated because, even if we do not know if they are dangerous, we are not sure of their safety [35].

Conclusions

This study highlights the need to provide comprehensive information on the use of plant-derived products to nursing women. In order to give them a qualified advice, the health care staff (e.g., general practitioners, gynecologists, pharmacists, nurses, pediatricians, and herbalists) should know how to access unbiased and reliable information sources, and should always update their knowledge on herbal products. This study could be of a wide audience interest and could contribute to the international knowledge, as the existing international research base on plant-derived products used during breastfeeding is still lacking.

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Conflict of Interest

All authors declare that no conflicts of financial and commercial interest exist.

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