ORIGINAL RESEARCH

Maternal experiences with and sources of information on galactagogues to support lactation: a cross-sectional study

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Abstract: An increase in the marketing and use of herbal galactagogues among breastfeeding mothers in the US has raised the issue of how best to provide support and information on the use of these products, particularly in light of limited availability of certified lactation counselors and continued suboptimal rates of breastfeeding globally. Currently, no cross-sectional data are available on the experiences and attitudes of mothers regarding the use of herbal and pharmaceutical galactagogues for lactation in the US. The findings of an online survey of 188 breastfeeding mothers on experiences with and sources of information on galactagogues are presented. Most mothers (76%) reported that while breastfeeding, they felt as though they were not making enough milk to meet the needs of their child, and yet 54% also indicated that they had not supplemented with formula. A large proportion of respondents reported utilizing galactagogues to increase lactation and finding them useful. The results indicated that most women learned about galactagogues from the Internet or by word of mouth through friends. Lactation consultants were the third-most reported sources of information on these products. While many respondents reported perceiving galactagogues as innocuous, more evidence on safety and efficacy is needed to support women properly who seek out and use them. Large-scale studies of the prevalence of galactagogue use in the US and rigorous evaluation of use globally are needed to ensure that mothers who choose to breastfeed may safely avail themselves of all options when counseling support is insufficient.

Keywords: galactagogue, breastfeeding, lactation, lactation support

Introduction

Further advances in improving the research and policy environment surrounding breastfeeding in the US are urgently needed to support women in achieving more successful lactation outcomes. Though the maternal and child-health benefits of breastfeeding are well documented,^{1–6} rates of breastfeeding in the US remain suboptimal.^{7,8} Only 18.8% of infants are breastfed exclusively at age 6 months, and only 26.7% are still being breastfeed at age of 12 months.⁹ Provision of breastfeeding counseling and support is a widely accepted strategy, but women may not be able to access certified lactation consultants, and must seek support from other sources.^{10,11}

Current breastfeeding-promotion interventions have not been adequately successful in addressing insufficient milk supply,^{12–16} the most common reason that women cite when they discontinue breastfeeding.^{15,17–19} In a 2001 study, 30% of mothers reported this as the major reason for discontinuation,¹⁵ while another study of participants in the Special Supplemental Nutrition Program for Women, Infants and Children (WIC) in the US reported that 46% who stopped breastfeeding before the recommended

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age did so because of perceived inadequate milk supply.²⁰ Consequently, mothers (notably, adoptive mothers seeking to induce lactation) and health care workers involved in supporting them have sought other modes of lactation support to address this concern, including using galactagogues: foods, medicines, herbal supplements, and teas purported to have lactogenic properties.²¹⁻²⁷ Breastfeeding women have accessed herbal medicines for the purpose of aiding lactation historically and in diverse settings.^{24,26–41} Fenugreek is one substance that has been widely used for lactogenic effect, and as a result has been growing in popularity globally.42 The scientific literature documenting the efficacy of herbal galactagogues, such as fenugreek, fennel, blessed thistle, and goat's rue, is quite limited.^{21,22,24,26,28,32,37,39-41,43-49} Galactagogues are assumed to enhance milk supply and production by increasing the level of the hormone prolactin, but ultimately the biological mechanisms by which they may or may not function are not well understood.48

Though numerous intervention studies have aimed at supporting breastfeeding continuation and exclusivity through lactation-consultant support,50-59 fewer have examined the use of pharmacological or herbal supplements as an additional lactation aid.^{24,26,32,39,40,60-63} Various challenges can impede successful breastfeeding initiation, exclusive breastfeeding during the first 6 months, and continuation. Socioeconomic factors and health disparities result in greater barriers for vulnerable populations, often related to the need to return to work soon after giving birth.⁶⁴ Maternal health factors, including delayed childbearing, cesarean section, multiple births, mode of conception,²⁹ and obesity may also contribute to potential challenges to breastfeeding.65 Maternal obesity in particular places a mother at increased risk of physiological difficulties during lactation and lower breast-milk production,66 and may be associated with insufficient secretion of the hormone prolactin, required for milk production.⁶⁷ Mammary hypoplasia, use of analgesics during labor, and family history of alcohol dependence may also put certain women at risk for challenges with lactation.⁶⁷ In first-time mothers, delayed onset of lactogenesis II can be common, and has been associated with risk of early discontinuation of breastfeeding.³¹ Currently, breastfeeding mothers in the US have very limited access to pharmacological interventions for increasing milk supply, and physicians may only prescribe these "off-label" or not for their intended use; the US Food and Drug Administration has not approved any pharmaceutical products for lactation.²⁷ In contrast, Canadian women frequently utilize prescription medication for lactation support.68

Given that many herbal and pharmaceutical options are increasingly sought and used,⁶⁹ despite the lack of evidence

about their efficacy to increase milk supply,^{69,70} additional studies for improved health information regarding galactagogue use are warranted. Studies involving mothers who have used pharmaceutical and herbal galactagogues are also critical, since participants can provide first-hand insight into experiences with and effects of galactagogue use, as well as sources of information that could be targeted for improvement.^{33,38} Breastfeeding knowledge is a key factor influencing infant feeding,71,72 and studies that examine mothers' experience and source of information are valuable in informing clinical guidelines for recommendation, as well as the selection of specific interventions to be tested through controlled trials.³⁰ Previous research on this topic has been limited to specific geographic regions, and to date no studies have been conducted in the US through use of a survey administered online. The current cross-sectional study aimed to add to the scarce literature on galactagogues and expand upon the recent studies reporting women's experiences using herbal supplements to improve lactation.^{24,25,30,46}

Materials and methods

The present survey was designed to explore mothers' experiences with galactagogues to improve lactation and sources of information on these products. The online questionnaire format administered in this study was developed to elicit information efficiently on experiences of mothers who were interested in using, currently using, or who had used galactagogues for breastfeeding. An exploratory cross-sectional approach was employed, and the protocol and study materials were reviewed by the Tulane University and Ochsner Clinic Foundation institutional review boards and deemed exempt from further oversight on the basis of research involving survey or interview procedures with adult subjects, as per criteria of 45 CFR 46.101(b)(2) (US Department of Health and Human Services). The STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) checklist for reporting on cross-sectional studies has been used to develop the following sections concerning details of this research, including information on the survey content.

Sampling

A convenience sample of women who use Internet-based breastfeeding websites was employed. Probability sampling was not possible, due to constraints in obtaining formal access to a list of populations, due to privacy considerations and the lack of a full description of the sampling frame. As a large proportion of women use the Internet for perinatal advice, including on breastfeeding, and numerous websites specific to lactation exist,⁷³ the Internet was the primary setting for

recruitment. In order to participate, mothers had to be aged 18 years, speak English, and have access to the Internet.

Survey

Participants were enrolled if they chose to click on a survey link, replied affirmatively to consent to participate, and confirmed being 18 years or older in the online survey questionnaire. An invitation to participate was distributed through the Internet, including through social media. Sites on which the survey invitation appeared included the Baby Center, Pinterest, Kelly Mom, and La Leche League websites and various Facebook pages in the New Orleans and Baton Rouge areas. Participants were also encouraged to distribute the survey widely by email or text message to other mothers, for snowball sampling. Doulas and lactation consultants located near the authors' research institutions were asked to send the survey to their contacts.

Data collection began in October 2015 and ended in December 2015. Participants were able to choose the setting in which the online survey was completed: any location with a computer, smartphone, or tablet computer. Individuals were informed that their participation was voluntary, consent was implied upon completion of the survey, and that responses would be anonymous. No incentive was provided, and there was no cost for participants in the survey. The survey included 28 items.

Closed-ended questions varied in format. Some closedended questions had binomial answers of either yes or no. Other questions allowed respondents to choose only one response, but these responses were not binomial. For example, the question "How many children have you ever breastfed?" allowed survey respondents to select only one response from several options. Still other closed-ended questions allowed respondents to select multiple answers by checking all that applied. Finally, some questions allowed respondents to choose only one response using a 5-point Likert scale format. Open-ended questions were included directly following closed-ended questions, giving respondents an opportunity to supplement their response with more information. A total of 188 participants took the survey; it was not mandatory that respondents answer every question.

Data analysis

The survey data were delivered and managed through the Health Insurance Portability and Accountability Actcompliant Qualtrics platform, which uses Transport Layer Security encryption, and then entered into Statistical Package for the Social Sciences (SPSS) for Windows version 23 (IBM Corporation, Armonk, NY, USA) for further analysis.

Results Demographic results

A total of 188 women from 27 states completed the questionnaire. The majority of respondents were residents of two states: Louisiana (52%) and Kansas (12%). Table 1 illustrates the sociodemographic characteristics of the study sample.

The vast majority of respondents were white (92%) and non-Hispanic (94%). Most were married (87%) and

Table I Characteristics of study participants

Characteristic	n	Percentage
Race		
American Indian/Alaska Native	I	0.6
Asian	3	1.9
Black/African-American	2	1.3
Native Hawaiian/Pacific Islander	3	1.9
White	144	91.7
Other	4	2.6
Total	157	
Ethnicity		
Hispanic or Latino	9	5.7
Non-Hispanic or Latino	148	94.3
Total	157	
Relationship status		
Single	7	4.5
Married	137	87.3
With partner	8	5.1
Divorced/separated	5	3.2
Total	157	
Number of people residing in home		
I–2	7	4.4
3–4	121	77
5 or more	29	18.5
Total	157	
Education		
High school or equivalent	5	3.2
Trade school	9	5.7
Some college	23	14.6
Undergraduate degree	65	41.1
Graduate degree	47	29.7
Professional degree	9	5.7
Total	158	
Employment		
Employed for wages	90	57
Self-employed	19	12
Out of work and looking for work	1	0.6
Out of work and not looking for work	6	3.8
Homemaker	39	24.7
Student	3	1.9
Total	158	
Income (US\$)		
<10k	I	0.6
10k-49.9k	40	25.5
50k-99.9k	54	34.4
100k–150k	37	23.6
>150k	25	15.9
Total	157	
	137	

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lived in a home with three or four people (77%). Most of the respondents were college-educated, with either an undergraduate (41%), graduate (30%), or professional degree (6%). Among the respondents who noted that they were employed, the majority worked for wages (57%) or were self-employed (12%). Household income levels varied for women who completed the survey. The largest proportion (34.4%) had a total household income between US\$50,000 and \$99,000, while many also reported a household income between \$10,000 and \$49,000 (26%), or between \$100,000 and \$150,000 (24%). The majority of respondents had given birth to one (51%) or two children (34%), and had breastfed one (53%) or two children (33%).

Breastfeeding characteristics and pattern

The vast majority of respondents (76%) reported that while breastfeeding, they felt as though they were not making enough milk to meet the needs of their child. Table 2 includes breastfeeding characteristics and patterns of mothers who responded to the survey. A majority of respondents (54%) also indicated that they had not supplemented with formula as a result of not making enough milk to meet the needs of their infant. More than half (60%) of mothers who responded mentioned they had consulted a health care provider about not making enough milk.

Sources of information and support

With regard to sources of information or support about not making enough milk, the vast majority of respondents (85%) indicated that they sought breastfeeding support from sources other than a lactation counselor, physician, or other health care worker. The most common way for mothers to learn about herbal galactagogues was the Internet. Internet sources consisted primarily of such websites as Kelly Mom or Baby Center and Facebook pages, while "other" non-Internet sources noted were books and in-person support groups through organizations like La Leche League and the Special Supplemental Nutrition Program for Women, Infants and Children (WIC). Other reported sources of information included lactation consultants (54%), friends (34%), family members (21%), pediatricians (20%), and obstetricians (16%).

Use of galactagogues and experiences with these

Most of the respondents (94%) did not take a prescription medication to help them produce milk. Among those who noted they took medication (6%), obstetricians were most likely (78%) to prescribe the medication. Most women (59%)

Table 2 Breastfeeding characteristics of respondents	;
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Characteristic	n	Percentage
Number of times given birth		
0 (adoptive parent)	I.	0.6
I ,	80	50.6
2	54	34.2
3	17	10.8
4 or more	6	3.8
Total	158	
Number of children breastfed		
I	94	52.8
2	59	33.1
3	18	10.1
4 or more	7	4
Total	178	
Felt she was not making enoug	h milk	
Yes	134	76.1
No	42	23.9
Total	176	
Supplemented with formula		
Yes	62	46.3
No	72	53.7
Total	134	
Consulted a health care provid	er	
Yes	81	60.4
No	53	39.6
Total	134	
Sources of support (check all the	hat apply)	
Lactation consultant	101	53.7
Friend	63	33.5
Family	40	21.3
Pediatrician	37	19.7
Obstetrician/gynecologist	30	16
Family practice pediatrician	12	6.4
Midwife	9	4.8
Doula	7	3.7
Other	2	1.1
Total	188	
Sought information from other	r sources	
Yes	114	85.1
No	20	14.9
Total	134	
Took pharmaceutical galactage	ogue	
Yes	9	6
No	141	94
Total	150	
Who prescribed pharmaceutic	al galactagogue	e?
Obstetrician/gynecologist	7	77.8
Other	2	2.2
Total	9	
Provider's recommendation wa	as important	
Yes	23	58.9
No	16	41
Total	39	

who reported taking medication mentioned their health provider's recommendation of the product was important to them. Tables 3 and 4 describe the use of milk-production aids, including herbal and pharmaceutical galactagogues, among the study sample.

Table 3 Use of milk-production aids

Aid	Heard of	Used,	Information source,
	this, n (%)	n (%)	n (% of sample)
Breast pumping	160 (85.1)	121 (64.4)	LC: 86 (45.7)
Fenugreek	162 (86.2)	86 (45.7)	Internet: 91 (48.4)
Fennel	95 (50.5)	30 (16)	Internet: 49 (26.1)
Milk thistle	109 (58)	24 (12.8)	Internet: 59 (31.4)
Goat's rue	37 (19.7)	4 (2.1)	Internet: 19 (10.1)
More milk (plus)	75 (39.9)	28 (14.9)	Friend: 19 (10.1)
Metoclopramide	18 (9.6)	3 (1.6)	Internet: 7 (3.7)
Domperidone	67 (35.6)	5 (2.7)	Internet: 36 (19.1)

Abbreviation: LC, lactation consultant.

Among the 188 women who responded to the survey, the majority had heard of (85%) and used (64%) breast pumping or manual expression to increase their milk supply. Women who had heard of breast pumping or manual expression were most likely to hear about this milk-production aid from lactation consultants (46%). The majority of respondents also reported they felt breast pumping or manual expression was very safe (98%), increased their milk supply (70%), they would use it again (99%), and would recommend it to a friend (98%). Fifteen percent of respondents reported experiencing side effects from breast pumping or manual expression, such as breast soreness or chafing.

Among both herbal and pharmaceutical galactagogues, fenugreek was the most well known among respondents (86%) and most used (46%) by those in the study sample. Nearly half (48%) of the women in the study reported hearing about fenugreek from the Internet. The least-known milkproduction aid among the study sample was the pharmaceutical drug metoclopramide (10%). The most commonly reported way for mothers to hear about pharmaceutical galactagogues was the Internet. Among all the milk-production aids included in the questionnaire, mothers reported using the two pharmaceuticals metoclopramide (2%) and domperidone (3%) the least.

More than half of the women in the sample also reported having heard of other herbal galactagogues, such as fennel (51%) and milk thistle (58%), but only 16% (fennel) and 13% (milk thistle) mentioned they had used them. A majority of respondents also reported fenugreek (54%), goat's rue (75%), and More Milk (56%) increased their milk supply, whereas most respondents noted they were not sure if fennel (59%) or milk thistle (52%) increased their milk supply.

The most commonly cited reason for not using a herbal galactagogue again or recommending one to a friend was that it was not working. Additionally, using an open-ended option for "other" galactagogues, some mothers reported using certain beverages and foods, such as beer, oatmeal, and brewer's yeast, for lactation.

Aid	Had side effects	ffects	Milk-supply results	lts	Would use again	again	Perception of safety		Would recommend	mmend	Reason not to recommend	mmend
	u (%)	Total	Effect (%)	Total	u (%)	Total	Safe (%)	Total	u (%)	Total	Reason (%)	Total
Breast pumping	18 (15.1)	119	Increased (69.7)	119	119 (92.2)	120	Very safe (98)	147	109 (98.2)	Ξ	Not working (0.5)	_
Fenugreek	38 (44.7)	85	Increased (53.6)	84	59 (69.4)	85	Very safe (48)	150	60 (76.9)	78	Not working (55.6)	27
Fennel	6 (20.7)	29	Not sure (58.6)	29	23 (79.3)	29	Very safe (55.2)	87	19 (76)	25	Not working (55.6)	6
Milk thistle	4 (16.7)	24	Not sure (52.2)	23	16 (66.7)	24	Very safe (37.4)	66	18 (81.8)	22	Not working (77.8)	6
Goat's rue	4 (2.1)	4	Increased (75)	4	3 (75)	4	Somewhat safe (40.6)	32	3 (75)	4	Not working (100)	_
More milk plus	4 (14.3)	28	Increased (55.6)	27	21 (75)	28	NA	AN	22 (88)	25	Not working (42.9)	7
Metoclopramide	2 (100)	2	Increased (100)	2	0	č	Somewhat unsafe (42.9)	14	l (33.3)	č	Side effects (100)	č
Domperidone	I (20)	S	Increased (60)	S	2 (40)	5	Neutral (40.7)	59	2 (40)	5	Side effects (33.3)	ε

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Perception of safety and side effects

When asked about the safety of herbal galactagogues, herbs that were considered "very safe" included fenugreek (48%), fennel (55%), and milk thistle (37%). Overall, a minority of respondents reported side effects for the herbal galactagogues, and the majority responded they would use them again or recommend them to a friend.

The largest number of respondents reported side effects for fenugreek (45%) among the herbal galactagogues. Some of the side effects reported by mothers included a maplesyrup smell emitting from the mother's body, gassiness in the baby, or breast-milk oversupply. Among two participants who reported using metoclopramide, both (100%) reported side effects. Overall, respondents reported that the pharmaceutical galactagogues increased their milk supply, but they did not consider them to be safe, would not use them again, and/or would not recommend them to a friend. The most commonly cited reason not to recommend a pharmaceutical galactagogue to a friend was side effects. Some of the side effects mothers indicated for pharmaceutical galactagogues were depression (metoclopramide and domperidone) and anxiety (metoclopramide).

Additional analyses

There were no statistically significant differences in the characteristics of study participants, nor associations with the use of galactagogues or mothers' opinions on herbal supplements. Only two relationships were significant (perception of insufficient lactation based on parity, and consulting a provider based on income level), so logistical models were built for those two relationships. The models prepared were an improvement over the null, but did not have practical significance to the research questions.

Discussion

Insufficient milk supply is cited as a primary reason for early termination of breastfeeding, and is a very important concern for lactating women, with 30%–80% of breastfeeding mothers globally naming this as a major reason for breastfeeding cessation.⁷⁴ A notable finding of the present study was that 76% of participants felt as though they were not making enough milk to meet the needs of their child, and yet a majority (54%) chose not to supplement or replace breastfeeding with use of infant formula. This indicates that an important proportion of women have the motivation to continue to find solutions to difficulties that they encounter in lactation and actively seek out support. Up to 15% of childbearing women in the US may use herbal galactagogues,

yet there is scant evidence on safety and efficacy.³⁹ Clinicians may also be asked by patients experiencing difficulties in lactation to prescribe drugs "off-label", as in the case of metoclopramide, or through compounding pharmacies, as in the case of domperidone.

Among the very few previous studies that have aimed to explore mothers' perspectives and experiences of using pharmaceutical and herbal galactagogues,^{24,75,76} no study to date has included a sample of US women. This online survey addressed this gap by sampling US-based breastfeeding women to document experiences with, safety of, and usefulness of herbal and pharmaceutical galactagogues, as well as sources of information on these. The current study contributes to efforts aimed at better understanding supportive aids for breastfeeding women to improve success in lactation.

The majority of our study respondents resided in southern areas of the US, a region where breastfeeding rates are 20%–30% lower than the national average, both for initiation and duration of breastfeeding.^{64,66} Given women and children have high rates of preventable chronic diseases, such as obesity, in this region,⁷⁷ breastfeeding has strong potential to improve health outcomes.

Mothers who have reported use of galactagogues, both herbal and pharmaceutical, in an effort to increase milk production for breastfeeding typically report an overall increase in milk supply.^{23,32,44,45,78,79} Our study findings were consistent with these previous studies: nearly all participants who used galactagogues in the current study reported an increase in milk supply.

The present sample consisted primarily of Caucasian women, similar to the composition of a sample from a previous study conducted in Australia. The majority of the Australian study participants, who were not recruited through the Internet, found galactagogues to be effective in increasing their breast-milk supply, and information on galactagogues was based on the recommendations of friends or family members or information they obtained through their own Internet research.24 This is in concordance with the present study findings, where the most likely reported source of information was the Internet. Nearly half (48%) of the women cited the Internet as the main source of information concerning fenugreek, which was also reported to be the most well-known (86%) and most used herbal supplement (46%). Fenugreek was the most effective in perceived, reported increase in milk supply to just over half of the women using it (54%), but it was also the most reported to have side effects (45%). However, the overall occurrence of side effects did not influence the report of efficacy or recommendations.

A large percentage of participants responded that they would use botanical galactagogues in the future. The participants perceived herbals to be safe and effective and would recommend them to others. Pharmaceutical galactagogues were reported as much less likely to be used again, due to side effects. Breast pumping was the second-most familiar milk-production aid used by women, followed by milk thistle, fennel, More Milk, domperidone, goat's rue, and metoclopramide. Almost every method (except fennel and milk thistle) was reported to be working, based on milk supply; however, the recommendations were not as positive. This could be due to the small sample size for "reasons not to recommend". This study revealed that women perceive herbal galactagogues, specifically fenugreek, as most effective in enhancing breast-milk production. The increased use of fenugreek over pharmaceutical galactagogues may be associated with innate comfort, traditional beliefs, high efficacy, and unknown toxicity of medicines.^{24,30} Herbal medicines, however, are less subject to rigorous evaluations for safety and quality compared to registered pharmaceutical medicines.24 In contrast, domperidone, with known efficacy and side effects, was less known and used in this study. Domperidone appears to be a safer alternative, and has been shown to be effective in increasing breast-milk volume with a low concentration of medication in breast milk in various small trials.^{41,60,62,80-83} However, pharmaceutical galactagogues, whether due to constraints on their use or safety concerns, are less widely used by the US lactation population.84

Limitations

Study limitations include those inherent in the use of convenience sampling, namely the potential of bias from underrepresentation or overrepresentation of particular groups within the sample, and lack of information on nonparticipants. The sample may not be representative of the population at large of breastfeeding women in the US, and was composed primarily of middle- to high-income Caucasian mothers. A strength was the use of a customized data-collection instrument for information on herbal and pharmaceutical galactagogues. This is the first research published to date on knowledge about and use of galactagogues in the US. The use of convenience sampling, though limited in generalizability, illustrates the utility of preliminary surveys to inform more detailed research protocols.

Exploring further the reasons that mothers may make use of particular galactagogues would contribute to health-education efforts, and additional experimental and observational research is required on the safety and efficacy of these. While there is a need for further evaluation of botanical galactagogues, particularly for those most widely used,⁸⁵ there are unfortunately barriers to conducting appropriate research, eg, the mismatch between clinical research protocols and traditional preparations used for study, as well as a lack of dedicated funding for this work.⁸⁶

This study brings further awareness of alternative methods of lactation support that breastfeeding mothers avail themselves of in an effort to improve lactation outcomes and overcome perceived or physiological barriers to breastfeeding. Breast milk is superior to all artificial food in terms of nutritional value, and the World Health Organization, among other international bodies, strongly advises that in the first 6 months of life, a baby should be fed only with breast milk,⁸⁷ yet women continue to experience barriers to doing so. Our findings emphasize that mothers, along with health professionals, such as pediatricians, nutritionists, obstetricians, nurses, and lactation consultants, need evidence-based information regarding herbal and pharmaceutical galactagogues, in order to make informed choices to improve lactation and successful breastfeeding.

Author contributions

All authors contributed toward data analysis, drafting and revising the paper and agree to be accountable for all aspects of the work.

Disclosure

The authors report no conflicts of interest in this work.

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