

A cross-sectional descriptive study of breastfeeding behaviour and galactagogue use among private-sector patients in Cape Town, South Africa

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Background. Failure to exclusively breastfeed is often caused by a perception of insufficient breastmilk supply. Galactagogues are frequently prescribed in these circumstances, but this is supported by sparse scientific data with safety concerns for both mother and infant. The exact extent of galactagogue use in South Africa (SA) is not well known.

Objectives. To assess breastfeeding behaviour, galactagogue use and perceived galactagogue side-effects among patients attending International Board Certified Lactation Consultant (IBCLC) private practices.

Methods. We administered a self-developed, expert-reviewed questionnaire in five IBCLC private practices within the Cape Town Metropole, SA. All patients attending the practices during an 8-week period were invited to participate.

Results. Data from 104 participants were included in the study. An exclusive breastfeeding rate of slightly more than 50%, associated with greater parity ($p=0.029$), was found. Perceived lack of breastmilk predicted galactagogue use ($p=0.013$). There was a high prevalence of galactagogue use (54%), with 80% of these participants using non-prescription medication. Sulpiride was the most common prescription medication used. Increased milk production was reported by 41% ($n=23$) of galactagogue users, while 30% ($n=17$) reported no effect. Most reported side-effects were minor.

Conclusions. Prevalence of galactagogue use exceeded other published data. Sulpiride was most frequently prescribed, despite not being recommended during breastfeeding. A large group of participants reported poor efficacy. The effect of vaginal delivery and immediate skin-to-skin contact after delivery on milk production might be smaller than previously reported in mothers who are personally motivated to breastfeed. Healthcare practitioners should acknowledge breastfeeding mothers' concerns regarding insufficient milk supply and emphasise correct breastfeeding technique.

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Exclusive breastmilk is the optimal feeding for infants up to 6 months of age.^[1] Breastfeeding has been associated with short-term benefits such as providing the child's first immunity and reducing infant morbidity and mortality associated with infections.^[2] Long-term benefits include lower mean blood pressure and total cholesterol in adulthood, and improved performance in intelligence tests.^[2] However, mothers struggle to achieve exclusive breastfeeding and according the World Health Organization (WHO)'s global database on infant and young child feeding the rate of exclusive breastfeeding in South Africa (SA) is among the lowest in the world, at 11.6% in infants <4 months and 8.3% in infants ≤6 months of age, compared with a global rate of 38%.^[3] There are many contributing factors leading to low breastfeeding rates, but the most common reason is insufficient breastmilk supply.^[4]

Galactagogues are often prescribed to augment breastmilk supply in resource-rich environments.^[5] Galactagogues are dopamine antagonists such as antipsychotics, antiemetics and natural supplements which enhance lactation by increasing serum prolactin.^[6] Galactagogue-mediated rise in serum prolactin may transiently increase milk production, but after 2 weeks postpartum it has no effect on lactational performance.^[5,7] A recent Cochrane review concluded that the use of galactagogues was not associated with a significant improvement in longer-term outcomes of breastfeeding in preterm infants.^[1] In addition, galactagogues have safety concerns in the mother and the infant.

The antipsychotics sulpiride and chlorpromazine cross into breastmilk, while chlorpromazine may adversely affect the developing central nervous system of the infant.^[4,8] In turn, mothers may develop movement disorders such as acute dystonic reactions.^[4] Antiemetics exploited for their blocking of dopamine receptors also have safety concerns.^[8] Metoclopramide is structurally related to the antipsychotic sulpiride and not recommended during breastfeeding.^[8] Domperidone has been associated with an increased risk of QT interval prolongation and sudden cardiac death.^[5] Natural supplements such as milk thistle and fenugreek have limited safety data during lactation (DRUG-REAX Database, Truven Health Analytics, Inc).

Taken together, the exact extent of galactagogue use in SA is unknown and the awareness of the benefit-risk of galactagogue use by breastfeeding mothers has not been documented. The objectives of this study were to describe breastfeeding behaviour, assess galactagogue use and determine perceived efficacy and side-effects in breastfeeding mothers and their infants.

Methods

The investigators developed a questionnaire based on specific research gaps identified in the literature, followed by review from relevant experts in paediatrics, neonatology and breastfeeding consulting. The questionnaire contained three sections. The

first section captured demographic information including factors previously shown to influence breastfeeding, such as type of delivery, parity and having skin-to-skin contact. It also assessed duration of breastfeeding, mixed feeding and reasons for not exclusively breastfeeding. The second section assessed galactagogue use, the type, duration, dose, who recommended it and what the perceived efficacy and duration of the effect were. The last section captured data regarding side-effects in the mother and infant (Table 1). According to the information gathered, participants were retrospectively classified into one of the following groups: exclusive breastfeeding, exclusive formula feeding, mixed feeding (breastfeeding and using formula milk concurrently), intermittent mixed feeding (exclusively breastfeeding, but who have used formula feeds in the past) and breastfeeding to formula feeding (mothers who are using only formula feeds, who in the past breastfed exclusively). The first day of data collection was used to pilot the questionnaire. No concerns were identified and the study commenced on the following day.

We approached the International Board Certified Lactation Consultants (IBCLCs) practising in the private sector in the Cape Town Metropole via the IBCLC's communication network. A total of 22 had been approached and 5 IBCLCs practising in Rondebosch, Bellville, Stellenbosch and Somerset West, agreed to participate in the study. All the mothers consulting the IBCLCs during an 8-week period (starting 6 October 2015) irrespective of the reason for the consultation, were asked to participate in the study by completing the questionnaire. The IBCLCs avoided data duplication by keeping a record of each participant who had completed a questionnaire.

Only data from participants who had signed informed consent and completed the questionnaire were included in the study. Questionnaires were excluded from the data set when, based on consensus by the researchers, answers were ambiguous or incomplete. Ethical approval was obtained from the Stellenbosch University Health Research Ethics Committee (ref. no. S15/04/093).

Results

A total of 108 participants signed informed consent and completed the questionnaires. Data from four participants were excluded due to incomplete data.

Exclusive breastfeeding in this population was achieved by slightly more than 50% of the participants, with a downward trend with increasing age of the infant. The most common reason for the use of formula milk was insufficient breastmilk production in the opinion of the participant. A statistically significant association was found between galactagogue use and perceived insufficient breastmilk supply ($p=0.013$). There was no statistically significant association between type of delivery and exclusive breastfeeding ($p=0.099$). A statistically significant increase in exclusive breastfeeding rate was shown in mothers with two or more children ($p=0.029$), compared with mothers with only one child. Having skin-to-skin contact within 1 hour of delivery was not associated with an increase in exclusive breastfeeding in this study ($p=0.308$).

Galactagogues were used by more than half of the participants (54%, $n=56$). Counselling on breastfeeding techniques to enhance breastmilk production prior to using galactagogues was given to 64% ($n=36$) of galactagogue users. Non-prescription medication was used by 80% of galactagogue users; the berry elixir-containing 'Jungle Juice', for which there appeared to be no standard ingredients, was most widely used (52%, $n=29$) (Table 3). The dose and use of 'Jungle Juice' varied greatly between 250 mL and 2 L per day. Fenugreek was mostly used in the capsule form, at ≤ 3 capsules per day (90%, $n=19$). Prescription medication was used by 48% of galactagogue users, of which low-dose sulphiride (50 mg 2 - 3 times per day) was the most frequently used (Table 2). The median age of infants when starting sulphiride was 2 weeks, while the duration of sulphiride use was 4 weeks, with the interquartile range 2 - 11 weeks. A single galactagogue was used by almost half of the participants (46%, $n=26$), while two and three galactagogues (including both prescription medication and supplements) were simultaneously

Table 1. Participant characteristics

Characteristic	Total number of participants, <i>n</i> (%) [*]	EBF, [†] <i>n</i> (%)	IMF, [‡] <i>n</i> (%)	MF, [§] <i>n</i> (%)	BF-FF, [¶] <i>n</i> (%)	EFF, <i>n</i> (%)
Participants included (<i>N</i>)	104	58 (56)	9 (8)	22 (21)	12 (12)	3 (3)
Type of delivery						
Caesarean section	78 (75)	40 (69)	7 (78)	22 (100)	6 (50)	3 (100)
Vaginal delivery	26 (25)	18 (31)	2 (22)	-	6 (50)	-
1 hour skin-to-skin contact post delivery	62 (60)	37 (64)	6 (67)	8 (36)	8 (67)	3 (100)
Live children of participants						
1	69 (66)	33 (57)	9 (100)	17 (77)	8 (66)	2 (67)
2	29 (28)	22 (38)	-	4 (18)	2 (17)	1 (33)
≥ 3	6 (6)	3 (5)	-	1 (5)	2 (17)	-
Galactagogue use	56 (54)	26 (45)	7 (78)	16 (73)	7 (58)	-
Breastfeeding advice received before galactagogue use	36 (64)	12 (46)	4 (44)	13 (81)	7 (100)	N/A

EBF = exclusive breastfeeding; IMF = intermittent mixed feeding; MF = mixed feeding; BF-FF = breastfeeding to formula feeding; EFF = exclusive formula feeding; N/A = not applicable.

^{*}Unless otherwise specified.

[†]Mothers only breastfeeding and using no other milk supplement.

[‡]Defined as mothers exclusively breastfeeding, but who have used formula feeds in the past.

[§]Mothers breastfeeding and using formula supplementation concurrently.

[¶]Mothers who are using only formula feeds, who in the past breastfed exclusively.

^{||}Defined as mothers using formula feeds only.

Table 2. Type of galactagogue used (N=56)

Type	N (%)	EBF	IMF	MF	BF-FF	EFF
Total galactagogue use	56 (54)	26 (46)	7 (13)	16 (29)	7 (13)	-
Prescription medication	27 (48)	7 (26)	3 (11)	10 (37)	7 (26)	-
Sulpiride	25 (48)	7 (28)	3 (12)	9 (36)	6 (24)	-
Metoclopramide	2 (4)	0 (0)	0 (0)	1 (50)	1 (50)	-
Supplements	45 (80)					
Herbal (fenugreek)*	21 (47)	7 (33)	5 (24)	7 (33)	2 (10)	-
Non-herbal (Jungle Juice [†] and Stoney [‡])	33 (73)	18 (55)	4 (12)	9 (27)	2 (6)	-
Miscellaneous [§]	12 (27)	2 (17)	1 (8)	8 (67)	1 (8)	-

**Trigonella foenum-graecum* is a herb containing phyto-oestrogens, which are plant chemicals similar to oestrogen. Diosgenin is specifically implicated to increase breastmilk production.

[†]A tonic made with blackthorn berry elixir (50 mL), rehydration mixes (sachets containing carbohydrates, electrolytes and possibly antioxidants), fruit juice or rooibos tea (1 L) and water (2 L). Rescue remedy drops are sometimes added in varying quantities.

[‡]A ginger-flavoured carbonated drink.

[§]Other galactagogues include:

Brewer's yeast – *Saccharomyces cerevisiae*

Prolac – homeopathic combination sublingual tablet to stimulate milk production (*Helonias ioica*, *Urtica urens*, *Ricinus communis*, calcarea carbonica, calcarea phosphorica, *Vitex agnus-castus*, ferrum phosphoricum, *Pulsatilla*, graphites, calcarea fluorica)

Lactagogue tea – herbal tea (can be made with the leaves of different herbal plants, although fenugreek is most commonly used)

Lactation cookies – oats-based cookie containing brewer's yeast and flaxseed

Protein powder – a powder containing one of three main proteins: whey, soy and casein

Oats – *Avena sativa*

Milk stout – stout containing lactose, often used in the fermentation of beer

Table 3. Reasons for the use of formula milk (N=46)

Reason	n (%)	Association of reason listed and the use of a galactagogue (p-value)				
		IMF	MF	BF-FF	EFF	
Perception of too little breastmilk	23 (50)	0.01	4	11	7	1
Mastitis, thrush or painful breastfeeding	6 (13)	0.93	1	4	1	0
Returned to work and could not express	2 (4)	0.29	0	2	0	0
Use of alcohol, nicotine and other harmful substances	1 (2)	0.17	0	1	0	0
Use of chronic medication and recommended not to BF	1 (2)	0.17	0	0	1	0
BF found to be emotionally challenging	5 (11)	0.21	0	1	2	2
Social pressures to stop BF	0	0	0	0	0	0
Infant refused to take breastmilk	10 (22)	0.25	0	3	7	0
Medical problems/medical advice to use formula milk	17 (37)	0.22	5	9	2	1
Other	9 (20)	0.63	2	5	1	1

used in 21% ($n=12$) and 12.5% ($n=7$) of participants, respectively.

A subjectively judged good increase in milk production was reported by 41% ($n=23$) of the galactagogue users and 30% ($n=17$) of the group reported no effect. The majority of the users who no longer used a galactagogue reported that the effect lasted only during use (56%, $n=18$), or a few days after stopping (28%, $n=9$). No statistically significant associations were found between any of the medications used as galactagogues and the effect on breastmilk production, or the duration of the effect after stopping (Table 3).

Only a few participants reported that they were counselled on possible side-effects (21%, $n=12$) before galactagogue initiation. Side-effects were reported in 9 mothers and 2 infants. The side-effects were mostly associated with sulpiride, varying from improved emotional wellbeing ($n=2$) to moodiness ($n=2$), which was subjectively noted to be severe in one case. One participant also mentioned that sulpiride contributed to difficulty in losing weight. Other side-effects were associated with brewer's yeast (cramps in an infant and vaginal pruritis in a mother), berry elixir (improved maternal energy levels) and fenugreek (increased heart rate and breast congestion in one mother).

In most cases (55%, $n=31$), galactagogues were recommended by medical practitioners, with obstetricians accounting for 35% ($n=20$). Nursing practitioners and certified lactation practitioners recommended galactagogues in 38% ($n=21$) of cases. Forty-five percent ($n=25$) of galactagogue users reported a recommendation from friends, family or other sources.

Discussion

Our study contributes to the limited SA data regarding breastfeeding behaviour, galactagogue use and perceived efficacy and side-effects in breastfeeding mothers and their infants. We found a high exclusive breastfeeding rate in all age categories compared with the national breastfeeding rates in SA,^[3] which could be explained by the specific population group who were seeking the advice of breastfeeding consultants, indicating a high level of motivation to breastfeed.

Successful breastfeeding has been associated with vaginal delivery, skin-to-skin contact in the first hour after delivery and a higher parity.^[9,10] In our study this association was found with parity, but not with the type of delivery or skin-to-skin contact. Reasons for

this can be attributed to the study population who, while seeking breastfeeding advice and assistance, also commonly make use of private-sector healthcare, where there is a high incidence of caesarean delivery. It may, therefore, also imply a smaller than expected role for these factors in predicting breastfeeding success in a motivated population. We found that galactagogues were frequently prescribed and used by more than half of the participants, which is higher than in high-income settings internationally, where a 5 - 33% prevalence of galactagogue use has been documented.^[11,12]

In our study, supplements were the most preferred galactagogues, with the use of fenugreek and berry elixir-containing juices being widespread, often in combination with prescription medications. Safety and efficacy data supporting the use of galactagogue supplements are limited. We found that the preferred prescription galactagogue was sulphuride. Internationally, domperidone is most frequently prescribed in high-income settings.^[5]

Given the high incidence of galactagogue usage observed, it is noteworthy that a relatively high percentage of participants found no effect on breastmilk production when using galactagogues. This, along with the high motivation of this study group to breastfeed, might explain the high incidence of the use of a combination of galactagogues. Although an objective analysis of efficacy is limited by the retrospective study design, our data do not support this practice to improve breastfeeding performance.

Most participants used galactagogues for a number of weeks, and often when their infants were beyond the neonatal period. Galactagogues should be prescribed with care with the best scientific evidence available, taking into account that there is no evidence to support the use of a galactagogue for longer than 2 weeks,^[5] and that after 2 weeks postpartum it has no proven effect on lactational performance.^[5,7] In addition, infant suckling is the most important factor for breast milk production once lactation is established, and not prolactin-induced increases in breastmilk volume.^[13]

We also assessed the subjective experience of potential side-effects. There are very limited data regarding the safety of galactagogues. The side-effects described by study participants were mostly minor complaints and some could be seen as positive effects. Of note is the relatively low rate of side-effects reported, especially in infants. The study design is such, however, that reliable conclusions cannot be drawn on the safety and potential risks of these medications.

Our study findings were limited by a number of factors, the first of which was the small sample size. Second, the study population was prone to selection bias, with only IBCLCs serving the private sector being included. It is likely that the clients attending these practices are highly motivated to breastfeed. While this allows the collection of data from those most likely to use galactagogues, it might skew the actual prevalence of galactagogue use in the general

population. Thirdly, we cannot exclude reporting bias, given that the study was designed to investigate women who are highly motivated to breastfeed and, lastly, the study design was retrospective and uncontrolled.

Future research should prospectively collect galactagogue safety and efficacy data given the large proportion of women found in our study who use galactagogues for extended periods of time.

Conclusion

This study found that galactagogues were frequently used, with a prevalence that exceeded other published data. We found that sulphuride was frequently prescribed even though it was not recommended during breastfeeding. Furthermore, the time of initiation and duration of galactagogue use was not in accordance with current guidelines. Doctors and other healthcare practitioners should acknowledge breastfeeding mothers' concerns regarding insufficient milk supply, and place more emphasis on correct breastfeeding technique and other behavioural factors.^[5]

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