Original Article

Lanolin for the treatment of nipple pain in breastfeeding women: a randomized controlled trial

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Abstract

Nipple pain and damage are commonly experienced by breastfeeding women and are associated with negative breastfeeding outcomes. Health care providers often recommend the application of lanolin to treat painful/damaged nipples, yet no randomized controlled trial has evaluated the effectiveness of lanolin on nipple pain and breastfeeding outcomes. The purpose of this study was to evaluate the effect of lanolin on nipple pain among breastfeeding women with damaged nipples. A randomized, single-blind, controlled trial was conducted at a tertiary care hospital in Hamilton, Ontario, Canada. Breastfeeding women ($N=186$) identified as having nipple pain/damage were randomized to apply lanolin (intervention group; $n=93$) or to receive usual postpartum care (control group; $n=93$). The primary outcome was nipple pain at 4 days post-randomization measured by the Numeric Rating Scale. Additional outcomes included nipple pain measured by the Short Form McGill Pain Questionnaire, breastfeeding duration/exclusivity, breastfeeding self-efficacy, and maternal satisfaction with lanolin treatment versus usual care. The results revealed no significant group differences in mean pain scores at 4 days post-randomization. Women in both groups experienced clinically relevant decreases in nipple pain by 7 days post-randomization. Significantly, more women in the lanolin group reported that they were satisfied with treatment compared with those receiving usual care. No significant group differences were found for other secondary outcomes. While more women were satisfied using lanolin, its application to sore/damaged nipples was ineffective for reducing nipple pain or improving breastfeeding outcomes.

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Introduction

Although there are many factors that contribute to a woman's decision to initiate and continue breastfeeding, evidence suggests that most women discontinue breastfeeding prematurely because of perceived difficulties rather than maternal choice (Dennis 2002). Nipple pain and damage is a common occurrence for breastfeeding women in the early postpartum period (Heads & Higgins 1995; Hewat & Ellis 1987; Ziemer et al. 1990; Buck, Amir, Cullinane & Donath, 2014) and is often implicated in breastfeeding cessation (Fetherston, 1995; Yeoung et al. 1986). The incidence of nipple pain is high, with reports of 95% of Canadian women (Hewat & Ellis, 1987), 77–79% of Australian women (Heads & Higgins, 1995; Buck,

Amir, Cullinane & Donath, 2014), 62% of women from France (Darmangeat, 2011) and 90–96% of U.S. women (Ziemer & Pigeon, 1993; Ziemer, Paone, Schupay & Cole, 1990) experiencing nipple pain in the early stages of breastfeeding.

Various interventions have been evaluated in the treatment of painful, damaged nipples including breastfeeding education (Clark 1985; Livingstone & Stringer 1999; Darmangeat, 2011; Cadwell, Turner-Maffei, Blair, Brimdyr & McInerney, 2004), breast shells (Gosha & Tichy 1988), compresses (Lavergne 1997), ointments (including lanolin) (Clark 1985; Livingstone & Stringer 1999; Kescu et al. 2001; Riordan 1985; Abou-Dakn et al. 2011; Dennis et al. 2012), LED phototherapy (Chavez et al. 2012) and tea bags (Lavergne 1997; Riordan 1995). Among all of the

published intervention studies, no single treatment for nipple pain/damage has been demonstrated to be effective. Results from a recent Cochrane systematic review suggest that there is no evidence that any one intervention is superior to the others in the treatment of nipple pain or trauma (Dennis et al. 2014).

Health care providers often recommend the application of lanolin to treat painful and/or damaged nipples. Aside from expressed breastmilk, lanolin is the only intervention that has received continued endorsement by the La Leche League International, the most predominant global, community-based breastfeeding support network for women. Lanolin is also recommended by the International Board Certified Lactation Consultants (IBCLC) and is included in their core curriculum for lactation consultant practice (Mannel et al. 2008). Lanolin is considered a pure and safe intervention (containing no preservatives, additives, water, chemicals or perfume), aimed at creating a moist healing environment for nipple trauma, and providing a semi-occlusive barrier that promotes retention of internal moisture and prevents dryness (Martin 2000). Lanolin may provide a moist dermal environment to prevent eschar formation, promote epithelial regrowth and decrease nipple pain (Cable et al. 1997; Pugh et al. 1996). However, there has been no randomized controlled trial specifically evaluating the effect of lanolin. The purpose of this trial was to evaluate the effect of lanolin on nipple pain among breastfeeding women with damaged nipples.

Participants

Women were recruited from a large tertiary care hospital in Hamilton, Ontario, Canada from May 2011 to March 2012. Eligible participants were breastfeeding

women who: (1) had nipple pain and visible nipple damage; (2) delivered a full-term (greater than 37 weeks gestation), singleton infant within the previous 72 h; and (3) were able to speak English. The exclusion criteria included: (1) infants not expected to be discharged home with their mother; (2) infants with a congenital abnormality that would impair breastfeeding, or ankyloglossia (tongue-tie); (3) maternal allergy to lanolin; (4) maternal health condition(s) that might interfere with breastfeeding; and (5) maternal aversion to, or, strong desire to use lanolin.

Sample size

The sample size was estimated based upon the goal to detect a minimum 20% reduction in mean NRS pain scores for women receiving lanolin within the first 36 h postpartum. In a 2012 randomized controlled trial (Dennis et al. 2012) comparing lanolin to an all-purpose nipple ointment, mean NRS pain scores decreased by 23% from baseline to 1-week post-randomization for women using lanolin for their nipple pain. Thus, with 90% power, a 30% loss to follow-up rate and a two-tailed α error of 0.05, a sample size of 186 (93 per group) was required.

Methods

Following approval by the Hamilton Integrated Research Ethics Board and the University of Toronto Health Sciences Research Ethics Board, a randomized, single-blind, controlled trial was conducted (Fig. 1). This trial was registered as an international randomized controlled trial with ClinicalTrials.gov, trial number NCT01420419. To recruit participants, the trial was briefly introduced to women who were identified by

Key messages

- Nipple pain and damage is common among breastfeeding women and is often implicated in breastfeeding cessation.
- This trial suggests that regardless of the use of lanolin or usual postpartum care, it is expected that nipple pain intensity will decrease by approximately seven to ten days postpartum.
- The findings of this study suggest that the application of lanolin to painful/damaged nipples in the immediate postpartum period does not significantly decrease nipple pain or improve breastfeeding outcomes when compared with usual care.

Fig. 1. Trial schema.

hospital nurses as having nipple pain and damage. Verbal consent was then obtained to have the Principal Investigator provide a detailed study explanation. Following informed consent procedures, baseline data were collected and the participants were randomized to either a control group or an intervention group. Randomization was achieved by using sealed, opaque, sequentially numbered envelopes containing randomly generated numbers. This procedure was constructed by a research assistant external to the trial. Women allocated to the control group ($n=93$) received usual postpartum in-hospital and community care, whereas those allocated to the intervention group ($n=93$) received usual postpartum in-hospital care, in addition to the lanolin intervention. Usual postpartum in-hospital care may have included breastfeeding education/assistance by an RN/RPN or lactation consultant. Acceptable strategies for pain relief may have included: application of warm/cool compresses to the affected nipple, analgesia (e.g. acetaminophen or ibuprofen), air drying the nipples or the use of breast shields. Once discharged from hospital, standard

community resources were available to all mothers including: public health breastfeeding programmes, outpatient hospital breastfeeding clinics, LaLeche League, community based breastfeeding support groups and hospital telephone assistance. All mothers could proactively seek support from any or all of these resources. To control for contamination, women in the control group were asked not to apply lanolin to their nipples for the trial period. Nurses on the postpartum unit and in the outpatient breastfeeding clinic were also instructed not to offer or recommend lanolin to women in the control group.

A research assistant blinded to participant group allocation telephoned all women at 4 and 7 days post-randomization and at 4 and 12 weeks postpartum to determine nipple pain, breastfeeding duration and exclusivity, breastfeeding self-efficacy and maternal satisfaction with treatment received. In addition, participants in the control group were asked at each follow-up if they used lanolin to treat their nipple pain.

Intervention

The intervention in this trial was a 40-g tube of Lansinoh® HPA® Lanolin (VA, USA) accompanied by an instruction pamphlet. Participants were instructed to wash their hands and to gently apply a pea-sized amount of lanolin to the nipple and the areola immediately surrounding the erectile portion of the nipple following every feed until resolution of symptoms or the end of the 7-day trial period. Women were free to continue using lanolin and/or other standard care resources if their symptoms had not resolved within the 7-day study period.

Outcome measures

Nipple pain

The primary outcome was nipple pain as measured using the Numeric Rating Scale (NRS) (McCaffery & Beebe 1989), where participants rated their pain on a scale ranging from 0=*no pain* to 10=*pain as bad as it could be*. The NRS is commonly used to assess pain intensity among a variety of adult populations and its reliability and validity have been well established (McDowell 2006; Jensen & Karoly 2001). The NRS was administered at baseline and at 4 days post-randomization. For many mothers, nipple pain appears to have the greatest intensity between the third and seventh day postpartum, with a peak in severity on the third day postpartum (Hewat & Ellis 1987; Ziemer et al. 1990). Given that participants were 1–3 days postpartum when they enrolled in the study, the follow-up at 4 days post-randomization was chosen to capture the period where pain severity tends to be the greatest, and to allow time for the intervention to take effect; that is, between 5 and 8 days postpartum.

Although the reliability and validity of the NRS have been well established among a variety of adult populations in both clinical and research settings, (Jensen & Karoly, 2001) there are no studies that specifically address the validity of the NRS among breastfeeding women. As such, the Short Form McGill Pain Questionnaire (SF-MPQ) (Melzack 1987) was also utilized to measure nipple pain intensity and quality, and to provide a further description of pain at baseline

and at 4 and 7 days post-randomization, as it provides other potentially valuable information beyond the sensory aspects of pain. The SF-MPQ is comprised of a Pain Rating Index (PRI) and a Present Pain Intensity (PPI) scale. The PRI is a 15-item questionnaire, which uses descriptors to evaluate sensory and affective dimensions of pain. Participants select adjectives that best describe their pain and rank the severity on a 4-point scale from 0=*none* to 3=*severe*. Scores are summed to produce a total score ranging from 0 to 45. The PPI is a 6-point scale to rate intensity ranging from 0=*mild* to 5=*excruciating*. The SF-MPQ also includes a visual analogue scale, which was not used in this trial as follow-up data were collected via telephone. The SF-MPQ has been widely used to assess the pain experience in a variety of adult patient populations (Wilkie et al. 1990). The psychometric properties of the SF-MPQ have been well documented (Wright et al. 2001).

Breastfeeding duration and exclusivity

Breastfeeding duration was assessed at 4 and 12 weeks postpartum and measured by asking women if they had breastfed within the past 24 h or not. Breastfeeding exclusivity was assessed at baseline, 4 and 7 days post-randomization and at 4 and 12 weeks postpartum and measured using Labbok & Krasovec's levels of breastfeeding (Labbok & Krasovec 1990). Responses included: (1) exclusive breastfeeding (breastmilk only); (2) almost exclusive breastfeeding (less than one bottle per week of non-human milk or other fluid); (3) high breastfeeding (less than one bottle per day of non-human milk, other fluid or food); (4) partial breastfeeding (1 bottle per day of non-human milk); (5) token breastfeeding (breast given to comfort baby, with minimal nutritional contribution); and (6) bottlefeeding (no human milk given).

Breastfeeding self-efficacy

This outcome was assessed at baseline and at 4 days post-randomization using the Breastfeeding Self-Efficacy Scale - Short Form (BSES-SF) (Dennis 2003). The BSES-SF is a 14-item self-report instrument developed to measure breastfeeding confidence. All items are preceded by the phrase 'I

can always' and anchored with a 5-point Likert scale where 1=*not at all confident* and 5=*always confident*. Scores are summed to produce a total score ranging from 14 to 70, with higher scores indicating higher levels of breastfeeding self-efficacy. The BSES-SF has been psychometrically tested and has demonstrated that it is a valid and reliable measure of breastfeeding self-efficacy (Gregory et al. 2008).

Maternal satisfaction

This outcome was measured at 12 weeks postpartum and included questions related to satisfaction with the treatment, how likely they would use the treatment again and if they would recommend the treatment to others. All items were rated on a 5-point scale where 1=*very satisfied* and 5=*very dissatisfied*. Additional questions with diverse formats were related to maternal report of side-effects and adherence to the treatment protocol. Table 1 summarizes the instruments and measurements utilized and their corresponding time-points.

Data analysis

Data were analysed using SPSS Version 20 and an intention-to-treat approach. For continuous data, means and standard deviations were calculated and differences between groups were examined using

independent samples *t*-tests. For categorical data, frequencies and percentages were calculated and differences between groups were examined using chi-squared tests. A two-sided significance level of 0.05 was utilized for all study outcomes.

Results

Sample characteristics

In total, 186 women were recruited into the study. Characteristics of participants are shown in Table 2. There were no clinically important differences in baseline characteristics between the two groups. Of the women that were randomized, 21 (lanolin group, $n=13$; control group, $n=8$) could not be contacted by telephone resulting in a 14% loss to follow-up (LTF) rate for the lanolin group, and a 8.6% LTF rate for the control group for the primary outcome (Fig. 1). The overall LTF rate was 11.3%. For the secondary outcomes, participants who were still breastfeeding at 4 weeks postpartum ($n=155$) were telephoned again at 12 weeks postpartum. Among the 155 participants, 22 (lanolin group, $n=13$; control group, $n=9$) did not complete the outcome assessment, resulting in a 16% LTF rate for the lanolin group and a 12.2% LTF rate for the control group. The overall LTF rate was 14.2%. All of the participants who did not complete the outcome assessments

Table 1. Summary of instruments and measurement times

Study variable	Measure	Timing
Baseline maternal information	Baseline questionnaire	Prior to randomization
<u>Primary outcome</u>		Baseline and at 4 days post-randomization
1. Pain intensity	11-point NRS	
<u>Secondary outcomes</u>		
1. Breastfeeding duration	Breastfeeding or not	4 and 7 days post-randomization and at 4 and 12 weeks postpartum
2. Breastfeeding exclusivity	*Labbok & Krasovec's levels of breastfeeding	Baseline, 4 and 7 days post-randomization and at 4 and 12 weeks postpartum
<u>Other outcomes</u>		
1. Pain intensity	11-point NRS	7 days post-randomization
2. Pain quality	SF-MPQ	4 days post-randomization
3. Breastfeeding self-efficacy	BSES-SF	4 days post-randomization
4. Maternal satisfaction with intervention	Maternal satisfaction questionnaire	12 weeks postpartum

*(Labbok & Krasovec, 1990). NRS, Numeric Rating Scale; SF-MPQ, Short-Form McGill Pain Questionnaire; BSES-SF, Breastfeeding Self-Efficacy Scale Short-Form.

Table 2. Baseline characteristics

Baseline characteristic (0–3 days postpartum)	Usual care <i>n</i> = 93	Treatment <i>n</i> = 93
Age, mean (<i>SD</i>)	29.0 (4.9)	29.5 (5.3)
	<i>n</i> (%)	<i>n</i> (%)
Marital status		
Married/Common-law	88 (94.6)	86 (92.5)
Single	5 (5.4)	7 (7.5)
Ethnicity		
Caucasian	81 (87.1)	81 (87.1)
Non-Caucasian	12 (12.9)	12
Education		
Elementary	0	4 (4.3)
High school	24 (25.8)	14 (15.1)
College	30 (32.3)	33 (35.5)
University	39 (41.9)	42 (45.2)
Annual household income ^a		
<\$39 999	19 (22.3)	14 (15.9)
\$40 000–99 999	29 (34.1)	38 (43.1)
>\$100 000	37 (43.5)	36 (40.9)
Breastfeeding level		
Exclusive	69(74.2)	67(72.0)
Almost exclusive	11(11.8)	18(19.4)
High	9(9.7)	6(6.5)
Partial	4(4.3)	2(2.2)
NRS, mean (<i>SD</i>)	6.5(2.3)	6.2(2.2)
SF-MPQ Total, mean (<i>SD</i>)	17.7(8.4)	16.9(7.9)
BSES-SF, mean (<i>SD</i>)	55.5(9.2)	55.6(8.9)

^aParticipants did not wish to disclose their annual household income (usual care group, *n* = 8; treatment group, *n* = 5). NRS, Numeric Rating Scale; SF-MPQ, Short-Form McGill Pain Questionnaire; BSES-SF, Breastfeeding Self-Efficacy Scale – Short Form.

could not be contacted by telephone despite three telephone calls followed by an emailed request for continued participation.

Participants were considered compliant if they described using lanolin after 75% or more of the feeds

for the 7-day study period: 63 (78.8%) of women in the lanolin group described using the lanolin as recommended. Almost half (*n* = 39, 49%) of the women used lanolin after every feed, 24 (30%) women used lanolin after 75% of feeds and 17 (21%) women used lanolin after 50% of feeds or less. Among the 85 women in the control group who completed the 4 days post-randomization outcome assessment, 10 (12%) reported using lanolin to treat their nipple pain. Among the 83 women in the control group who completed the 12-week follow-up, 13 (16%) reported that they had used lanolin at some point during the study period. Among these women, 9 (11%) reported using lanolin after every feed and 4 (5%) reported using lanolin after 75% of feeds.

Clinical outcomes

Nipple pain

Both groups reported less nipple pain on all pain outcome measures from baseline to 4 days post-randomization. No significant group differences were found in pain scores for the NRS or the SF-MPQ subscales (Table 3). While there were clinically meaningful reductions in nipple pain on all pain outcome measures from baseline to 7 days post-randomization for both groups, no significant differences in pain scores were found between groups.

Breastfeeding duration and exclusivity

At 4 weeks postpartum, 20 (24%) women in the control group had discontinued breastfeeding compared with 12 (15%) in the lanolin group. At 12 weeks postpartum,

Table 3. Nipple Pain Measures Between Groups

Variable	Usual Care	Treatment	Mean Difference Between Groups (T - UC)	<i>t</i> (<i>df</i>)	<i>p</i>
	$\Delta(T_2 - T_1)$ <i>M</i> (<i>SD</i>)	$\Delta(T_2 - T_1)$ <i>M</i> (<i>SD</i>)	$T_{\Delta} - UC_{\Delta}$ <i>M</i> (<i>SD</i>)		
NRS 4 Days P.R.	- 0.5(3.0)	- 0.7(3.1)	- 0.3(0.5)	- 0.5(163)	0.6
NRS 7 Days P.R.	- 2.5(3.0)	- 2.4(3.2)	- 0.0(0.5)	- 0.0(158)	0.9
SF-MPQ 4 Days P.R.	2.5(10.6)	1.3(11.4)	- 1.2(1.7)	- 0.7(163)	0.5
SF-MPQ 7 Days P.R.	- 5.3(8.6)	- 4.3(11.0)	1.0(1.6)	0.6(158)	0.5

Δ denotes change in scores over time (NRS, Numeric Rating Scale; P.R., post-randomization; SF-MPQ, Short-Form McGill Pain Questionnaire; T, treatment; UC, usual care).

Table 4. Breastfeeding exclusivity

Time	Infant feeding category	Usual care	Treatment	$\chi^2(df)$	<i>p</i>
		(<i>n</i> = 84)	(<i>n</i> = 78)		
		<i>n</i> (%)	<i>n</i> (%)		
4 weeks postpartum	Exclusive or almost exclusive	52 (61.9)	51 (63.0)	3.2(2)	0.2
	High or partial	12 (14.3)	18 (22.2)		
	Token or bottle-feeding	20 (23.8)	12 (14.8)		
		Usual care	Treatment		
		<i>n</i> (%)	* <i>n</i> (%)		
12 weeks postpartum	Exclusive or almost exclusive	42 (50.0)	43 (55.1)	1.5(2)	0.5
	High or partial	11 (13.1)	13 (16.7)		
	Token or bottle-feeding	31 (36.9)	22 (28.2)		

**n* = 81.

31 (37%) women in the control group had discontinued breastfeeding compared with 22 (28%) in the lanolin group. However, these differences between groups were not statistically significant (Table 4). Breastfeeding exclusivity levels were also similar among groups at both 4 and 12 weeks postpartum with no statistically significant differences between the groups (Table 4).

Breastfeeding self-efficacy

Women in both groups reported high levels of breastfeeding self-efficacy at baseline and at 4 days post-randomization (Table 2). No significant difference was found among the groups for changes in breastfeeding self-efficacy scores at 4 days post-randomization with the control group having a mean score of 55.4 (*SD* = 10.4) compared with 56.3 (*SD* = 11.8) for the treatment group.

Maternal satisfaction

Overall, the majority (*n* = 42, 53%) of women in the lanolin group were 'very satisfied' with the effects of lanolin in treating their nipple pain. Conversely, only 18 (22%) women in the control group were 'very satisfied' with the care they received to manage their nipple pain. This difference in maternal satisfaction between the groups was statistically significant, χ^2 (2, *n* = 160) = 20.8, *p* ≤ .001). Only 1 (1%) woman in the lanolin group was 'very dissatisfied' with the treatment they received compared with 11 (14%) women in the control group. No side effects were reported by those in the lanolin group.

Discussion

This is the first randomized controlled trial to rigorously evaluate the effect of lanolin on nipple pain among breastfeeding women with damaged nipples. Overall, lanolin was ineffective in reducing nipple pain or improving breastfeeding duration and exclusivity rates. No significant difference was found among the groups for mean changes in nipple pain intensity scores, nor for SF-MPQ scores at 4 or 7 days post randomization. Both groups had moderate pain (Serlin et al. 1995) at baseline (mean NRS rating between 5 and 6) and continued to have moderate pain 4 days later. At 7 days post randomization NRS scores were in the mild range (1–4) for both groups, and these findings were similar to an RCT using lanolin as a control group (Dennis et al. 2012). Based on the data from this trial and those from another study (Abou-Dakn et al. 2011), it is suggested that regardless of the use of lanolin or usual care, it is expected that nipple pain intensity scores will decrease by approximately seven to ten days postpartum. Our baseline results did not differ from previous nipple pain studies where moderate pain levels were also found (Abou-Dakn et al. 2011; Dennis et al. 2012).

Although compliance for this trial was high, it is plausible that amount of lanolin and/or the frequency of application to the nipple were insufficient to achieve a therapeutic effect. Prior literature reporting on the use of lanolin for nipple pain has been inconsistent with respect to what is considered a therapeutic dose, and how compliance is defined and measured. The

overall goal of moist wound healing is to keep wounds *continuously* moist throughout the stages of re-epithelialization. In this trial, women would not have continuous moist wound healing. Furthermore, it would be unfeasible to expect under realistic conditions that women would be able to keep their nipples covered with lanolin 100% of the time. Clothing and movement results in lanolin wearing off over time, leading to periods where the nipple tissue would become dry. As such, in this trial the reasonable and expected use of lanolin did not have an effect on the severity of nipple pain when compared with usual care.

The secondary research question addressing the effect of lanolin on breastfeeding duration and exclusivity did not find any statistical differences between the groups. In one previous trial which evaluated the effect of an all-purpose nipple ointment vs. lanolin as a control group, lanolin had no effect on breastfeeding duration and/or exclusivity at 12 weeks postpartum (Dennis et al. 2012). In this trial, no differences were found among women using lanolin vs. an all-purpose nipple ointment, and similar breastfeeding duration and exclusivity rates were found at 12 weeks postpartum.

This is the first trial to examine the effect of lanolin for the treatment of nipple pain on breastfeeding self-efficacy. Mean BSES-SF scores between study groups at baseline and 4 days post-randomization were similar with no significant differences found. Baseline scores were also high, in contrast to scores reported in an exploratory study of breastfeeding self-efficacy (Kingston et al. 2007). This study found that mothers experiencing moderate to severe nipple pain during the first 48 h postpartum had significantly lower BSES-SF scores than those experiencing no nipple pain (Kingston et al. 2007). This is in contrast to this trial, where BSES-SF scores were high despite all women experiencing some degree of nipple pain. It is plausible that the BSES-SF scores were high for this trial as a result of the recruitment site having Baby Friendly Hospital Initiative (BFHI) (World Health Organization 2009) status. Hospitals with BFHI assess, monitor and educate staff on how to foster the establishment and maintenance of breastfeeding among women. As such, women who deliver their infants at BFHI accredited hospitals are more likely to receive various efficacy-

enhancing experiences from staff such as the provision of assistance and guidance with breastfeeding and encouragement and verbal persuasion.

Significantly more women who received lanolin were very satisfied with the treatment they received compared with those who received usual care to manage their nipple pain. It is plausible that participants using lanolin may have felt a greater sense of control over their nipple pain by doing 'something' rather than 'nothing', in turn leading to a greater sense of satisfaction. This increased satisfaction is similar to results found in a trial evaluating an all-purpose nipple ointment where participants in the lanolin group had significantly higher levels of satisfaction with breastfeeding vs. those in the all-purpose nipple ointment group ($p < .01$) (Dennis et al. 2012).

Although this trial has numerous methodological strengths including random generation of group assignment, strong participant adherence to trial protocols and several mechanisms to prevent contamination and crossover, it is not without limitations. Potential limitations of this study may include the usage of a single recruitment site and that nipple infection was neither assessed nor treated. Another limitation may be the recruitment hospital's BFHI status. It is well established that hospitals accredited with BFHI have superior breastfeeding initiation, duration and exclusivity rates vs. non-BFHI accredited hospitals (Kramer et al. 2001). Finally, although only 12% of the control group admitted to using lanolin, there is the potential of social desirability response bias. As such, the use of lanolin by the control group may have been higher than reported.

One of the most important findings in this trial was that almost all women independent of study group allocation experienced less nipple pain after approximately 7–10 days postpartum. Numerous studies support the role of anticipatory guidance as an effective intervention to help mothers cope during the postpartum period (Meleis 1975; Meleis & Swendsen 1978; Swendsen et al. 1978). Noting that nipple pain peaks at around 3 days postpartum and decreases thereafter, the provision of health teaching that pain will likely subside in about a week may help sustain breastfeeding during the most painful period and beyond.

Finally, because there are no known interventions to effectively treat nipple pain (Dennis et al. 2014), the

importance of preventing nipple damage and pain in the early hours and days postpartum cannot be overlooked. Nipple damage often results from improper latch or positioning at the breast (Woolridge 1986; Tait 2000). To prevent nipple damage and pain it is imperative to provide newly breastfeeding women with education regarding proper positioning and latch, but to also frequently observe breastfeeding in the early postpartum period, to provide hands-on assistance if needed.

Conclusion

The application of lanolin to painful nipples in the immediate postpartum period did not significantly decrease nipple pain, nor did it improve breastfeeding duration and exclusivity; it also did not have an effect on breastfeeding self-efficacy, a known modifiable variable predictive of breastfeeding outcomes. As such, the provision of lanolin in-hospital and/or the recommendation of lanolin by health professionals to treat breastfeeding-related nipple pain is questionable and warrants further investigation to ensure the provision of evidence-based care.

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Conflicts of interest

The authors declare that they have no conflict of interest.

Contributions

KTJ conceptualized and designed the study; acquired, analysed and interpreted the data; wrote the first draft of the manuscript; critically reviewed the manuscript and approved the final manuscript as submitted. CLD conceptualized and designed the study; contributed to the interpretation of the data; critically reviewed the manuscript and approved the final manuscript as submitted.

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