Prevention of Nipple Cracks With Guaiazulene Versus Breast Milk in Nursing Mother: A Randomized, Controlled, Double-Blind Trial

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Abstract

Objective: The objective of the present study is to evaluate the efficacy of guaiazulene ointment versus breast milk application in the prevention of cracked nipples during breastfeeding.
Material and Methods: This prospective, randomized, double-blind trial was conducted in mother-infant care wards in a tertiary care training and research hospital. Two hundred postpartum puerperal women with normal nipples who were breastfeeding after a vaginal delivery at 37 or more weeks of gestation were included in the study. Participants were assigned randomly to one of the two treatment groups with 0.05% guaiazulene ointment or her own breast milk application. Participants applied the treatments after each breastfeeding, from postpartum day 1 to 30. Rate of occurrences of nipple cracks at day 30, nipple pain measured with visual analogue score at day 15 and 30 were the primary endpoints of the trial.
Results: Forty-seven women have either not fulfilled the final criteria for statistical analyses or lost to follow up, so 153 subjects have completed the study; guaiazulene group (n=76) or breast milk group (n=77). During the study period, the overall incidence of nipple cracks (48 of 153) was 31.4%, being 18.4% (14 of 76) and 44.2% (34 of 77) in guaiazulene and breast milk treated groups, respectively (p=0.001, RR=0.42, 95% CI: 0.24-0.71). The magnitude of nipple pain was significantly lower in the guaiazulene group at day 15 (p<0.05) and at day 30 (p<0.05) compared to breast milk group.
Conclusion: The application of guaiazulene 0.05% ointment in the breastfeeding mother at least four times a day effectively reduces the occurrence of sore and cracked nipples. It's a highly satisfactory form of treatment with a low discontinuation rate for the prevention of sore and cracked nipples.

Keywords: breastfeeding, guaiazulene, nipple cracks, sore nipples

Özet

Emziren Lohusalarda Memebaşı Çatlaklarının Önlenmesinde Gayazulen ve Anne Sütünün Etkinliğinin Karşılaştırılması: Randomize, Kontrollü, Çift-kör Çalışma

Amaç: Çalışmamızın amacı emzirme döneminde memebaşı çatlakları ve ağrısından korunmada gayazulen pomat ile anne sütü uygulamalarının etkinliğinin karşılaştırılması.
Materyal ve Metot: Çalışma prospektif, randomize, çift kör olarak eğitim ve araştırma hastanesi kadın hastalıkları ve doğum kliniği lohusa servisinde tasarlandı. Her iki memebaşı sorunsuz, 37. tamamlanmış gebelik haftası sonunda doğum yapmış 200 lohusa çalışmamızın materyalini oluşturdu. Lohusalar, memebaşı çatlaklarından korunmak için tamamen rastgele olarak, meme başına gayazulen %0.05 pomat veya kendi sütünü emzirme sonrası uygulaması ile postpartum 1-30 günler arası takip edildi. Memebaşı ağrısı 15. ve 30. günlerde vizüel analog skoru kullanılarak ölçüldü; memebaşı çatlağı ise 30. günde oluşum oranlarına göre araştırıldı.
Sonuçlar: Kırk yedi lohusa gerek istatistiksel analiz için gerekli çalışma protokolüne uymadıklarından, gerekse takipten kayboldukları için çalışma dışında kaldı ve 153 olgu çalışmayı tamamladı; gayazulen grubu (n=76), anne sütü grubu (n=77). Çalışma sonunda memebaşı çatlağı oluşma oranı 153 hastanın 48'inde (%31.4) bulundu ve çatlama oranı gayazulen grubunda %18.4 iken anne sütü uygulayan grupta %44.2 idi (p=0.001, RR=0.42, %95 GA: 0.24-0.71). Ayrıca memebaşı ağrısı skorunun 15. günde (p<0.05) ve 30. günde (p<0.05) gayazulen grubunda anne sütü grubundan daha düşük olduğu bulundu.

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Tartışma: Emziren annelerde memebaşına günde en az dört kez %0.05 gayazulen uygulaması memebaşı ağrısını ve çatlaklarını azaltmaktadır. Emziren annelerin memebaşı çatlaklarından korunmasında ilaç bırakma oranlarının düşük olması ve yüksek etkinliği nedeniyle bu tedavi yöntemi uygulanabilir.

Anahtar sözcükler: emzirme, gayazulen, memebaşı çatlakları, ağrılı memebaşı

Introduction

Nipple pain and cracks are common reasons for the avoidance or termination of breastfeeding. According to World Health Organization's recommendation, all babies should be exclusively breastfed for 6 months, followed by the introduction of appropriate weaning foods which are given in conjunction with breastfeeding until two years of age (1). Breastfeeding has been clearly established as the optimal source of infant nutrition. The process contributes to both maternal and infant health and to the prevention of numerous childhood diseases (2).

Breast pain is one of the most common complaints that an obstetric or pediatric care provider will encounter in his or her breastfeeding patients. Nipple and/or breast pain is the second most common factor causing mothers to abandon breastfeeding, with perceived insufficient milk supply reported as the most common reason (3).

Despite these known benefits and clear recommendations, many women decide not to breastfeed their babies. As with uptake, trends in breastfeeding duration appear to be associated with factors such as social class, maternal age and age at completion of full-time education. Sadly, 90% of women questioned stated they would have liked to have breastfed for a longer period of time (4). Women cite a number of reasons for discontinuing breastfeeding, with insufficient milk, painful nipples and breasts, and refusal of the baby to suck or latch on to the breast, being the most common factors (4). It is argued that these reasons for cessation have been widely documented and typify difficulties that may have been alleviated by appropriate positioning and attachment of the baby at the breast, together with unrestricted feeding (5). Concern about breastfeeding prevalence has prompted a number of initiatives aimed at both increasing uptake and supporting women to continue breastfeeding including WHO/UNICEF Baby Friendly Hospital Initiative (6).

The utmost importance of breastfeeding necessitates avoiding lactating women from preventable causes of withdrawal. It is customary for health care professionals to prescribe some type of ointment to prevent or treat sore and cracked nipples to encourage the nursing mother. The efficacy of these ointments is insufficiently documented and because the studies have not identified any one specific treatment as superior, lactation professionals may recommend a variety of these techniques.

The aim of the present study was to evaluate the effectiveness of guaiazulene ointment versus breast milk application in the prevention of cracked and sore nipples during breastfeeding period.

Material and Methods

A total number of 200 early puerperal women who gave birth to singletons with an uncomplicated vaginal delivery having both breasts without mammoplasty and normal nipples without cracks, were assigned randomly to one of the two treatment groups with 0.05% guaiazulene ointment or her own breast milk application. During the recruitment period of the trial, a questionnaire was applied to the subjects and the ones who had systemic diseases, gave births for multiple fetuses, death fetus or had a history of mammoplasty were excluded from the study. Participants who were mentally and physically in good condition accepted to participate in this trial with their signed consent.

Randomization was carried out with sequentially numbered; opaque, sealed envelopes that had been generated with the use of computer assisted random number function.

Guaiazulene was taught to be implemented after each breastfeeding period at least four times a day and had to be swapped off before nursing. During the one month of study period, subjects were asked to report any adverse event. At day 15 and 30, one of the researchers checked subjects for the regular application, side effects or drop-outs. Breast milk after each lactation period was applied to the nipple surface and left for drying for a minute or two. Sore nipples were measured by visual analogue scale (VAS) by the subjects at day 15 and the 30. They marked the pain level on a 100 mm long line in which the right hand tip of the line equaled no pain and left hand tip of the line equaled the highest pain level that the patient have ever experienced on the prepared questionnaire. These indications were measured in centimeters from the no pain tip of the line and recorded on the data sheet for statistical analyses. The noncompliance for the application was noted with its reasons and end-results.

Occurrence of nipple cracks, reduction of nipple pain at day 15 and 30 were the main outcome measures of the trial.

Clearly, the design required the comparison of outcomes would be undertaken in women who were taught breastfeeding skills using the standard methods which were currently in use. The outcomes to be compared had to be both measurable and quantifiable; therefore, the adoption of an experimental design was considered to be appropriate for this study. Randomization into guaiazulene and breast milk groups would be desirable to ensure equivalence of the two groups. However, randomization of women in the same ward at the same time, where some entered the guaiazulene group whilst others in the breast milk group, was not practicable due to likely contamination effects int-

roduced by the staff using the questionnaire. So, maximum effort was employed by the staff to prevent this contamination.

Strict entry criteria were adopted in order to ensure similarity of participants. This resulted in recruitment taking place in only one of the five postnatal wards within the hospital as the remaining one ward was classified as 'high-risk' and did not admit women who fulfilled the inclusion criteria.

On admission to the postnatal ward, women who fulfilled the inclusion criteria were approached by a member of the ward and given verbal and written information about the study. They were then given some time to consider whether they would like to be included and written consent was then provided by those women wishing to participate. There were no documented refusals to inclusion. Once women had confirmed their willingness to be recruited, they were given a copy of the questionnaire which they took home with them to complete on day 15 to 30 and return to the researcher. The recruiting researcher made a record of the women's details such as address, telephone number and hospital unit number in a recruitment log which was kept together with all the signed consent forms for use by the coordinator. Thus information and support continued to be offered when required by the women; however the information given was consistent in nature. Recruitment again took approximately 24 months to complete. At both stages of the study, support was recorded in order to allow evaluation of frequency and time spent by staff.

The key outcome measures investigated were nipple cracks and degree of nipple pain reported by the participants at day 15 and 30. The measure of nipple pain was quantified by VAS which was also used by many researchers in this field for the same purpose (7-9).

Data was collected by means of a questionnaire which was completed on day 15 and hospital interview and nipple examination by a blinded dermatologist 30 days after the birth. Data were entered on a personal computer-held database and were analyzed with the Statistical Package for the Social Sciences (version 11,5; SPSS Inc, Chicago, Ill). Variables that were normally distributed were presented as mean and standard deviation and were analyzed with the independent samples paired t test or Mann Whitney U test. The Pearson chi square or Fisher's exact test were used as appropriate for independent nominal data. Confidence intervals were used where appropriate and statistical significance was defined as a probability value of <0.05.

Approval to undertake the study was granted by the Local Research Ethics Committee. Permission to conduct the study was also obtained from the hospital management team.

Results

Recruitment period for the study was 24 months and 153 patients were found to be appropriate for final analyses. In Table 1, demographic parameters revealed homogenous distribution of groups according to their age, gravidity, parity and birth weight. Forty-seven of the participants did not complete the study because 31 of them were lost to follow up, 3 patients quitted breastfeeding for some reasons other than nipple pain or cracks, 1 patient experienced an early neonatal loss and was ablactated, and 12 of them reported that they had changed their medication for nipple care by their physician or by themselves. Compliance to treatment was the same between the guaiazulene (n=76) or breast milk (n=77) treated groups.

At day 30 of the study, nipple cracks were evaluated by a blinded dermatologist (Figure 1) and the overall incidence of cracks (48 of 153) was 31.4% among the participants whereas it was 18.4% (14 of 76) and 44.2% (34 of 77) in guaiazulene treated and breast milk treated groups, respectively (p=0.001, RR=0.42, 95% CI: 0.24-0.71)

Nipple pain was assessed by VAS at 15 and 30 days and mean±sd measurements of sore nipple indicated by subjects in guaiazulene and breast milk groups were 9.99±15.38 cm and 19.18±19.42 cm (p=0.001) at day 15 and 8.28±14.58 cm and 24.65±25.06 cm (p<0.0001) at day 30, respectively (Figure 2). We also analyzed the VAS scores at day 15 and 30 according

Table 1. Demographic parameters of subjects

	GROUP	Mean	Std. Deviation	p
AGE	guaiazulene	25.25	3.441	0.830
(years)	breast milk	25.36	3.120	
GRAVIDA	guaiazulene	2.34	1.466	0.210
	breast milk	2.64	1.423	
PARA	guaiazulene	1.05	1.210	0.205
	breast milk	1.30	1.182	
FETAL	guaiazulene	3156.97	313.169	0.118
WEIGHT(gr)	breast milk	3237.14	317.871	

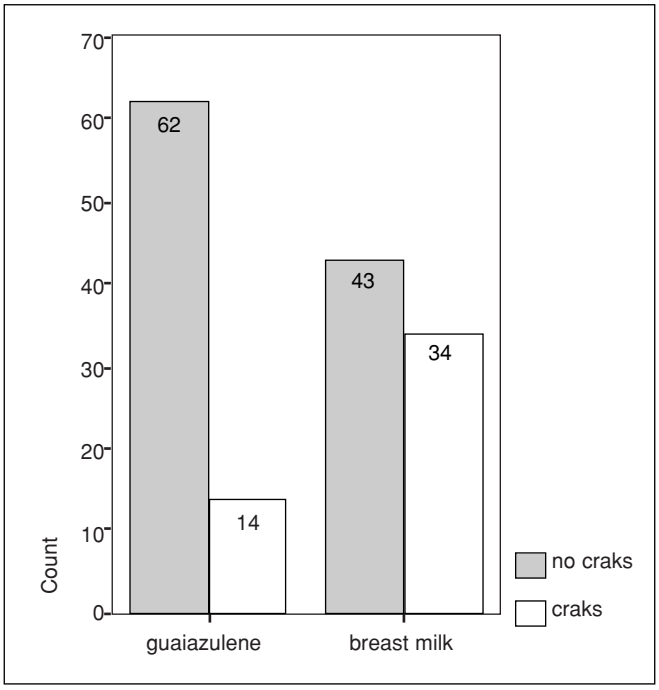

Figure 1. Nipple cracks count between groups.

to their nipple crack status. In women without cracks, the overall VAS scores at day 15 and 30 were 3.77±7.1 cm and 2.84±6 cm, respectively (paired *t* test p=0.028). Nevertheless, in women with cracks the overall VAS scores at day 15 and 30 were 38,33±10,28 cm and 46.44±12.69 cm, respectively (paired *t* test p<0.0001). So, women without cracks reported their nipple pain to be more intensive at day 15 than day 30, whereas women with cracks reported more painful nipples at day 30 than day 15 (Figure 3).

At day 15, trial arms were compared for their crack status (Figure 4). There were no statistically significant difference at day 15 between guaiazulene and breast milk groups in women with nipple cracks (p=0.74). Nevertheless, there was a statistically significant difference at day 30 between guaiazulene and breast milk groups in women with nipple cracks (p<0.001) (Figure 5).

Nipple crack status of the patients was evaluated according to fetal weight and mean±sd fetal weight were 3194.3±318 gr and 3203.9±318 gr in women without and with cracks, respectively (p=0,6).

Fetal sex was also determined in women with cracks (41.7% male and 58.3% female) and without cracks (52.4% male and 47.6% female) which revealed statistically no significance (Pearson chi square p=0.219).

When comparing nipple cracks according to maternal age, mean±sd age were 25.23±3.27 years and 25.48±3.3 years in women without and with cracks, respectively (p=0.97).

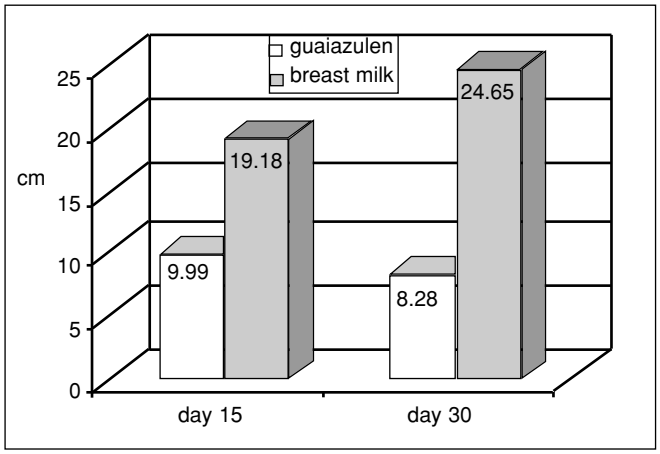

Figure 2. The distribution of sore nipples of participants at day 15 and 30 assessed by VAS (values indicate the mean measurements from no-pain tip of VAS line in milimeter); p<0.05 between subsequent bars.

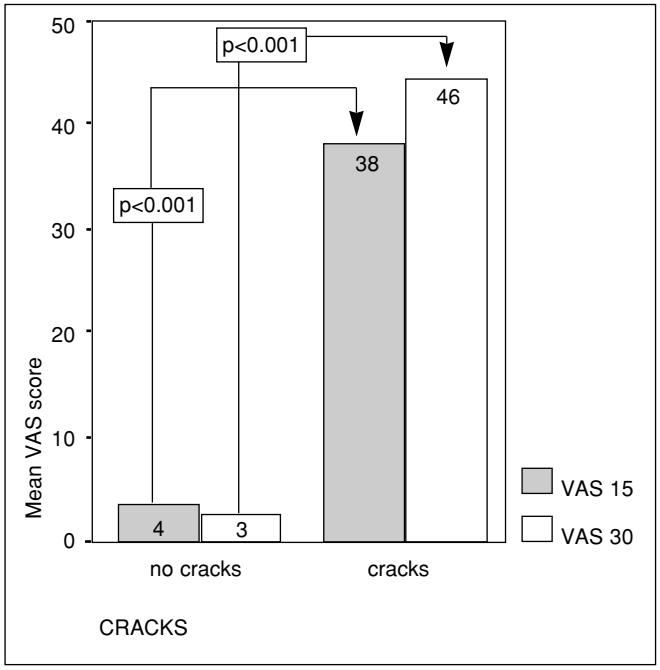

Figure 3. The distribution of overall participants' mean VAS scores at day 15 and 30 according to their crack status (Figures on the bars in mm).

Discussion

This study represents the first rigorous assessment of the use of a specific ointment (0.05% guaiazulene) by the health care professionals, who are not designated specialists in breastfeeding, in order to support women to continue breastfeeding effectively. On the whole, the results of the key outcome variables of nipple cracks and nipple pain at 15 and 30 days, showed the satisfactory outcome of lower incidence of nipple cracks and less nipple pain in the group whose care included the use of guaiazulene 0.05% ointment. These trends did achieve statistical significance. The questionnaire was also shown to be a practicable and acceptable intervention which appeared to be well-

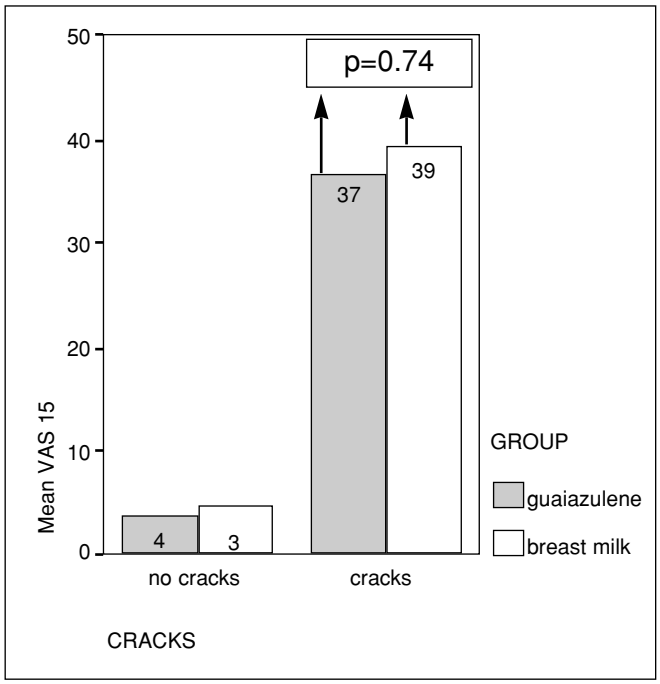

Figure 4. The distrubituon of mean VAS results in guaiazulene and breast milk treated groups according to their nipple crack status at day 15 of the trial. There was no statistically significant difference between VAS results of breast milk and guaiazulene groups according to their cracks status (Figures on the bars in mm).

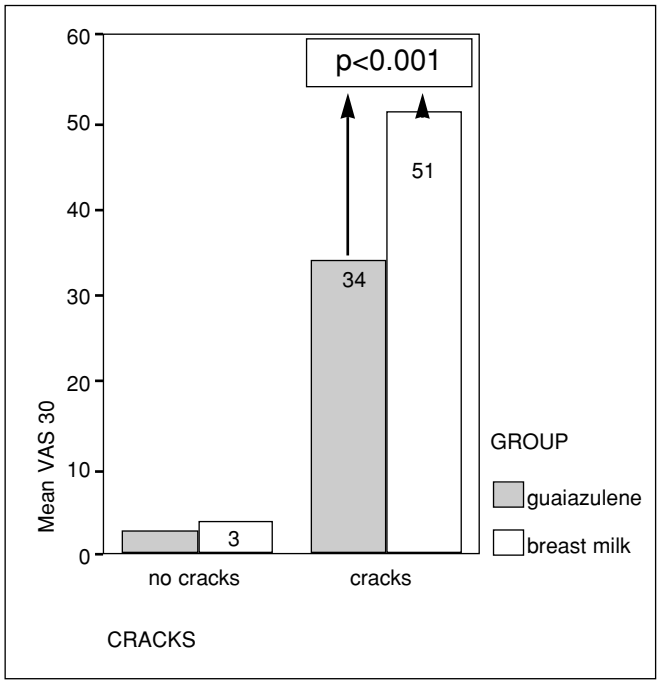

Figure 5. The distrubituon of mean VAS results in guaiazulene and breast milk treated groups according to their nipple crack status at day 30 of the trial. There was no statistically significant difference between VAS results of breast milk and guaiazulene groups in no cracks part whereas statistically significant difference was found in cracks part (Figures on the bars in mm).

received by the women involved in this study. Poor positioning of the infant and/or poor latch-on is believed by many to be the most common cause of persistent sore nipples (7,10-14).

As no other study was available to allow power calculations to determine the sample size for this study, recruitment of 200 women was planned with the aim of conducting the study as a pilot to allow calculation of the sample size required for further study. This number also represented a practical sample which was achievable by the researcher. The findings from this study would possibly justify a future, larger scale study for efficacy of an ointment. It is perhaps more useful to consider at this point whether the effect size found in this study, if replicated in a larger study, was sufficiently large to be clinically significant. An intervention such as this is easy to implement and relatively cheap to use. If the questionnaire was to be compared to other potential interventions, it could have been seen that it represented a cost-effective option. An individual session (15-17) or small group session with a lactation consultant may show greater effect. However, not all women have access to such a person and the cost of employing such a specialist to see all breastfeeding women may not be practicable. The benefits of the guaiazulene ointment approach are that it can be used by any member of staff and be accessed by all women who have chosen to breastfeed.

There are, of course, other methodological limitations to this study which should be considered. In any study using a longitudinal design such as this, it is possible that the differences between the pre- and post-intervention groups are due to some effect other than the intervention being studied. This may include, for instance, consistent differences in the breastfeeding behavior of women giving birth in different months of the year, or a general increase in breastfeeding due to some other cause, such as a positive portrayal of breastfeeding in a popular soap opera at the time when the ointment was in use (Such confounding factors may work in opposition to the intervention under study as well as in its favor). In future large-scale studies to confirm these preliminary findings the cluster randomization of units to the intervention and control conditions would be desirable. Use of a single ward in a single site clearly has implications for the generalisability of the study findings. Staff on this ward may not be typical of the general population of postnatal care staff, and this would have implications for the efficacy of the application in other sites.

In addition to considering the methodological constraints of the findings of this study, it is also useful to review the possible mechanisms by which this ointment may have impacted on staff and new mothers. A number of authors have highlighted the negative effect of a lack of confidence in ability to breastfeed on breastfeeding success (18-20). By informing women of the skills required in order to effectively position and attach their baby, it could be argued that the ointment may enhance their confidence in their ability to achieve this aspect of breastfeeding. However, such a conclusion at this stage remains unverified.

Rajan highlighted women's expressed needs as "clearer information, non-conflicting advice, and practical support specifically aimed at overcoming the initial physical barriers to breastfeeding." It appears possible that an ointment used for this purpose may help to achieve these (21).

Achieving effective prevention from nipple cracks and pain clearly reduces the incidence of breastfeeding problems associated with cessation. However, it would seem that wider influences also dictate success or failure. Previous studies have indicated that women often overcome problems and subsequently breastfeed successfully (17,22). The guaiazulene ointment may have been successful in overcoming one obstacle to breastfeeding success; however, many other obstacles clearly exist. During the intervention stage of the study, reasons for cessation such as fear of feeding in public, returning to work, family pressure and dislike of breastfeeding emerged (23). They argue that women's decisions regarding infant feeding are complex, related to their health, the health of their babies, the needs of other children and family members, living conditions and other demands on their time and energy. They recognize that much research fails to acknowledge the interdependence, interaction and complexity of the total breastfeeding experience. The guaiazulene ointment application may begin the process of ensuring women to be enabled to position and attach their infants effectively, however, in that it only addresses one obstacle to breastfeeding, in a predominantly bottle feeding culture, it constitutes only part of the wider picture.

Brent et al reported in a randomized study which compared the safety and efficacy of a hydrogel moist wound dressing with the use of breast shells and lanolin cream in the treatment of maternal sore nipples associated with breastfeeding that prevention of sore nipples by teaching proper technique on the initiation of breastfeeding should be instituted. For those cases in which sore nipples do develop, breast shells and lanolin in association with instruction in breastfeeding technique are more effective than moist wound dressings. Lanolin and shells should remain the first-line therapy (24).

In a recent study conducted by Dodd and Chalmers to evaluate the use of hydrogel dressings for the prevention and treatment of nipple soreness in lactating women as compared with the common intervention of lanolin ointment, the hydrogel dressings group had significantly greater reduction in pain score mean values at baseline, on study day 10, and on study day 12, in comparison to the control group. Participants using the hydrogel dressings discontinued treatment sooner than participants in the lanolin ointment group. The lanolin ointment group had eight breast infections, whereas the hydrogel dressings group had none.

They concluded that hydrogel dressings were a safe, available treatment that provided more effective pain management for nipple soreness than the common intervention of lanolin ointment (25).

On the contrary, Centuori et al reported that no difference was found between the control (n=96) and the intervention group (n=123) in the incidence of sore and cracked nipples in breastfeeding duration. However, they pointed out that several factors were associated with sore nipples and with breastfeeding duration. The uses of a pacifier and of a feeding bottle in the hospital were both associated with sore nipples at discharge. Full breastfeeding up to 4 months postpartum was significantly associated with the following early practices: breastfeeding on demand, rooming-in at least 20 hours/day, non-use of formula and pacifier, no test-weighing at each breastfeed. The incidence of sore and cracked nipples and the duration of breastfeeding were not influenced by the use of a nipple ointment. Other interventions, such as providing the mother with guidance and support on positioning and latching, and modifications of hospital practices may be more effective in reducing nipple problems (26).

Conclusion

Further study is indicated to investigate whether an intervention such as the guaiazulene ointment application is effective in improving breastfeeding outcomes. A combined approach to include an antenatal intervention, together with the postnatal ointment may represent a suitable approach. A further study should use a larger sample size, in order to assess whether the trend towards improvement demonstrated in this study is sustained. The high proportion of women who ceased to breastfeed due to perceived milk insufficiency indicate that ways of educating and reassuring women about how to recognize effective breastfeeding are needed.

Our results indicate that the application of guaiazulene 0.05% ointment in the breastfeeding mother at least four times a day effectively reduces the occurrence of sore and cracked nipples. It's a highly satisfactory form of treatment with a low drop-out rate in the prevention of sore and cracked nipples.

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