Sore Nipples in Breast-feeding Women

A Clinical Trial of Wound Dressings vs Conventional Care

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Background: Sore nipples in breast-feeding mothers are a common cause of premature weaning, and are difficult to treat owing to recurrent trauma and exposure to the infant’s oral flora.

Objective: To compare the safety and efficacy of a hydrogel moist wound dressing (Elasto-gel, Southwest Technologies Inc, Baltimore, Md) with the use of breast shells and lanolin cream in the treatment of maternal sore nipples associated with breast-feeding.

Design: Randomized controlled trial comparing the above treatments for sore nipples. Patients were seen for a maximum of 3 follow-up visits within 10 days, or until the resolution of symptoms.


Patients: A referred sample of 42 breast-feeding women who presented to the Maternal-Infant Lactation Center for the treatment of sore nipples. All patients with breast infection or chronic unrelated pain conditions were excluded from the study.

Intervention: After informed consent, patients were randomized to receive either a hydrogel wound dressing or breast shells and lanolin. All patients underwent a history, physical examination of the infant and the mother’s breasts, assessment of breast-feeding technique, and breast-feeding instruction.

Main Outcome Measures: The degree of pain on self-report questionnaires and the change in scores for physical examination, breast-feeding technique, and pain behaviors during breast-feeding.

Results: Although both treatments, in association with instruction in breast-feeding technique, were effective, greater improvement was seen in the group using breast shells and lanolin. This reached statistical significance for physician-rated healing (P<.01) and self-reported pain (P<.05). There were significantly more infections in the dressing group (P<.05), which resulted in early discontinuation of the study.

Conclusions: Prevention of sore nipples by teaching proper technique on the initiation of breast-feeding should be instituted. For those cases in which sore nipples do develop, breast shells and lanolin in association with instruction in breast-feeding technique are more effective than moist wound dressings. Lanolin and shells should remain first-line therapy.


SORE NIPPLES associated with breast-feeding is a common problem, with an incidence ranging from 11% to 96%, and may lead to premature weaning. This frequently occurs from suction trauma to the nipple secondary to incorrect positioning at the breast. In addition, traumatized nipples can readily become superinfected with bacteria or yeast, the presence of which can delay healing, even when positioning and latch-on are corrected. Unfortunately, many women delay seeking treatment until substantial damage already has occurred. Thus, effective wound healing, in addition to the teaching of proper techniques, must occur before painless breast-feeding can resume.

Healing of sore nipples in breast-feeding mothers is particularly difficult for several reasons. First, the nipple is exposed to repeated trauma from the infant’s suckling. Second, in addition to
SUBJECTS AND METHODS

SUBJECTS

Subjects were recruited from the Maternal-Infant Lactation Center of the Mercy Children’s Medical Center, Uptown Pediatrics (the faculty practice plan of Mercy Children’s Medical Center), Allegheny County Breast-Feeding Helpline, LaLeche League International, and local lactation consultants in Pittsburgh, Pa.

Subjects included healthy, lactating women who presented to the Maternal-Infant Lactation Center for treatment of bleeding, cracked, or crusty nipples and/or who reported pain with breast-feeding. Exclusion criteria included breast infection (mastitis, breast abscess, fungal infection), non-English-speaking mother, and the presence of other persistent pain-related conditions. Mastitis was diagnosed clinically as the presence of focal warmth, erythema, tenderness, induration with or without the presence of fever, myalgias, and other systemic symptoms. Fungal infection was also diagnosed clinically by history consisting of intense stabbing or burning pain radiating to the back and persisting or intensifying after the feeding is over, as well as by physical examination of the mother. The latter findings can consist of bilateral concentric streaking starting from the nipple, erythema, flaking, edema, or totally normal-appearing nipples. Sample size, as determined by power analysis, was deemed to be 80 total subjects, with 40 in each group, to detect a clinically significant effect size. However, owing to the clinical impression that a large number of infections were occurring in the dressing group, an interim analysis was performed. This confirmed a significantly higher infection rate in the dressing group, and the investigation was ended prematurely (see “Results” section).

PROCEDURES

The project was approved and informed written consent was obtained in accordance with the Human Rights Committee guidelines of the Mercy Hospital of Pittsburgh. Prior to examination, subjects were randomized into the experimental or conventional treatment group. All potential study candidates received a comprehensive history and physical examination by an investigator (L.A.R.) experienced in breast-feeding management, who established eligibility and was kept blinded to treatment group. This investigator then took photographs of the nipples, completed a standardized clinical assessment instrument, and collected the self-report pain questionnaires.

Treatment was provided by a second investigator (B.R.) who was kept blinded as to the physical examination and self-report pain data. All participants, regardless of treatment assignment, were observed during a nursing session with the results recorded on the Mother-Baby Assessment (MBA). This is a tool developed for clinical use to assess breast-feeding techniques. All mothers received instruction in proper positioning and latch-on of the infant at the breast, as well as instruction in general breast-feeding management. Finally, this investigator rated pain behaviors directly observed during the feeding session and instructed subjects on the use of the assigned treatment method.

The conventional treatment consisted of instructions to massage their own milk onto the nipple after feeding, allow the nipples to air dry, and then apply lanolin cream and breast shells. The rationale behind putting mother’s milk into the nipples is that the presence of antibodies, inflammatory cells, and other anti-inflammatory factors (lactoferrin, bifidus factor, and others) will help the healing process. The experimental treatment condition consisted of instructions to massage their own milk onto the nipple after feeding and then apply the hydrogel dressing before feeding, the wound is exposed not only to maternal skin flora but to the infant’s oral flora as well, predisposing to infection. Finally, the wound continuously varies between the wet environment of the infant’s mouth and dry air and clothing in between feedings. These factors result in a cycle of damage, healing, and redamage, as well as infection. For these reasons, standard treatments of sore nipples generally have proven inadequate.

Numerous methods of healing sore and cracked nipples have been used, including the application of human milk, tea bags, Masse cream (Advanced Care Products, Raritan, NJ), A & D ointment (Schering-Plough Healthcare Products, Liberty Corner, NJ), lanolin cream, and breast shells. A common therapeutic approach to sore nipples presently consists of dried-on human milk, modified lanolin (medical grade), and the wearing of breast shells (hard plastic devices that provide an air barrier to protect the skin from friction and/or pressure from overlaying clothing and other contact). In none of the published studies, however, has any method been completely efficacious, and sore nipples remain a frustrating clinical dilemma. This prompted us to investigate alternative treatment methods and to test their safety and efficacy.

A newer approach to wound healing in other clinical settings is the use of occlusive wound dressings. A dressing that does not adhere to the skin, can be easily and painlessly removed for feeding, and absorbs large amounts of fluid (ie, breast milk as well as wound exudate) would be an ideal candidate for use in breast-feeding mothers with sore nipples.

Elasto-gel (Southwest Technologies Inc, Baltimore, Md) dressing is a glycerine-based hydrogel dressing that is absorbent, nonadhesive, and has bacteriostatic and fungistatic properties. It can be lifted gently from the skin without disintegrating or causing pain or trauma to new, sensitive skin. The dressing is 1⁄8-in thick, providing protection against friction. It also exhibits soothing, cooling properties for pain relief.

Despite clinicians’ fears of increased infection with the use of occlusive dressings, an extensive literature review demonstrates just the opposite. In fact, it has been shown that some occlusive dressings prevent invasion of pathogens into wounds. These dressings, therefore, seemed ideal candidates for the treatment of sore and damaged nipples in breast-feeding mothers. However, important differences exist in this setting compared with those in which the dressings have previously been studied (eg, chronic ulcers, surgical wounds, chronic nonhealing trauma), where they were applied and left in place for several days. In the breast-feeding...
the nipple had dried. A new dressing was applied after each feeding.

Subjects, regardless of treatment group, who found their condition too painful to nurse their infants (Table 1) were instructed in the use of and supplied with a hospital-grade electric breast pump until the condition allowed resumption of breast-feeding. Subjects were seen for a maximum of 3 follow-up visits within the next 10 days or until resolution of symptoms, whichever came first. If healing had not occurred after 10 days, subjects were offered the other treatment modality.

MAIN OUTCOME MEASURES

Physical Examination Measures

Nipple attributes were noted on physical examination, including erythema, edema, crust, ecchymosis, peeling, blisters, and exudate. These characteristics were quantified on individual 4-point scales that rated the severity of the attributes. The scale values range from 0 to 3, with anchor descriptions of none, mild, moderate, and severe. Each subject’s scores for the attributes were summed to provide a nipple attribute score. The size of nipples as well as fissures were documented in millimeters and in photographs.

Observational Measures

Breast-feeding technique of both the mother and infant and the amount of instructional help needed were assessed and documented by the MBA. Specific instruction was provided on positioning the infant facing in toward the mother (“tummy-to-tummy”), with the infant aligned in a straight line (ear, shoulder, hip) and horizontal across the mother’s lap. It was also stressed that in latching-on, the infant should open his or her mouth wide and the mother should guide him or her onto the breast in a quick but even fashion, making sure as much as possible of the areola is inside the infant’s mouth. In addition, the presence of 7 common pain behaviors such as wincing, body stiffening, eye closing, and so forth observed during the instruction period were recorded and summed to form a total pain behavior score.21

Self-report Measures

Patient self-report measures of breast pain were collected at the initial evaluation and before each treatment session. A brief standardized questionnaire was used, composed of questions that have been demonstrated to be reliable, valid, and sensitive to treatment effects for other pain conditions, including normative information specific to acute pain management in women.23 Pain severity scores, measured on 11-point scales (0 = no pain; 10 = extreme pain) were collected. Additionally, several questions were designed to measure subjects’ satisfaction with the prescribed treatment and with breast-feeding.

DATA ANALYSIS

The study design represents a 1-between, 1-within completely balanced factorial design. The between factor is treatment condition (2 levels, conventional vs dressing treatment groups), and the within or repeated factor is time (2 levels, pretreatment vs follow-up). Mixed-model analysis of variance (ANOVA) was used to evaluate treatment effects and group differences for continuous measures. Power or square-root transformations were applied to 2 variables to achieve adequate normality for the ANOVA analyses. Exact probability χ² analyses, computed with the StatXact program,24 were used to analyze dichotomous and ordinal measures. P<.05 was considered statistically significant.

The complication rate between treatment groups was statistically significant (P<.05). These complications consisted of 1 case of dermatitis and 7 cases of infection in the dressing group and 2 cases of infection in the conventional group. Statistical analyses of demographic and birth complication information revealed no significant differences between groups (Table 1 and Table 2). A complete history and physical examination was performed on all infants at presentation and all results were found to be within normal limits. Of those infants who completed the investigation, 39% were exclusively breast-fed.

Table 3 presents the physical examination data for pretreatment and follow-up assessments. Adverse nipple attributes included erythema, edema, ecchymosis, crust formation, peeling, blisters, and exudate. Both size and degree of intensity were rated. No subjects in either group had flat or inverted nipples. Although the sum of adverse nipple attributes was higher on presentation in the conventional treatment group than in the experimental treatment group, this did not reach statistical significance. The sum of the adverse nipple attributes rated during examination of both groups significantly decreased

RESULTS

Twenty-one subjects were randomized to each of the conventional and dressing treatment groups. One subject in the conventional group and 2 subjects in the dressing group were unavailable for follow-up. Treatment was discontinued in 2 subjects in the conventional group and in 7 subjects in the dressing group because of complications. The complication rate between treatment groups was statistically significant (P<.05). These complications consisted of 1 case of dermatitis and 7 cases of infection in the dressing group and 2 cases of infection in the conventional group. Statistical analyses of demographic and birth complication information revealed no significant differences between groups (Table 1 and Table 2). A complete history and physical examination was performed on all infants at presentation and all results were found to be within normal limits. Of those infants who completed the investigation, 39% were exclusively breast-fed.
The dressing group at follow-up had higher adverse nipple attribute scores compared with the conventional group, but this difference also did not reach statistical significance. However, the number of patients displaying a good to excellent degree of healing at follow-up (Table 3) was significantly higher in the conventional group compared with the dressing group (P < .01).

Standardized MBA observational data for feeding techniques and pain behaviors are shown in Figure 1. The MBA scores displayed significant increases in proper breast-feeding techniques at the time of the follow-up assessment (P < .001), with no significant differences found between groups. The total number of the 7 pain behaviors rated that were present during initial evaluation significantly decreased at the time of the follow-up evaluation (P < .001). No significant differences for pain behaviors were found between groups.

The self-report data are shown in Figure 2. For general daily pain, both groups displayed statistically significant improvement between the pretreatment and follow-up assessments (P < .001), and the magnitude of general pain improvements was not significantly different between the 2 treatment groups. However, for pain ratings during feeding, although both groups displayed significant improvement at follow-up (P < .001), the conventional group had larger reductions in feeding pain compared with the dressing group (P < .05). As shown in Figure 1, satisfaction with breast-feeding improved significantly in both groups (P < .01). Although the patients in the conventional group reported somewhat higher satisfaction scores compared with the dressing group, this difference was not statistically significant. Treatment satisfaction ratings were generally high in both groups, with no significant differences occurring between groups. There was no correlation between patients' subjective complaints of pain severity and objective findings. Subjective complaints of general pain and pain during feeding as scored on self-report questionnaires were compared with the sum of nipple attributes on physical examination (Table 3). Both pretreatment data and the difference between pretreatment and posttreatment data were compared. Critical values of Pearson r values were ±0.32 for P < .05; thus, none of the correlations were statistically significant.
This investigation compared 2 treatments (conventional and dressings) of sore nipples associated with breast-feeding. Both treatments, in combination with instruction on proper breast-feeding management, were effective. However, greater improvement and fewer complications occurred with the conventional treatment. By self-report (Figure 2), pain was reduced significantly in both groups. However, the conventional group had larger reductions in pain related to feedings than the dressing group. This trend was also seen in the direct observation of pain behaviors (Figure 1) and in physical examination of the nipple, as noted by the sum of nipple attributes (Table 3). The physician-rated degree of healing was significantly better in the conventional group than in the dressing group (P < .01, Table 3). Breast-feeding technique, as assessed by the MBA, improved equally in both groups. This finding was expected because both groups received the same breast-feeding instruction from a single clinician, who was blinded to self-report pain ratings and physical examination findings.

The relationship between subjective complaints of pain and objective physical findings has been heavily researched with regard to other clinical conditions. However, data related to breast-feeding have not been previously available. In this study, there was no correlation between patients’ subjective pain scores and objective physical findings. Thus, one should not be surprised to encounter a patient complaining of intense pain with near-normal–appearing nipples, nor one whose nipples appear cracked, bleeding, and fissured but who complains of only mild pain.

The only previously published investigation of moist wound dressings for sore nipples in breast-feeding women looked at an adhesive polyethylene film dressing. Results showed that both total eschar and pain improved more in the control group than in the dressing group. Our investigation sought to use a nonadhesive hydrogel dressing, so that dressing removal would not cause pain or skin damage. However, this dressing too was less effective than conventional treatment (P < .05) and, in fact, exposed the patients to a higher risk of infection (P < .05). How is this explained in light of dressings’ superiority over dry wound healing and decreased incidence of infection in other settings?

One explanation could be that the true healing intervention was that of breast-feeding instruction and that both the experimental and conventional treatments were incidental to that. It is commonly held that sore nipples are caused by incorrect positioning and/or latch-on and that pain during breast-feeding can be corrected by merely repositioning the baby at the breast. This is the one component of treatment that was common to both groups. A single lactation consultant instructed both groups of patients in breast-feeding techniques, and her instruction was consistent between individuals. Both groups improved over time and the MBA scores went from 5.3 to 9.6 in the conventional group and from 5.1 to 9.1 in the dressing group. There was no statistically significant difference between groups in the MBA scores before and after instruction. A comparison group of instruction only was not included, because it was thought that the existing damage needed to be treated and that instruction would merely prevent further damage from occurring. It is therefore impossible to determine whether this was the most important component of treatment.

Another difference between this setting and the usual setting in which moist wound dressings are applied (eg, surgical wounds, chronic ulcers) is that the wound is repeatedly exposed to the infant’s oral flora. When combined with milk leakage and its high glucose and fat content, the development of infection is not surprising. A final explanation for the dressings’ lack of superiority as a treatment may lie in compliance. Assuming similar com-
pliance in both groups, noncompliance in the dressing group might lead to further worsening of the condition (changing from wet to dry environment); however, in the conventional group it would merely lead to lack of improvement.

A significant limitation of this investigation lies in the number of patients. It was originally calculated that a total of 80 patients (40 in each group) would be needed to have adequate statistical power to detect at least moderate effect differences (0.50) between groups. However, because of the high rate of infection in the experimental group and the lack of difference in efficacy, it was deemed prudent to end the study early. The increase in statistical power realized by a larger sample size may well have led to statistically significant differences for some of the marginal findings that indicated the conventional treatment produced better outcomes than the dressing treatment.

In summary, when combined with proper breast-feeding management, the use of breast shells and lanolin resulted in greater improvement than the use of moist wound dressings, although both groups showed significant improvements in at least some areas. In light of both the cost and the risk of infection, first-line treatment should remain breast shells and lanolin. These results suggest the need for future investigations using larger study populations comparing breast-feeding instruction alone with instruction combined with shells and/or lanolin as well as the use of occlusive dressings after ruling out the presence of infection.

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