# EVALUATION OF THE APPLICATION OF TEA BAGS TO SORE NIPPLES IN BREASTFEEDING WOMEN

SUBMITTED BY: NOELIE ANNETTE LAVERGNE

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# EVALUATION OF THE APPLICATION OF TEA BAGS TO SORE NIPPLES IN BREASTFEEDING WOMEN

BY

NOELIE ANNETTE LAVERGNE

A Thesis submitted to the Faculty of Graduate Studies of the University of Manitoba in partial fulfillment of the requirements of the degree of

MASTER OF NURSING

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# DEDICATION

This particular work has been in progress for a number of years. Throughout that time, I have had unending support, encouragement, and patience from my husband Maurice. This work is dedicated to him.

As well, I want to dedicate it to my children Diane, Andre, and Melanie, and thank them for their patience and help. It came in many ways such as: bringing me snacks and drinks as I sat at the computer, playing quietly in another section of the house, and celebrating with me when a stage of the process had been completed. Your support was tangible and needed.

# ABSTRACT

The purpose of this research was to test a common treatment used within the postpartum period for mothers who are experiencing sore nipples related to breastfeeding. The treatment was the application of moistened tea bags to sore nipples.

This study used an experimental design and evaluated the effectiveness of tea bag compresses, warm water compresses, and no treatment for women experiencing sore nipples. Participants carried out their assigned treatment for five days, and evaluated their nipple soreness after every feeding during this time period.

Statistical analysis demonstrated that the tea bag and water compresses were more effective than no treatment. There was no statistically significant difference between the two compresses in relation to soreness scores.

Correlation was used to assess whether frequency and duration of breastfeeding affected nipple soreness, and to identify a relationship between objective assessment of the nipples, and subjective soreness ratings. Analysis revealed no relationship at all between these factors.

Recommendations for nursing practice and future research are made based upon these study results.

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# CHAPTER I:

# INTRODUCTION

## Statement of the Problem

Breastfeeding provides optimal infant nutrition (Clark & Beal, 1982; Cunningham, Jelliffe, & Jelliffe, 1991; Houston, 1981; Janke, 1988). This statement is supported by various professional organizations including the American Academy of Pediatrics (1978, 1982), the Canadian Pediatric Society (1979), and the organization of Obstetric, Gynecologic, and Neonatal Nurses (NAACOG, 1991). The World Health Organization (WHO) and Unicef have jointly published the Innocenti Declaration on the protection, promotion, and support of breastfeeding (1989), in which they concur that breastfeeding benefits mothers and their infants in both developed and developing countries, for at least the first year of life. However, in Canada and the United States, the proportion of women breastfeeding declines dramatically within the first month postpartum (Ellis & Hewat, 1984; Goodine & Fried, 1984; Gray-Donald, Kramer, Munday, & Leduc, 1985; Houston, 1981; Janke, 1988; Kearney, Cronenwett, & Barrett, 1990; Mogan, 1986; Yeung, Pennell, Leung, & Hall, 1981).

Maternal benefits of breastfeeding include enhanced uterine involution, consequent decreased puerperal blood loss, as well as increased convenience, enhanced attachment to the infant, and decreased cost (Dix, 1991). Possible

long term benefits include a protective effect against breast carcinoma. Infant benefits include decreased illness rates, consequent hospitalization, and allergies (Dix, 1991; Humenick & Van Steenkiste, 1983; Newman, 1992). Numerous studies have linked breastfeeding specifically with lower prevalence of respiratory illness, otitis media, and meningitis (Cunningham et al., 1991). In most circumstances breastfeeding offers the perfect balance of nutrients for normal infant growth and development (Beske & Garvis, 1982).

Since the 1980's, the prevalence and mean duration of breastfeeding have increased (Goodine & Fried, 1984; Yeung et al., 1981). The proportion of low income women lags behind that of middle and upper income women in both initiation and duration (Hawkins, Nichols, & Tanner, 1987; Yeung et al., 1981). A study of low income women participating in the Women, Infants and Children Program (WIC) reported that 40% were breastfeeding in hospital, but only 28% were breastfeeding by two months postpartum (Hawkins, et al., 1987).

Factors associated with early weaning in both lower and middle/upper income women include decreased satisfaction with breastfeeding, an irritable baby, perception or fear of insufficient milk, and painful breasts and nipples (Goodine & Fried, 1984; Humenick & Van Steenkiste, 1983; West, 1980; Yeung et al., 1981). Lower income women also reported that discouragement from family, and lack of confidence shortened

their intended duration of breastfeeding (Beske & Garvis, 1982; Hawkins, et al., 1987; Loughlin, Clapp-Channing, Gehlbach, Pollard, & Mecutchen, 1985). Identifying effective treatment to decrease early breastfeeding discomfort could increase and sustain breastfeeding prevalence at all socio-economic levels.

Nipple soreness has been reported in 33% to 96% of postpartum women (Chapman, Macey, Keegan, Borum, & Bennett, 1985; Ziemer, Paone, Schupay, & Cole, 1990). L'Esperance (1980) reported that 35% of her sample experienced moderate to extreme nipple discomfort. Nipple pain is most prevalent within the first week postpartum (Chapman et al., 1985; Graef, McGhee, Rozycki, Fescian-Jones, Clark, Thompson, & Brooten, 1988; Hewat & Ellis, 1987; Ziemer et al., 1990) and can last up to one month (Mogan, 1986). The resulting pain and frustration can lead to premature weaning (Ellis & Hewat, 1984; Feinstein, Berkalhamer, Gruszka, Wong, & Carey, 1986; L'Esperance, 1980; Mogan, 1986; West, 1980), and suppress the milk ejection reflex which in turn can decrease milk production (Woolridge, 1986). A frequent reason for cessation of breastfeeding within one month postpartum is lack of milk, or fear that milk production is inadequate (Clark & Beal, 1982; Ellis & Hewat, 1984; Feinstein et al., 1986; Hawkins et al., 1987; Simopoulous & Grave, 1984; West, 1980; Yeung et al., 1981).

Various interventions have been used to treat sore

nipples, including application of colostrum, ointments, warm wet compresses, and wet tea bags. Some of these have not been evaluated adequately and their use has been based on ritual and anecdotal support, rather than appropriate randomized trials.

Application of warm wet tea bags has been used in Winnipeg for over fifteen years. How this intervention became popular is unrecorded, and its continuation has been the result of favourable anecdotal reports. However, use of tea bags for this purpose is open to question due to lack of evidence of its efficacy or for that matter, that the intervention does no harm.

Tea bags are relatively inexpensive and easily obtainable as a treatment for sore nipples. A study evaluating the effectiveness of this common treatment was undertaken. As it is not known if the healing effect of the tea bag is due to the contents of the tea bag, or to the compress effect, tea bags and warm water compresses were evaluated and compared.

## Purpose

The purpose of this study was to evaluate the effectiveness of warm compresses and moistened tea bags, in treatment of sore nipples postpartum. Breastfeeding primiparous women experiencing nipple pain were recruited in hospital, and randomly assigned to treatment groups.

## Conceptual Framework

Prompt identification and effective treatment of nipple soreness could intercept certain events that could result in early weaning. Prevention of early weaning benefits maternal and infant health. The primary objective of preventive care is to oppose or intercept causes that impair individual health (Leavell & Clark, 1965; Shamansky & Clausen, 1980). Treatment regimens are included in the concept of prevention.

Infant positioning, frequency and length of feeds, nipple care, and prevention of engorgement, are primary strategies identified to prevent early weaning, but not tested by this study.

Secondary prevention is best accomplished by early diagnosis and prompt treatment (Leavell & Clark, 1965; Shamansky & Clausen, 1980). Its objectives are to cure or arrest disease or disability in time to prevent complications and prolonged disability. These objectives would be met if treatment of nipple irritation prevented further complications such as severe pain, cracking, bleeding, inadequate milk ejection and ultimately premature weaning.

Tertiary prevention is used with fixed disability (Shamansky & Clausen, 1980) to allow optimal use of the individual's remaining capacities (Leavell & Clark, 1965). Rehabilitation is its goal, assisting the individual to

reach the highest level of health possible given an unremitting situation (Shamansky & Clausen, 1980). This concept applies to postpartum women who continue to experience significant nipple pain despite use of all treatment options. In such circumstances, weaning may be prescribed as the best or only solution. Strategies that will help such women achieve the highest attainable level of health for themselves and their infants might include instruction about proper formula preparation, care of engorged breasts, and opportunities to share their feelings about their breastfeeding experience.

Primary prevention of breastfeeding disruption involves and teaches strategies to encourage, assist, and sustain breastfeeding. Secondary prevention identifies early feeding problems and treats them effectively and promptly. Tertiary prevention should be applied when breastfeeding has been or must be discontinued due to unremitting difficulties.

Treatment of sore nipples is a secondary prevention strategy. This study compares two specific secondary prevention strategies for breastfeeding women experiencing sore nipples. The results and discussion address whether these treatment choices are appropriate for breastfeeding mothers experiencing nipple discomfort postpartum.

## Research Questions

This study's questions focused on the first to fifth postpartum day and were as follows:

1. Does application of tea bags decrease nipple soreness significantly in breastfeeding primiparous women?
2. Does application of warm compresses decrease nipple soreness significantly in breastfeeding primiparous women?
3. Is there a significant difference between the effect of these two treatments?
4. Is there a relationship between frequency and duration of feedings and nipple soreness?
5. Is there a relationship between objective nipple damage and subjective nipple soreness?

## Definitions

The three key variables of this study were defined as follows:

**Nipple soreness:** Intensity of pain reported by a breastfeeding woman on a rating scale.

**Breastfeeding frequency:** Number of feedings within a specific duration interval.

**Breastfeeding duration:** Number of minutes the infant suckles per feeding.

## Summary

This study focused on two options to treat nipple pain, a common problem in the first postpartum week, which can lead to early weaning, particularly insufficient milk

supply.

Using a secondary prevention framework, treatment with tea bags versus warm compresses was compared by randomized prospective application to primiparous breastfeeding women with sore nipples. Measured independent variables included frequency and duration of breastfeeding, and the dependent variable of nipple pain was measured by a subjective rating scale.

# CHAPTER II:

# LITERATURE REVIEW

## The healing properties of tea bags and compresses

Application of compresses to enhance wound healing has been used through the centuries. Warm compresses are alleged to promote healing by improving blood flow to the injured body part, and promoting movement of waste products and nutrients. Warmth also promotes comfort (Potter & Perry, 1993).

Graham (1992) reported that tea is the most widely consumed beverage aside from water and outlines its composition and chemistry. Tea composition varies with climate, season, and techniques used during harvesting. The three most common forms of tea are green tea, black tea, and oolong tea. One of its most significant components are catechins. These substances have astringent properties and play a major role in oxidation. Graham (1992) concluded that in spite of research, knowledge of the composition of tea is incomplete.

Tea and its components have been studied variously. Tannic acid has inhibitory effects against herpes simplex virus (Rodu, Russell, & Mattingly, 1991). Tannic acid has been identified as an effective debridement agent for root canals (Bitter, 1989). Tannic acid has also been shown to be a dentine conditioner, making its collagen more resistant to tryptic digestion (Okamoto, Heeley, Dogon, & Shintani,

1991). Epigallocatechin gallate, the main constituent of green tea, is a practical cancer chemopreventive agent in mice. It is a non toxic compound that inhibits tumour production on mouse skin (Fujiki et al., 1992).

**Benefits of Breastfeeding**

Maternal benefits of breastfeeding include and are not limited to enhanced closeness of mother and infant (American Academy of Pediatrics, 1978; Freed, Landers, & Schanler, 1991; NAACOG, 1991; Sweeney & Gulino, 1987), increased convenience, decreased blood loss, and decreased cost (Dix, 1991). That it may offer some protection against subsequent breast carcinoma has been alleged but the evidence is controversial.

Infants benefit from breastfeeding in diverse ways. Breastfeeding offers infants optimal nutrition for normal growth and development (American Academy of Pediatrics, 1978; Beske & Garvis, 1982; Sweeney & Gulino, 1987). The composition of human milk changes as lactation progresses to meet the changing nutritional needs of a growing infant. Certain of its components provide breastfed infants with specific advantages. Lipase aids digestion of human milk fats (NAACOG, 1991). High cholesterol levels may foster neural myelination (American Academy of Pediatrics, 1978; NAACOG, 1991).

An early advantage of breastfeeding is that colostrum ingestion colonizes the infant's bowel with bifidus flora.

These bacteria provide significant protection against pathologic protozoa and enteropathic bacteria. Mature breast milk (that is, produced after colostrum) continues to protect the infant immunologically. Maternal immunoglobulin IgA protects against various bacteria and viruses within the infant's intestinal tract preventing micro-organisms from passing through the intestinal wall (American Academy of Pediatrics, 1978; Cunningham et al., 1991; NAACOG, 1991).

Breastfeeding reduces allergic sensitization by delaying introduction of allergens contained in solid foods (Cunningham et al., 1991; Freed et al., 1991; Sweeney & Gulino, 1987). Breastfed infants have lower prevalence of respiratory and gastro-intestinal infections, as well as otitis media (Cunningham et al., 1991; Freed et al., 1991; Sweeney & Gulino, 1987).

In conclusion, there is sufficient evidence regarding the benefits of breastfeeding to warrant health professionals support and promotion of breastfeeding.

## Factors Relating to Breastfeeding Duration

Numerous parameters, one of which is nipple soreness influence breastfeeding duration. These will be presented as they interact with presence or absence of sore nipples in this context.

### Sore Nipples

One of the most common problems identified by women as contributing to early weaning is nipple pain. Marx,

Izquierdo, Driscoll, Murray, and Epstein (1985) reported that 60% of women suffer from sore nipples postpartum, whereas Ziemer et al. (1990) and Clark (1985) reported prevalences of 96% and 90%. Whitley (1978) studied evolution of nipple soreness and identified that 83% of subjects who breastfed for less than six weeks reported nipple pain compared with 41% who breastfed for over 24 weeks. Similarly, West (1980) and Rentschler (1991) reported that sore nipples lead to early weaning. Beske and Garvis (1982) reported that breast and nipple tenderness were frequent at one month postpartum. For some women these problems persisted until 6 months postpartum or weaning. Goodine and Fried (1984) found that between three and six months postpartum, 20% of subjects reported mastitis or cracked nipples. Chapman et al. (1985) found that women still complained of sore nipples three months postpartum. Graef et al. (1988) found that 57% had nipple pain and blisters four weeks postpartum. Yeung et al. (1981) cited sore nipples and infection as primary reasons for weaning. In contrast, Hall (1978) found sore nipples in all of her subjects regardless of the number of weeks they nursed their infants. However, none of her subjects rated this as a major problem. Conversely in the studies by Ellis and Hewat (1984), and Kearney et al. (1990), sore nipples were the most commonly identified postpartum difficulty, and were rated as a major problem.

The differences between these results could have arisen in a variety of ways. Hall (1978) was involved in teaching two-thirds of her subjects. The nature of that instruction was not specified, but a portion of subjects may have been advised or may have inferred that sore nipples were transitory and nothing to worry about. The other authors identified problems that their subjects had experienced without co-interventions of teaching strategies and support.

Nipple pain is primarily due to early postpartum skin changes. This evolution was studied by Ziemer and Pigeon in twenty caucasian lactating women using pain ratings and a series of photographs of each subject taken on postpartum day one, three, five, and seven. Ninety percent of subjects experienced nipple pain and 100% had nipple and areolar skin changes and edema. Both edema and pain ratings were highest on days three and five. The observed skin changes were similar in all subjects. There were no statistically significant differences between women of differing skin tone. Some healing was evident by day seven, but healing was not yet complete.

The authors recommended identification of effective treatments for nipple soreness. Study limitations were small sample size, lack of correlation with nipple damage, and lack of specification of treatments or controls.

**Insufficient Milk**

Goodine and Fried (1984) stated that 50% of women

weaning their infants within one month reported perception of insufficient milk as their primary reason. Feinstein et al. (1986) reported that 45% of subjects had weaned for that reason. Yeung et al. (1981) identified that the greatest proportion of weaning was during the first postpartum month and that perceived lack of milk or fear of lack of milk was the primary reason. Maternal perception of insufficient milk was reported as a major problem by Ellis & Hewat (1984). Loughlin et al. (1985) and Mogan (1986) found that mothers expressed concerns about amount of breast milk into the second and fourth postpartum month respectively. Primiparous women who weaned prior to six weeks postpartum were less knowledgable about their production and supply of breast milk than those who breastfed longer (Rentschler, 1991).

Graef and colleagues (1988) reported that mothers are also concerned about frequency of feeding. This concern is paired with the notion of insufficient milk. Simopoulos and Grave (1984) identified that 48% of lactating women are concerned about adequate milk supply. Brousseau and Langer (1991) and Cerutti (1981) found nipple pain and perception of insufficient milk to be commonly associated postpartum. The two difficulties are interrelated in that unresolved nipple pain can cause milk production to decrease by suppressing the milk ejection reflex (L'Esperance, 1980).

**Demographic Variables**

Education beyond high school and higher incomes are associated with increased choice and longer duration of breastfeeding (Buxton, Gielin, Faden, Brown, Paige, & Chwalow, 1991; Clark & Beal, 1982; Feinstein et al., 1986; Goodine & Fried, 1984; Grossman, Fitzsimmons, Larson-Alexander, Sachs, & Harter, 1990; Houston, 1981; Rentschler, 1991; and Simopoulos & Grave, 1984; Yeung et al., 1981). Reasons cited by younger, less advantaged women for not breastfeeding include anticipated inconvenience, embarrassment, and discomfort (Dix, 1991). Low income women also report discouragement from family, lack of confidence, and fear of insufficient milk, as factors that shorten their breastfeeding duration (Beske, & Garvis, 1982; Hawkins, et al., 1987; Loughlin, et al., 1985)).

It is unfortunate that less advantaged families resort to formula feeding more frequently as this results in a substantial drain of their economic resources. Ironically, families who can afford to formula feed more often choose not to. The income parameter is more evident in developed countries. In developing countries, advantaged families formula feed their infants for various reasons. They see formula feeding as more convenient, and nutritionally equivalent to or better than breastfeeding. These values may filter through to lower income women, causing them to question the value of breastfeeding. In these countries

there is also the problem of overdilution and contamination of formula. The end result may be increased poverty and illness for these families (Houston, 1981).

Women who receive more information about breastfeeding are more likely to choose breastfeeding over bottle feeding (Matich & Sims, 1992).

Yeung et al. (1981) found that 55.6% of women with high school education and 80.1% with university education breastfeed. In contrast Hall (1978) found success with breastfeeding to be unrelated to education. However as outlined earlier, her sample size was 40 and she intervened with 28 (70%) of her participants which could have biased her results.

Support from friends and family may influence mothers' infant feeding decisions. The infant's father is usually the most influential person (Beske & Garvis, 1982; Coreil & Murphy, 1988; Grossman et al., 1990; Matich & Sims, 1992).

Grossman et al. (1990) studied upper and lower income women and the basis for infant feeding decisions. Lower income women who chose to breastfeed were similar in medical and social descriptors, but more closely resembled upper income women in their availability of social support.

Discouragement of breastfeeding by members of a woman's social network may influence duration of breastfeeding. In one study, women who breastfed for less than three months had received more discouragement than women who breastfed

for a longer period. All subjects received increasing discouragement the older their infant became, most often from grandmothers, husbands, and other family members. Specific discouragement focused on milk supply adequacy and infant satisfaction with breastfeeding (Beske & Garvis, 1982).

Yeung et al. (1981) and Goodine and Fried (1984) both identified that non-smokers were significantly more likely to nurse for an extended period than smokers. Feinstein et al. (1986) reported that more non-smokers than smokers breastfed their infants. Clark and Beal (1982) and Feinstein et al. (1986) found that older mothers were more likely to breastfeed, and Beske and Garvis (1982) found longer duration of breastfeeding among older women. In contrast, Goodine and Fried (1984) found age to be unrelated to breastfeeding duration. In summary, older, non-smoking women in higher income brackets having advanced education, choose to breastfeed and do so for longer than women without these attributes.

**Formula Supplements**

The use of formula supplements during early breastfeeding has been identified as a possible contributor to early weaning (Bergevin, Dougherty, & Kramer, 1983; Beske & Garvis, 1982; Coreil & Murphy, 1988; Feinstein et al., 1986; Frank, Wirtz, Sorenson, & Heeren, 1987; Goodine & Fried, 1984; Newman, 1992; Snell, Krantz, Keeton, Delgado, &

Peckham, 1992; Whitley, 1978). Bergevin et al. (1983) studied 406 women randomly assigned to receive or not receive a formula gift pack at discharge. Follow up was done by telephone three months postpartum by a nutritionist blinded to the mothers' treatment group.

Receipt of formula samples was not associated with statistically significant differences in breastfeeding duration among healthy, well educated, multiparous women. In contrast, women who were less educated, primiparous, and reported illness postpartum, had significantly shorter duration of breastfeeding when they received formula samples.

Similar outcomes were found by Frank and her colleagues (1987) who studied the effects of enhanced breastfeeding counselling and provision of formula gift packs in a group of low income women. All subjects received a gift pack, half of them being routine formula gift packs and the other half being gift packs without formula, and containing breastfeeding information that was consistent with World Health Organization (WHO) code of breastfeeding. Random assignment of the two interventions produced four treatment groups:

- enhanced education and gift pack consistent with WHO code regarding breastfeeding;
- enhanced education and routine formula gift pack;
- routine education and routine formula gift pack; and

- routine education and gift pack consistent with WHO code regarding breastfeeding.

Telephone follow up was carried out at four months postpartum by a nutritionist blinded to the treatment groups. Enhanced breastfeeding education produced no measurable effect. Women who had received the WHO pack were more likely to prolong exclusive breastfeeding, to be still partially breastfeeding at four months, and to delay use of solid foods.

Snell et al. (1992) studied the relationship between distribution of formula samples and breastfeeding duration in low income Hispanic women. Data was gathered at one and three weeks postpartum by telephone. No differences were observed in exclusive breastfeeding at one week postpartum, whereas at three weeks postpartum, women who had received formula had significantly lower rates of exclusive breastfeeding.

Gray-Donald et al. (1985) assessed the impact of formula supplementation on duration of breastfeeding and found that it did not cause discontinuation but could be a marker predicting early weaning. Hawkins et al. (1987) found supplementation common in low income mothers who weaned by four weeks postpartum, but identified early introduction of solids as a stronger threat to sustained lactation than formula supplementation.

**Prenatal Intent to Breastfeed**

Breastfeeding duration is influenced by the timing of the mother's choice of it. Goodine and Fried (1984) reported that women who decided to breastfeed prior to pregnancy nursed their infants for a mean of 9.5 months, whereas women who made the decision during pregnancy breastfed for an average of 7.9 months, a statistically significant difference. Similarly, Coreil and Murphy (1988) identified timing of prenatal intent as the strongest predictor of breastfeeding duration.

Women who planned to breastfeed but never initiated it or quit within the first week were found to have made their choice late in pregnancy, to have less confidence in their ability, and to report positive attitudes to formula (Buxton, et al., 1991).

**Research Design Critique**

The studies presented above dealt with reasons for initiation and termination of breastfeeding. In many, results were gathered over 12 to 18 months (Beske & Garvis, 1982; Clark & Beal, 1982; Coreil & Murphy, 1988; Feinstein et al., 1986; Goodine & Fried, 1984; Hawkins et al., 1987; West, 1980; Whitley, 1978; Yeung et al., 1981;). Buxton et al. (1991), Loughlin et al. (1985), Bergevin et al. (1983), Rentschler, 1991, Gray-Donald et al., 1985, and Frank et al. (1987), collected information from one to four months postpartum, to minimize temporal bias. Many studies were

retrospective, introducing potential for inaccuracy from recall bias.

Result contamination can occur if subjects in different treatment groups share information, which threatens a study's internal validity. Bergevin et al. (1983) avoided this by giving formula sample subjects their gift pack as they were leaving the hospital. In contrast, Frank et al. (1987) did not control for contamination as women in the same hospital room were allocated to different treatment groups.

Simopoulos and Grave (1984) criticized studies on breastfeeding initiation and termination which failed to control for socio-demographic characteristics influencing its success including age, socioeconomic status, parity and education. Randomization would control for confounding factors but is difficult when most subjects are self selected, and this type of design limits generalizability of results.

Specifically conducting studies with groups of low income women (Frank et al., 1987; Hawkins et al., 1987) assists in identifying variables that influence infant feeding decisions among women with different demographic characteristics.

Questionnaires were completed by participants or through telephone interviews. Return rates ranged from 70-88%. As no studies used the same measurement tools,

comparisons between them are both difficult and questionable. Coreil and Murphy (1988) noted attrition of younger primiparas and less educated members of their sample which could have biased their results.

Study sample sizes varied greatly, from 456 (Clark and Beal, 1982) to 34 (Whitley 1978).

A common definition of breastfeeding duration was not used. Some authors specified duration in days whereas others used months. Some do not give any definition of duration, and definitions were inconsistent as well for breastfeeding frequency and exclusivity. Many studies examined breastfeeding success, but none defined it in similar terms. Due to all of these discrepancies, comparability and generalizability of results is doubtful.

## Prevention of Nipple Pain

Empirical but unsupported advocacy on prenatal nipple preparation dates back to the 19th century. Chavasse (1879) identified that sore nipples are common postpartum, and suggested preventive toughening of nipples by washing them during pregnancy with eau de cologne or equal parts of brandy and water. Jellett and Madill (1929) advised women to rub lanolin into their nipples twice a day and gently draw them out without force. More recently, Brown and Hurlock (1975) randomly assigned 57 women to one of three methods of prenatal nipple conditioning (nipple rolling, expression of colostrum, or application of Masse cream

{TM}). Their sample included women from different racial groups, all breastfeeding for the first time, who served as their own controls by only preparing one nipple. Subjective nipple soreness was reported by each subject and assessed objectively by blinded examination for ten days postpartum. No significant difference was found subjectively or objectively between sides or among the three methods. The authors concluded that prenatal nipple preparation did not prevent soreness postpartum.

In contrast, Atkinson (1979) found that in a sample of 17 women acting as their own controls, less pain was reported in the prepared nipple (gentle rubbing, nipple rolling, and airing nipple). Storr's (1988) group of 25 women also prepared one nipple prenatally (gentle rubbing and nipple rolling). There was significantly less subjective soreness on the prepared side, but all subjects expected preparation would have this effect. This inherent expectation bias threatens reliability and validity of conclusions of these study designs particularly with subjective measurements, although Storr reported that objective assessments were consistent with the subjective evaluations.

A study by Hewat and Ellis (1987) failed to support nipple preparation. The authors found that 83% of women who had prepared their nipples experienced tenderness. L'Esperance (1980) evaluated prenatal nipple preparation as

ineffective in a study of factors correlated with nipple damage.

Limiting time at the breast in the first few days has been suggested to prevent nipple soreness. However, three studies demonstrated that frequency and duration of feeding does not increase prevalence or severity of nipple pain (De Carvalho, Steven, & Klaus, 1984; L'Esperance, 1980; and Whitley, 1978). In spite of the lack of supportive evidence, many health professionals continue to advocate limiting time at breast during the first few days.

Newton (1952) suggested that limiting nursing time could lead to engorgement and that a baby learning to nurse could not feed well from an engorged breast. Storr (1988) studied prevention of engorgement with unilateral breast self-massage, four to five times a day from delivery until day four postpartum. Breast massage prevented engorgement, but whether the baby nursed the same amount on both sides was not specified. L'Esperance (1980) identified that engorgement was associated significantly with nipple pain. Several authors advocated unlimited nursing time as the best method to prevent engorgement and hence nipple soreness (De Carvalho et al., 1984; Riordan & Countryman, 1980; Lauwers & Woessner, 1983).

"Conventional wisdom" has suggested that fair skinned, blonde and redheaded women are at higher risk of nipple pain and damage postpartum. Gans (1958) had this impression in a

study of 1,027 subjects, however admits that this impression was not tested statistically. Studying nipple preparation, Atkinson (1979) reported more pain in fair skinned women. Hewat and Ellis (1987) recorded subjects hair and skin color and concluded that they were not related to nipple tenderness. Brown and Hurlock (1975) and L'Esperance (1980) agreed. However, Ziemer et al. (1990) found that women with darker pigmentation had a higher incidence of postpartum nipple pain and hypothesized that health professionals may minimize or ignore trauma and pain in darker skinned women if they believe that such a cohort is at decreased risk of those consequences.

In summary, prenatal nipple preparation has been advocated for over one hundred years, but recent empirical evidence does not support it.

**Assessment of Nipple Pain, Prophylaxis and Treatment**

Newton (1952) compared six different nipple treatments' effects on pain and damage (alcohol, soap and water, plain water, vitamin A&D liquid concentrate {TM}, vitamin A&D ointment {TM}, and lanolin) using both subjective and objective measurements. To control for examiner bias, a second observer did random assessments, which correlated well with the primary investigator's assessments. However, not all mothers were assessed daily and some refused to comply with the regimen assigned due to dislike of it or development of nipple pain. These women

were excluded from analysis. Women in the alcohol and soap cohorts had more pain and visible damage than controls. Vitamin A&D concentrate {TM} was highly irritating to some and was associated with more nipple damage than controls. There were no significant differences between cohorts using Vitamin A&D ointment {TM} and lanolin, and controls. In summary, recognizing study limitations, no method was effective and some produced the problem rather than preventing it.

Gans (1958) conducted a similar study assigning three different preventive regimens, stilboestrol cream, silicone barrier cream, and water, to a sample of 1,027 women. Regimens were introduced one at a time for a period of four months each. This strategy increased internal validity by controlling for contamination (for example, subjects becoming aware of other treatments and perhaps trying them). Reported complications included engorgement (48%), pain (34%), cracked nipples (16%), and mastitis (2%). Forty-two percent of the sample had more than one complication. Gans concluded that none of the three interventions was preferable, as the frequency of complications did not differ significantly between treatments.

Riordan (1985) tested use of tea bags and lanolin for treatment of sore nipples in two different groups, self controlling by unilateral application. There was no significant difference in either group. It was concluded

that tea bags and lanolin do not prevent or reduce nipple soreness. However, this study had no objective assessment of nipple breakdown and the sample size was inadequate, with only three women in the tea bag group, and eight in the lanolin group.

Hewat and Ellis (1987) tested application of lanolin and self-expressed breast milk for the first 10 days postpartum. Each women used one intervention on each nipple, thus there was no control nipple, to which no treatment was applied. Subjective assessments of nipple pain were collected after each feeding using a four point scale. Objective assessments of nipple trauma were done four times by an investigator blinded to treatments. Neither treatment was superior. All women experienced some nipple trauma. Engorgement was positively and significantly associated with nipple trauma.

Expressed breast milk as treatment for sore nipples was also studied by Adcock, Burleigh and Scott-Heads (1988) who compared an experimental group of 60 women to 38 women on another ward offered topical applications currently in use in the facility. There was no control (no treatment) group. Subjective assessments revealed that 73% of mothers who used breast milk had no nipple problems or only initial tenderness compared with 47% of those who used standard topical applications, a statistically significant difference. There was no significant difference in

incidence of cracked nipples between groups. The groups had similar proportions of women who had prepared their nipples prenatally. The authors concluded that breast milk should be used to treat sore nipples as it is easily available, costs nothing, and appears to help.

Rotersept {TM} spray, composed of chlorhexidine and alcohol, has been used extensively in Great Britain for relief of nipple trauma and prophylaxis of mastitis. Its efficacy was compared to a control spray of distilled water (Herd & Feeney, 1986). Two hundred women participated, half in each treatment group. Nipple condition was assessed before hospital discharge, and weekly for four weeks, using a zero to five rating. The authors did not specify whether the score was assigned by the mother, or the investigator or whether the same investigator assessed each mother's nipples each week, or if the rater was aware of previous scores. There is no mention of score assignment to right versus left sides. The conclusion was that Rotersept {TM} spray decreased nipple trauma and discomfort more than the control spray.

Application of expressed breast milk was compared against treatment with Rotersept {TM} spray by Rickett (1986). Two groups ($N$=95) used one or the other treatment, assigned according to their hospital ward assignment. Objective assessment was carried out daily. Inter-observer reliability was unspecified. Twenty-seven percent of women

who applied breast milk developed cracked nipples compared with 20% of the group using Rotersept {TM} spray. There is no mention of whether this difference is statistically significant. Although there were no comments on nipple pain or other trauma, the author concluded that since the incidence of cracked nipples was similar in both groups, a change in local practice was warranted, as many women disliked the spray and preferred breast milk application.

Buchko, Puch, Bishop, Cochran, Smith, & Lerew (1994) studied effectiveness of three treatment regimens for nipple soreness prompted by lack of evidence supporting their facility's standard use of tea bag compresses.

Primiparous breastfeeding women were recruited in hospital and randomly assigned to apply, tea bag compresses, warm water compresses, expressed breast milk, or nothing. Subjects were instructed to use the treatment at least four times daily from first to seventh day postpartum.

Using visual analogue scales, participants rated intensity of infant's suck, intensity of nipple pain, and unpleasantness of nipple soreness daily. Highest pain intensity was reported on day three, and highest pain unpleasantness on day four. Throughout the study, the warm water compress group reported the least pain intensity and unpleasantness. The authors did not report pain ratings for the other two treatments, or the control group.

Nipple soreness was investigated over ten days by

Spangler and Hildebrandt (1993). Fifty-two women, all breastfeeding for the first time applied lanolin to one breast and nothing to the other. Nipple pain was similar for all participants with very little reported on the first day breastfeeding, with soreness peaking on day three to six, and diminishing for days seven through ten. There was no statistical significance between ratings of zero to three (no tenderness, to pain at start of feeding and nipple beginning to crack) using a modified version of Storr's (1988) five point scale. Statistically significant differences occurred at pain rating four (pain at start and during feed, and/or nipple cracked and bleeding). The authors concluded that lanolin is effective when used as a treatment but not effective for prophylaxis.

A quasi-experimental design was used by Clark (1985) to study four methods (sunshine and/or heat lamp and cream as desired by the mother, heat at least three times a day with no creams, vitamin A cream, or lanolin cream, used after each feeding) of nipple care in a sample of 114 women. A different method was used in each of four months to control for contamination. Results were collected by nurses caring for the patients thus bias could have been introduced if the nurses favoured one treatment over another. Second, validity is questionable, in the absence of measures of interobserver reliability. Ninety percent of the group experienced nipple irritation. Women who had prepared their

nipples prenatally had higher incidence of cracking and earlier weaning. The highest incidence of cracking was experienced by women who had applied dry heat. Those who were symptom free at discharge had used creams, especially lanolin. However, there was no statistical analysis, it is impossible to determine the study's reliability, validity, significance, or relevance.

Gosha and Tichy (1988) studied use of breast shells to treat sore nipples. They felt that use of a shell would decrease nipple discomfort by increasing exposure to air. Subjects served as their own controls, wearing the shell only on one side. Pain was assessed subjectively, but there were no objective assessments of tissue damage. There was no significant difference between the side treated with the shell and the control.

According to Marx et al. (1985), vitamin E cream is often recommended to nursing mothers in spite of the lack of evidence demonstrating its effectiveness. Serum concentration of vitamin E was measured in infants whose mothers were using it topically. Ten mothers were instructed to apply vitamin E from a capsule after every feeding for 3 days. Ten used either no treatment or lanolin. Adequacy of sample size was determined by power analysis. Infant serum vitamin E levels on day six were normal, but significantly higher in the experimental group than in the controls. The authors speculate that excessive

or prolonged use of this agent might result in potentially harmful effects in the newborn. They did not assess the efficacy of Vitamin E treatment.

In summary, various nipple treatments have been evaluated. The two treatments that have received favourable results are lanolin and expressed breast milk.

**Research Design Critique**

Using women as their own controls when testing an intervention helps avoid confounding variables such as feeding frequency, infant sucking behaviour, and maternal characteristics such as skin type, nipple preparation, attitude to breastfeeding, and nutritional status. Storr (1988), Hewat and Ellis (1987), Gosha and Tichy (1988), Spangler and Hildebrandt, (1993), and Riordan (1985) all made use of this design.

Data contamination is a potential problem when comparing different treatment regimes in cohorts exposed to each other. Gans (1958) and Clark (1985) controlled for this by introducing studied regimens at different times. In this way, all subjects were using the same method simultaneously. Adcock et al. (1988) and Rickett (1986) attempted to control for contamination by assigning different treatments to patients in separate hospital wards. Both authors did not state if women from the different wards had contact with one another. Newton (1952), Buchko et al. (1994), and Herd and Feeney (1986) do not specify if

data contamination was controlled.

One potential confounding variable is positioning of baby at breast. Appropriate positioning is one key to prevention of sore nipples (Woolridge, 1986; Minchin, 1989). Positioning was assessed by L'Esperance (1980) and taken into account when results were analyzed, in contrast to Storr (1988), Hewat and Ellis (1987), Gans (1958), Riordan (1985), Newton (1952), Clark (1985), Rickett (1986), Adcock, et al. (1988), Spangler and Hildebrandt (1993), Gosha and Tichy (1988), Herd and Feeney (1986), and Buchko et al. (1994).

Study sample sizes varied widely. Gans (1958) had the largest sample of 1,027 women. Newton (1952) studied 287 subjects, and the remainder assessed samples ranging from 11 to 114. Only one study mentions use of power analysis to determine appropriate sample size (Marx et al., 1985). No author discussed the process of choosing which breast would be experimental and no evidence of randomization of sides exists. Thus, factors such as handedness might bias assignment, positioning, and results, as could more subtle maternal side preferences.

A variety of scales were used to assess nipple pain and damage. These had some similarities, but varied from three to five point formats. Studies that relied solely on mothers' subjective assessments, such as mothers' conscious or unconscious preference for one treatment regimen, incur

problems with reliability and validity, (Gosha & Tichy, 1988; Riordan, 1985; Spangler & Hildebrandt, 1993). Studies using subjective and objective assessments (Clark, 1985; Hewat & Ellis, 1987; Newton, 1952; Rickett, 1986; Storr, 1988) tend to be more reliable and their results may be generalized with greater confidence.

## Summary

Sore nipples are a problem for many nursing mothers from the early postpartum period and potentially lasting for many months. Many treatments have been suggested, some reasonably well studied, but in general, results should be interpreted and applied with caution due to subjective assessment methods and small sample sizes.

This review supports use of expressed breast milk to treat sore nipples postpartum. This substance is at least as effective as lanolin, free, physiologic to mother and newborn, and easily obtained and applied.

Some health professionals advocate use of moistened tea bags to sore nipples, but this intervention has been evaluated only twice, once by Buchko et al. (1994), and once by Riordan (1985), in a completely inconclusive sample of only three women. It is appropriate that this commonly advocated intervention be evaluated for evidence of its effectiveness.

# CHAPTER III:

# METHODOLOGY

## Introduction

The purpose of this study was to evaluate two treatment regimens for sore nipples. Some health care professionals recommend application of moistened tea bags as therapy for this situation. While anecdotal reports suggest that this is effective, acceptable evidence is lacking. If there is a healing effect, it is not known if that is due to the contents of the tea bag or to the warm compress effect. In this study, the effect of tea bags were compared to that of warm compresses, as well as to no treatment to determine if either intervention was effective.

## Research Design

This experimental study used randomized single blinded balanced incomplete block design. The three study cohorts used tea bag compress, warm water compress, or no treatment. Each subject served as her own control, applying two different treatments to each of her nipples. Treatment and right or left nipple assignment were randomly allocated by having each subject chose an envelope that contained information regarding her specific therapy.

Since there were three study groups and subjects had two sites for application, an incomplete block design was chosen. This method is useful when it is not practical or possible to apply all treatments to every subject (Hicks,

1973). It was not possible to blind recruits to the interventions, but the investigator was blinded to treatment.

Power analysis was conducted with the assistance of a statistician. It was concluded that a sample of 20 subjects per group would provide:

- a 98% chance of seeing a large effect size,
- a 50% chance of seeing a moderate effect size, and
- a 11% chance of seeing a small effect size.

Sixty-five women were recruited and randomized to treatment groups. Within each group, two interventions were carried out by the recruits, one on each side. The interventions were equally and randomly applied to right and left nipples (Table 1) to avoid or reduce handedness bias and other unrecognized side biases.

**Table 1**

**Number of Subjects per Treatment Group**

| Groups | Treatments | | |
|---|---|---|---|
| | Tea Bags | Compress | Nothing |
| #1 n=21 | n=10 left | n=10 right | |
| #2 n=22 | | n=11 left | n=11 right |
| | | n=11 right | n=11 left |
| #3 n=22 | n=12 right | | n=12 left |
| | n=10 left | | n=10 right |

According to Hicks (1973), the following results can be extracted from this design.

b= # blocks or # people; b= 65

t= # treatments; t= 3

k= # treatments per block k= 2

r= # replications of given Tx r= 43

N= total # observations, bk N= 130

$\lambda$ = # times each pair or Tx appears together, $\lambda$ = 21.5
$\lambda$ = r (k-1)/(t-1) = 43(2-1)/(3-1)

## Analysis

Since three cohorts subjectively measured nipple soreness over time, the results were analyzed by repeated analysis of variance (Shott, 1990).

Null hypotheses were as follows:

1. Application of moistened tea bags after feeding does not decrease nipple soreness.
2. Application of warm compresses after feeding does not decrease nipple soreness.
3. There is no significant difference in nipple soreness between women using moistened tea bags and those using warm compresses.
4. There is no relationship between frequency and duration of breastfeeding and nipple soreness.
5. There is no relationship between objective and subjective measures of nipple soreness.

Rejected null hypotheses, were subjected to multiple comparison tests to determine differences between means (Shott, 1990). Frequency and duration of breastfeeding were analyzed as independent variables to identify association between them and nipple soreness as the dependent variable. Subjective and objective ratings of nipple soreness and breakdown were correlated.

## Protection of Subjects' Rights

An invitation to participate was provided to eligible candidates specifying the study purpose and outlining what

they were requested to do (Appendix A), as well as potential risks and benefits of participation. Confidentiality and anonymity were guaranteed by identifying participants only by number. The investigator kept a confidential master list with subjects' names and participant numbers. Invitation to participate included the investigator's phone number (24 hour access) as well as that of her advisor. Subjects were encouraged to call if they had any questions.

Participants were asked to sign a consent (Appendix A) which was kept by the investigator in a locked cupboard. All results will be stored for seven to ten years as recommended by the University of Manitoba Ethics Committee, then destroyed.

Access to mothers' and infants' charts was obtained to determine delivery type, episiotomy, and analgesic use.

## Population and Setting

Since painful nipples are common in the early postpartum period, recruitment occurred soon after delivery. Access to postpartum patients was granted by St. Boniface General Hospital, a Level III Perinatal Intensive Centre with approximately 4200 births per year.

A convenience sample was selected using the following eligibility criteria:

- primiparas who had chosen to breastfeed;
- gestation 37 weeks or more;
- mother and infant in Integrated Family Centered Care

Unit (IFCC);

- maternally graded nipple soreness as 1, 2, or 3 (Appendix B);

- vaginal delivery;

- mother did not have inverted nipples.

Primiparous women were selected to minimize experience bias from past used treatments for sore nipples. Infants born at gestational age over 37 weeks were chosen to minimize co-variables related to prematurity including feeding and sucking behaviour, endurance, and maternal psychologic and biologic reactions to preterm birth.

IFCC eligibility was chosen to confirm newborn health and provide a standard rooming in environment.

Vaginal delivery was chosen to avoid co-variables such as post-surgical pain, difficulty with positioning, and affective consequences of surgical delivery.

Women with inverted nipples were excluded because that feature may cause trouble initiating breastfeeding and such women might not experience tenderness within the same interval as those with everted nipples.

Since the prevention methods were of secondary type, sore nipples were a required entry criterion.

## Procedure

Women meeting the inclusion criteria were identified by ward staff by chart review. Within 24 hours of their delivery, staff nurses asked eligible mothers for their

permission to be interviewed by the investigator (N.L.). Women who consented were identified on a list left for the investigator at the nursing station. The investigator met with each recruit, explained the nipple soreness rating scale to her (Appendix B), and asked her to use it. If discomfort was rated as 1, 2, or 3, the study was explained and they were invited to participate. After informed consent had been obtained (Appendix A), participants were randomly allocated to treatment options, and right, left assignments by sealed envelope method.

Each recruit selected an envelope whose number became the participant's identification number, and was recorded on her data collection forms, demographic questionnaire (Appendix C), and the five nipple soreness rating sheets. This maintained anonymity of all subjects. The secured master list with all participant numbers and treatment regimens, was used only for result analysis.

The demographic information (Appendix C) was recorded by the investigator during an interview of maximum length of ten minutes. Following the interview, missing information was obtained by chart review.

The investigator assessed and recorded (Appendix D) the condition of the participant's nipples following the interview. Subjects were asked to open and read the treatment instructions, told not to tell the investigator what their group assignment was, and provided with the

needed supplies (breast pads, tea bags, or both).

On the morning of postpartum day two, or at discharge (whichever came first), the investigator re-assessed and recorded the subjects' nipples' condition (Appendix D). The morning of day two was chosen as most subjects were discharged on that day. Subjective and objective assessments were analyzed using Spearman's correlation coefficients, to identify any relationship between subjective discomfort and objective evidence of tissue damage.

Before discharge, the investigator provided participants with the supplies needed to continue the same treatment at home. At this time the investigator inevitably became aware of the participants' assigned treatment group. A stamped addressed envelope was provided for the subject to return her nipple soreness rating scales.

On day three, the investigator phoned subjects at home, or saw them if they were still in hospital, to answer any questions and respond to conflicting advice the mother may have received from friends or health professionals.

## Treatment Instructions

Written instructions were given to each mother covering the protocol to which she had been assigned (Appendix E), each of six designed to complement the three treatment groups. Tea bag assigned recruits were supplied with Red Rose {TM} tea bags for the tea bag treatment, and breast

pads provided for use by compress group. Recruits were asked to apply assigned treatments after every feeding beginning 24 hours postpartum until the end of the fifth postpartum day.

## Instrument

The nipple soreness rating scale used was published by Storr (1988). She stressed that subjective measurements are more important in this context than objective ones as mothers' perception of soreness is more likely to influence their continuation of breastfeeding than second party objective assessment.

Instrument reliability can change over time and between populations. Storr (1988) first used her scale in 1987, evaluating the effectiveness of prenatal nipple preparation on early postpartum discomfort in primiparous breastfeeding women. Sample characteristics were similar to those of the sample obtained for this study.

Because the degree of discomfort is likely to change during the early postpartum period, examining the stability of the scale is unnecessary (Polit & Hungler, 1987).

Validity refers to how well an instrument measures what it is designed to measure (Polit & Hungler, 1987). Content validity is based on judgment. Storr's scale used words and phrases describing subjective feelings of breastfeeding women. When this scale was shown to women who had previously breastfed, they agreed with the phrases used,

confirming face validity.

The subjects were asked to rate their nipple discomfort during the initial interview, which allowed the investigator to verify their understanding of the scale. Any questions were answered and further explanation provided if necessary.

Subjective assessment is limiting but appropriate as pain is inherently subjective as are the perceptions which determine breastfeeding duration. Objective assessments by the investigator were done twice, to explore the relationship between objective and subjective measures.

## Data Collection

Following every feeding and treatment from 24 hours postpartum until the end of day 5, recruits recorded feeding duration, nipple soreness, and whether or not treatment was carried out.

The investigator assessed subjects' nipples twice for each recruit, once at recruitment and once on the morning of day two or at time of discharge whichever came first, according to the following scale:

0 - normal colour

1 - reddened

2 - cracks visible

At discharge, the investigator ensured recruits had their reporting forms and a stamped envelope addressed to the investigator. Questions were answered and a supply of treatment items provided. The investigator confirmed that

all participants knew how to contact her if they had questions or concerns. The investigator contacted each subject on day three to answer their questions and again, during their second postpartum week to inquire if they had been able to complete the study and had mailed their information.

## Pilot Test

Pilot tests are recommended to discover defects in methodology and instruments (Brink & Wood, 1989; Polit & Hungler, 1987). This study was piloted to rule out method and instrument defects with six recruits. Pilot subjects were asked to comment on the invitation to participate, consent, interview, instructions, nipple assessment sheets and asked to offer their thoughts and feelings about the study protocol.

Six women were recruited for the pilot study, one in each treatment group. Their ages ranged from 16 to 31, with a mean of 26.3. All recruits lived with their partners, except for the 16 year old, who lived with her parents. Five of the six had some university or community college education, whereas the youngest was in high school. All had decided to breastfeed before pregnancy or early in that pregnancy. Five out of six were able to complete the study. One was unable to follow the protocol as a result of her reaction to information received in hospital that her baby had dextrocardia.

The pilot group offered no comments on the consent form or interview. No subject was able to perform the assigned treatment after every feeding. Subjects applied treatment as often as possible, on average four times per day. Using the five point nipple soreness scale (Appendix B), three women rated their soreness as 1.5 because neither 1 nor 2 described their soreness adequately.

Subject recruitment for the pilot study was more difficult than anticipated. Whereas recruitment was to be at less than 24 hours postpartum, many women who were eligible were not yet experiencing nipple soreness.

Objective assessments were carried out using a three point scale developed by the investigator. Subsequently, the investigator determined that that scale did not allow enough options to grade and describe visible nipple damage.

Once the pilot was completed the study protocol was modified as follows:

1) Subjects would be recruited within 36 hours of delivery (Appendix F).

2) Subjects were asked to perform treatment at least four times a day, rather than after every feeding (Appendix G).

3) A sixth gradation was added to the nipple soreness rating scale (Appendix H).

4) The fourth gradation was added to the objective nipple assessment scale (Appendix I).

Once these changes had been approved by the ethics and access committees, the study was begun. Results of the pilot project were not included in study analysis as the protocol had been altered following the pilot effort.

# CHAPTER IV:

# RESULTS

## Data Analysis

This study's purpose was to evaluate effectiveness of warm compresses and moistened tea bags in treatment of sore nipples postpartum. Specific null hypotheses tested included:

1. Application of moistened tea bags after feeding does not decrease nipple soreness.
2. Application of warm compresses after feeding does not decrease nipple soreness.
3. There is no statistical difference effect between tea bag and compress treatment.
4. There is no relationship between breastfeeding frequency and duration and nipple soreness.
5. There is no relationship between objective and subjective nipple soreness assessment.

Data for this study were collected over eight months from October 1993 until May 1994. Resulting information was coded by the investigator, and transferred to a computer file wherein the SAS statistical package was used for analysis.

With the help of a statistical consultant, results were analyzed for differences in soreness between the two treatment groups and controls. Demographic details were obtained from all participants and analyzed to describe the

sample characteristics.

Statistical significance was defined as $p=0.05$. Subjective pain ratings were collected over five days, and a repeated measures Anova used for their analysis. Since there were significant differences between nipple soreness means, multiple comparison tests were carried out.

Frequency and duration of feedings were analyzed as independent variables to identify association with nipple soreness.

To identify association between subjective pain ratings and objective tissue damage, Spearman's rank correlation coefficients were used as these variables did not have normal distributions.

The remainder of this chapter consists of the findings from the study and description of the sample.

## Sample Characteristics

One hundred and eighteen primiparous women were recruited, and 65 of these completed the study. Participants ranged in age from 19 to 36, with a mean of 27.4 years. Four participants (6%) had some high school education, and ten (15.4%) had completed high school. Eight (12%) had some university education, and 66.1% had either completed university (n=21) or community college (n=22). Annual family income ranged from <$15,000 to >$50,000, with a mean of $45,000 (Table 2).

The majority of participants lived with their partners

(98.5%), the remainder residing with other family members. No participants lived alone. Their decision to breastfeed was made before pregnancy by 32.3%, early in the pregnancy by 56.9%, during mid pregnancy by 7.7% and near the end of pregnancy by 3.1%.

Length of hospital stay, ranged from 29 to 178 hours, with a mean of 57.8. Three participants length of stay was over 100 hours. One was due to treatment of the infant for hyperbilirubinemia, one due to maternal urinary retention, and one was unexplained. Infant birth weights ranged from 2147 -4352 grams, with a mean of 3375 grams.

Participants were asked if they had experienced complications during prenatal, intrapartum or postpartum. None reported anemia, haemorrhage, or infection. Eight percent had urinary retention, and 18.5% reported having perineal pain. Fatigue was reported by 7.7%. Two women experienced pregnancy induced hypertension, and two reported gestational diabetes.

Of the 65 infants, 56.9% female and 43.1% male. Their mothers reported newborn problems as follows: mucousy (6.2%); infection (4.6%); jaundice (6.2%); low blood sugar (3.1%); difficulty breastfeeding (6.2%).

**Table 2**

**Demographic Data**

| Variable | | Mean | No. | % |
|---|---|---|---|---|
| Age (years) | | 27.4 | | |
| Length of stay (hours) | | 57.8 | | |
| Income | | $45,000 | | |
| | <15,000 | | 5 | 8.1 |
| | 15,000 - 20,000 | | 2 | 3.2 |
| | 20,000 - 30,000 | | 9 | 14.5 |
| | 30,000 - 40,000 | | 13 | 21 |
| | 40,000 - 50,000 | | 9 | 14.5 |
| | > 50,000 | | 24 | 38.7 |
| Education | Some High School | | 4 | 6 |
| | Completed High School | | 10 | 15.4 |
| | Some Community College | | 0 | 0 |
| | Completed Community College | | 22 | 33.8 |
| | Some University | | 8 | 12 |
| | Completed University | | 21 | 32.3 |
| Live With | Partner | | 64 | 98.5 |
| | Other | | 1 | 1.5 |
| | Alone | | 0 | 0 |

The study's attrition rate was high with 53 recruits (44.9%) unable to complete it. That cohorts age ranged from 18 - 40 years with a mean of 24.8. Their level of education was as follows: some high school (5.7%), completed high school (12.2%), some university (12.2%), some community college (28.6%), completed community college (18.4%), and completed university (14.3%). Their annual mean family income was $36,000. The majority lived with their partners (84.9%), whereas 9.4% lived alone, and 5.7% lived with other family members. Their decision to breastfeed was made before pregnancy by 20.8%, in early pregnancy by 71.7%, in mid pregnancy by 7.5% of these women. Participants unable to complete the study did not differ significantly in these demographic factors.

Complications were similar between those who completed the study and those who did not. The cohort who quit reported problems as follows: fatigue (7.5%); pregnancy induced hypertension (3.7%); perineal pain (13.2%); haemorrhage (1.9%). Infant problems were reported as: infection (1.8%); jaundice (3.7%); difficulty breastfeeding (5.6%).

The majority (67%) of those who quit, did not give a reason for withdrawing from the study. Thirteen stated they had completed the study but had not mailed the results. That groups report never arrived. Fatigue was a major excuse for not completing the study for seven percent of the

attrition group. One woman stated that her baby refused to nurse on the side where the tea bag had been placed, three (5.6%) withdrew because they did not find the treatment helpful and three (5.6%) withdrew because of other breastfeeding problems.

As with most breastfeeding studies, subjects who did not complete the study were slightly younger and less educated than those who completed it. The attrition rate of 45% is high, but the first postpartum week can be stressful. Mothers are commonly fatigued, learning new skills, and are exposed to uncontrolled factors such as visitors and disruptive infant sleep patterns. Such factors may have contributed to the attrition rate because the study required substantial voluntary effort, in keeping a record of all feedings, and self treatment at least four times per day.

## Results of Treatment Effects

**Null Hypotheses #1 and #2:**

1. Application of moistened tea bags after feeding does not decrease nipple soreness.
2. Application of warm compresses after feeding does not decrease nipple soreness.

All participants were asked to apply their prescribed treatment at least four times a day after feeding and that if they found treatment helpful, they could apply it more often as long as the number of times was noted. They were asked to rate nipple soreness after every feeding, on a

score between zero and five, using a modification of a scale developed by Storr (1988). Daily nipple soreness ratings were determined by calculating the median score. The median was chosen rather than the mean to minimize the possibility of bias from outlying scores.

Median soreness scores were highest for the control nipple at 2.47, followed by the compress at 2.19, and lowest for the tea bag at 2.01. Rating patterns were similar in the control and compress group (Figure 1) whose levels of pain peaked on day three (2.68 and 2.32 respectively) then subsided gradually. The tea bag group reported a different pattern whose soreness ratings were highest on day one (2.54) and steadily decreased until day five's median rating of 1.70. The Anova suggested statistically significant differences between soreness ratings (F value of 8.16 with $p = 0.0001$, Table 3). To identify variables affecting soreness scores, treatment, day, treatment by day, and participant, were entered into a General Linear Models procedure. This is similar to a multi-factor Anova, in that it identifies what factor or factors account for differences, given others that may be important (Table 4).

This method identified two factors with significant effect on soreness ratings, treatment and individual participant effect. Null hypotheses one and two were rejected as there were statistically significant differences in scores when either tea bags or compresses were applied.

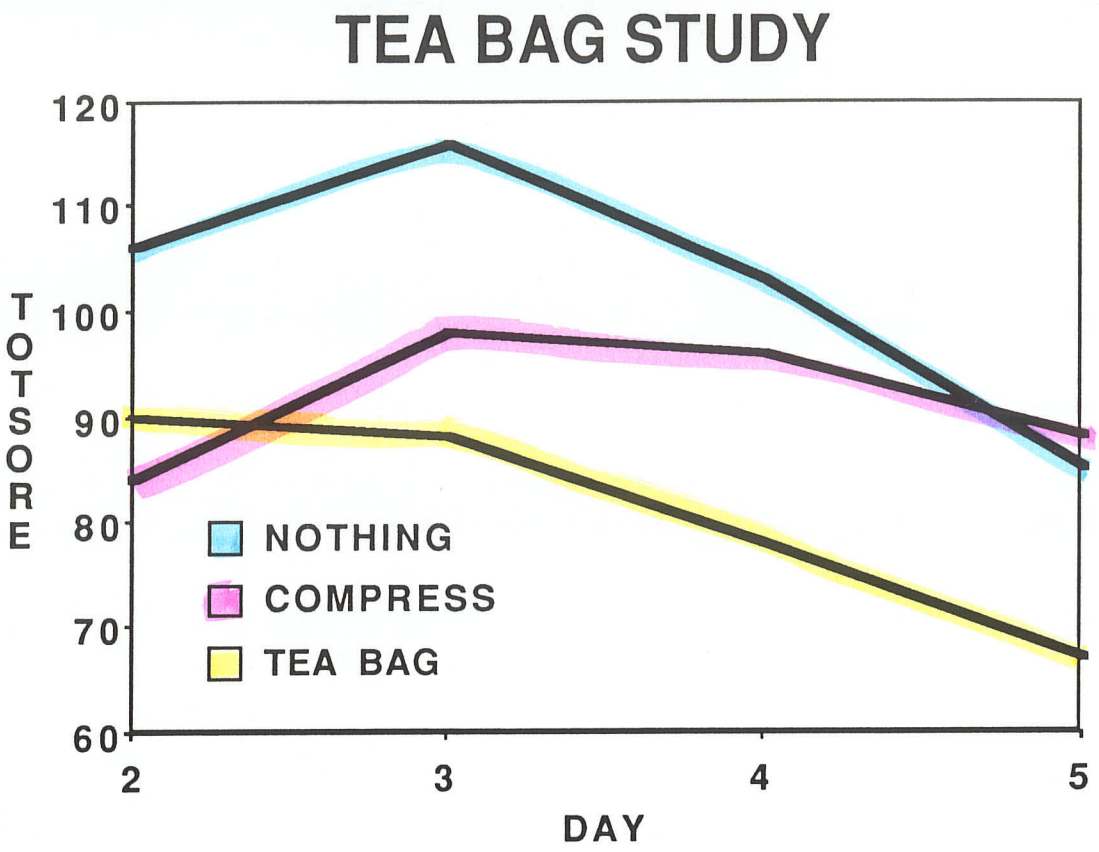
TEA BAG STUDY
120
110
100
90
80
70
60
TOTSORE
NOTHING
COMPRESS
TEA BAG
2
3
4
5
DAY

**Figure 1**

**Table 3**

**One Way Repeated Measures Anova**

| Source | DF | Sum of Squares | Mean Square | F | P |
|---|---|---|---|---|---|
| model | 78 | 446.70057817 | 5.72707152 | 8.16 | 0.0001 |
| error | 465 | 326.50119756 | 0.70215311 | | |
| total (corrected) | 543 | 773.21277574 | | | |

**Table 4**

**General Linear Models Procedure**

| Source | DF | Type III SS | Mean Square | F | P |
|---|---|---|---|---|---|
| treatment | 2 | 16.16231669 | 8.08115834 | 11.51 | 0.0001 |
| day | 4 | 6.10672336 | 1.52668084 | 2.17 | 0.0709 |
| tx*day | 8 | 6.31732586 | 0.78966573 | 1.12 | 0.3450 |
| partici-pant | 64 | 409.92475922 | 6.40507436 | 9.12 | 0.0001 |

**Null Hypothesis #3:**

3. There is no statistical difference in soreness between the effect of moistened tea bags and warm compresses.

Multiple comparison tests were carried out. Both T test and Tukey's were done on all data comparisons. These demonstrated significant differences between the control and the compress groups, as well as the control and tea bag groups. The difference between compress and tea bag groups was not statistically significant (Tables 5 & 6). Further multiple comparison tests were conducted to find soreness rating differences by postpartum day. T test results suggested significant soreness differences between postpartum days three, four, and five, but no significant differences between other days. The same data was analyzed using Tukey's, which produced slightly different results. The only significant difference shown in soreness ratings with this analysis was between day three and five. Tukey's test is more conservative which likely explains this difference.

Null hypothesis number three was accepted as the differences between soreness in tea bag and compress groups were not statistically significant.

**Table 5**

**T TEST**

| Treatment Comparison | Lower Confidence Limit | Difference Between Means | Upper Confidence Limit | P |
|---|---|---|---|---|
| nil-compress | 0.10858 | 0.28076 | 0.45295 | * |
| nil-tea bag | 0.28144 | 0.45387 | 0.62630 | * |
| compress-nil | -0.45295 | -0.28076 | -0.1.858 | * |
| compress-tea bag | -0.00119 | 0.17311 | 0.34740 | |
| tea bag-nil | -0.62630 | -0.45387 | -0.28144 | * |
| tea bag-compress | -0.34740 | -0.17311 | 0.00119 | |

* p = 0.05

**Table 6**

**Tukey's Studentized Range**

| Treatment Comparison | Lower Confidence Limit | Difference Between Means | Upper Confidence Limit | P |
|---|---|---|---|---|
| nil-compress | 0.07475 | 0.28076 | 0.48678 | * |
| nil-tea bag | 0.24756 | 0.45387 | 0.66018 | * |
| compress-nil | -0.48678 | -0.28076 | -0.07475 | * |
| compress-tea bag | -0.03544 | 0.17311 | 0.38166 | |
| tea bag-nil | -0.66018 | -0.45387 | -0.24756 | * |
| tea bag-compress | -0.38166 | -0.17311 | 0.03544 | |

* p= 0.05

**Null Hypothesis # 4:**

4. There is no relationship between frequency and duration of breastfeeding and nipple soreness.

Participants kept a log of all feedings, specifically the number of times the infant was fed daily, as well as the total number of minutes the infant was fed, on each breast. This information and its relationship to soreness was assessed using Spearman's correlation coefficient. There was only one significant correlation between these factors. On day four significant but low correlation was seen between breastfeeding frequency and soreness (0.21, $p = 0.01$), but not on any other day. There was positive correlation between frequency and duration; as the more frequently the infant fed, the more minutes the infant was fed.

Null hypothesis number four was accepted.

**Null Hypothesis # 5:**

5. There is no relationship between objective and subjective nipple soreness scores.

Subjective and objective nipple soreness scores were analyzed using Spearman's correlation coefficient. It might be assumed that more objective damage to the nipple would result in more pain being reported. Objective assessments were done on all participants on day one and two, using a four point scale. This rating was compared to the participants subjective rating (Table 7).

**Table 7**

**Objective Evaluation and Subjective Pain Ratings**

| Day | P value | Spearman's Correlation |
|---|---|---|
| 1 | 0.1050 | 0.38359 |
| 2 | 0.8749 | 0.01406 |

There were no correlations between these ratings. Null hypothesis number five was accepted.

## Summary

In conclusion, warm compresses and tea bag compresses alleviated nipple discomfort in this group of breastfeeding primiparas. Both treatments were better than none. Therefore, null hypotheses one and two are rejected. Null hypothesis three was supported as there was no statistically significant difference between the effects of tea bags and compresses. Differences in soreness were accounted for by treatment and participant effect and not related to postpartum day. Null hypothesis four was supported as there was no relationship between frequency and duration of feedings and nipple soreness. Null hypothesis five was also supported as there was no relationship between objective examination and subjective nipple soreness.

# CHAPTER V:

# DISCUSSION

## Treatment Effect

This study supports the effectiveness of tea bag or warm water compress application in reducing nipple soreness in early breastfeeding. The reason for this is unknown. A placebo effect may be in effect, as women applying a treatment to only one breast found either treatment helpful, in contrast to no treatment of the opposite breast.

Warm compresses of various types may improve blood flow to an injured body part. Inflamed tissue responds favourably to application of moist heat which promotes nutrient supply and removal of waste products (Potter & Perry, 1993). Both warm compresses and tea bag compresses enhanced this physiological response.

Buchko et al. (1994) reported that women using warm compresses had significantly less pain than those using tea bags or no treatment. Women in Buchko's et al.(1994), study did not act as their own controls, and the scale used to rate soreness was substantially different from that used in this project. Subjects rated pain intensity, and pain unpleasantness, daily, using a visual analogue scale. Daily rating forces a mother to collapse her daily nipple discomfort into one score. This could bias reporting toward the sensation following the most proximal feeding. In contrast, this project gathered pain ratings immediately

after each feeding. This should increase likelihood of reliability and validity of pain ratings. This difference may have produced the observed variation between Buchko et al. (1994) and the present results.

**Pain Pattern**

Review of pain patterns demonstrates that this study's subjects experienced soreness similar to that of the population of breastfeeding women.

The pain pattern was similar regardless of which treatment was applied, and peaked on day three. De Carvalho et al. (1984), Hewat and Ellis (1987), Spangler and Hildebrandt (1993), Buchko et al. (1994), Ziemer et al. (1990), and L'Esperance (1980), all report that peak nipple soreness occurred on postpartum day three. Gosha and Tichy (1988) report peak pain on day two, and Riordan (1985) on day four. These differences could be attributed to sample size as Gosha and Tichy (1988) studied 20 subjects and Riordan (1985) had 11. Sample size ranged from 32 - 102 in the studies reporting that soreness peaked on day three.

Ziemer and Pigeon (1993) reported pain patterns consistent with physical changes in nipple integrity. Initial nipple skin changes included erythema in all subjects. This inflammation increased from day one to three and corresponded with increasing discomfort. Following day three, erythema decreased gradually as did discomfort.

**Frequency and Duration**

Some health care professionals believe that a positive relationship exists between nipple soreness and frequent, long feedings, despite lack of evidence that this is the case (De Carvalho et al., 1984; Hewat & Ellis, 1987). This study further dispels this myth as it produced no evidence that women who fed frequently and longer, suffered more nipple damage and discomfort.

**Objective and Subjective Nipple Soreness Ratings**

One might assume that a woman with obvious physical damage would experience more nipple pain. In this project there was no relationship between objective assessment and subjective pain rating. Lack of a relationship between these factors also was reported by Hewat and Ellis (1987).

Conversely, Ziemer and Pigeon (1993) reported higher pain ratings in the presence of inflammation, but that blisters did not correlate with higher pain ratings.

These opposing findings are likely due to varying standards of assessment of tissue damage. In this study, nipples were visually observed and rated on a four point scale (appendix I). In contrast, Ziemer and Pigeon (1993) assessed damage using a lighted magnification lens, measured areas of breakdown, and took photographs which were later closely examined.

**Conceptual Framework**

At the time of study recruitment, all participants were

experiencing some nipple soreness, and as recruitment occurred within 36 hours of delivery, all subjects were in early stages of pathogenesis. Early diagnosis of nipple soreness coupled with prompt treatment is a secondary prevention strategy (Leavell & Clark, 1965; Shamansky & Clausen, 1980), which aims at curing the problem and preventing disability.

Differences in soreness between control and treatment, demonstrate that application of tea bag or warm water compresses reduce soreness and that both have the potential to prevent further complications such as cracking, bleeding, and untimely premature weaning.

## Study Limitations

Limitations of this project exist in sample characteristics and the nipple soreness scale. As with most breastfeeding studies, the sample was homogeneous, and did not represent women of lower socioeconomic status or women under the age of 20. Thus the results cannot be generalized to younger and less advantaged women.

The attrition rate was high at 44.9%. Spangler and Hildebrandt (1993) experienced a completion rate of 52% in their study of nipple discomfort. Conversely, Buchko et al. (1994) had a completion rate of 78%. This difference may be related to the amount of time and effort subjects needed to devote to this study. For Buchko et al. (1994), participants rated the intensity and unpleasantness of

discomfort once a day, in contrast to this project's requirements of at least four times per day and immediately following feeding, when other demands might be given priority.

The goal of this work was to recruit a minimum of ten participants per treatment group. This was achieved, but a sample larger than 65, might have demonstrated statistical significance between compress and tea bag treatments.

Storr's (1988) original nipple soreness scale was utilized by Spangler and Hildebrandt (1993). In this work it required modification following the pilot study. These modifications are presumed to be valid as participants had no difficulty rating their soreness, but further testing and development would be required to prove this.

## Implications for Practice

Sore nipples are common during the early postpartum period. Many remedies have been suggested, but few are supported by evidence. Current frequent practices are, applying expressed breast milk, tea bags, and lanolin. This study's results suggest that both tea bag and warm water compresses are effective in providing early relief.

The first treatment advised should be warm water compresses in that this option is cheap and likely harmless. If mothers are not relieved after using this remedy, a tea bag compress could be advised. Possible unfavourable effects of the latter include, changing taste and smell of

the nipple, and introducing whatever remains of the contents, on the nipple into the infant's mouth. Recent evidence exists that newborns' rooting behaviours are influenced by maternel breast odor (Makin & Porter, 1989; Varendi, Porter, & Winberg, 1994).

Costs of both options are minimal. Tea bag treatment uses two tea bags, as well as two breast pads to ensure that the woman's cloths do not become wet. Wet compress application uses two wet and two dry breast pads. In this study, tea bag cost was .03 cents each, and breast pad cost was .06 cents each, therefore tea bag compress to both nipples is .18 cents and warm water compress to both nipples is .24 cents.

This study confirmed that nipple soreness peaks on day three and gradually diminishes during the first week. This information could be used to reassure a mother through the first days as breastfeeding is established. It might be enough to encourage her to persist through the soreness to the benefit of herself and her infant.

## Recommendations for Future Research

Nipple soreness is common postpartum. Persisting through this difficulty and continuing to breastfeed offers advantages to both mother and infant. Remedies for this situation should be supported by evidence of their effectiveness and evidence that they cause no harm. Both tea bag and warm water compresses help. A larger

confirmatory study is now needed with approximately 100 subjects per group in order to measure treatment effect size. A sample of this size would be sufficient to adequately measure treatment effect. Future research could also compare the effectiveness of compresses and expressed breast milk. A design similar to that used in this study could compare effectiveness of expressed breast milk versus tea bags, and between expressed breast milk and warm water compresses.

Lower attrition rates might result from not collecting information on frequency and duration of feeds. Objective nipple assessments should be abandoned as they do not correlate with subjects' pain ratings (Hewat & Ellis, 1987). Attrition and lost data could be decreased by phoning participants daily and requesting that they provide verbal information on treatment use and soreness ratings.

## Conclusions

This study has demonstrated that warm compresses, using either tea bags or warm water, alleviate nipple pain in breastfeeding primiparous women during the first five postpartum days. Effective inexpensive treatments for sore nipples may assist women to establish and continue lactation.

Through use of a secondary prevention framework, this study supports applying warm water compresses or tea bag compresses in that both options reduced nipple pain.

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# APPENDICES

# APPENDIX A

## TREATMENT FOR SORE NIPPLES

### Invitation to Participate & Consent Form

Dear

This letter is to invite you to take part in a study being done as part of my Master's thesis. I work at St. Boniface Hospital as a nurse educator, but my role here has no bearing on this study. This study will measure the effect of two treatments for sore nipples in breastfeeding women. The two treatments are wet tea bags, and wet compresses. We know that some breastfeeding women suffer from sore nipples. We would like to find out which treatment makes nipples feel better.

Should you agree to participate in this study, you will be asked to pick at random an envelope which will give you the directions to follow. You will be asked to apply a tea bag, a warm compress, or nothing, to each nipple after every feeding. After feeding, you will be asked to record the soreness on each nipple, as well as how long you fed the baby on each breast. The treatment will take you about 20 minutes (during which you can resume most normal activities), after every feed forthe first five days postpartum. Rating your nipple soreness will take you less then 5 minutes after every feed. You will start the treatments 24 hours after the birth of your baby and continue them for 5 days. You will be given the items you

need to carry on the treatments at home. The investigator will look at your nipples twice during your hospital stay to assess their condition. You will also be asked for some information about yourself and your baby. This interview will take 5-10 minutes of your time. The investigator may need to look at your chart (or baby's chart) for other information. The investigator will phone you after you leave the hospital to make sure you do not have any questions. If you have any allergies to tea or tannic acid, or any skin sensitivities, you may not want to participate. This research has been approved by an Ethical Review Committee.

To ensure confidentiality, none of the information will have your name on it. You will be assigned a participant number. This number will be on all the forms you complete. The information gathered will be shared with members of my committee, Dr. Janet Beaton, Annette Gupton, and Dr. Philip Hall, but only after it has been grouped with other participants, and anonymity has been provided. The results of the study may be published.

Your participation in this project is completely voluntary. There is no known risk to you or your baby. You may refuse to participate, refuse to answer certain questions, or drop out of the study at any time. Your care will not be affected by your decision to participate or drop out. If you agree to participate in this study, please complete the

consent below.

Women who choose to breastfeed their infants in the future, may benefit from the results of this study. If you have any questions about the study, feel free to contact myself or my advisor.

I consent to take part in this study as explained. I understand that my rights as an individual will be protected. I understand that my participation is voluntary and that I may drop out of the study at any time. Refusing to take part or dropping out will not affect my care at any time.

NAME:_____ SIGNATURE: _____

ADDRESS: _____

_____

PHONE NUMBER: _____ DATE:_____

Sincerely,

Noelie A. Lavergne, RN, BN
Graduate Nursing Student
University of Manitoba
Phone # (B):
Beeper # (24 Hours):

Dr. Janet Beaton
Dean, Faculty of Nursing
University of Manitoba
Phone # (B):

APPENDIX B

## NIPPLE SORENESS RATING SCALE

MOTHER'S IDENTIFICATION NUMBER_____

POSTPARTUM DAY _____

| FEEDING TIME | | DURATION/MIN | TREATMENT | NIPPLE SORENESS |
|---|---|---|---|---|
| #1 | R | | | |
| | L | | | |
| #2 | R | | | |
| | L | | | |
| #3 | R | | | |
| | L | | | |
| #4 | R | | | |
| | L | | | |
| #5 | R | | | |
| | L | | | |
| #6 | R | | | |
| | L | | | |
| #7 | R | | | |
| | L | | | |
| #8 | R | | | |
| | L | | | |
| #9 | R | | | |
| | L | | | |
| #10 | R | | | |
| | L | | | |

INSTRUCTION FOR USE

Feeding/Time: Indicate the time of feeding

R: right breast

L: left breast

Duration/Minutes: Note number of minutes baby breastfed on each side for each feeding.

Treatment: place a check mark when you do the treatment assigned to your right and left nipples.

Nipple Soreness: Score nipple soreness 0, 1, 2, 3, 4, after you have completed the treatment, according to the explanation below:

0 - normal colour, no tenderness

1 - nipple slightly red and/or tender for first 5 to 10 seconds of feeding

2 - tender between feedings, makes me grimace when baby starts feeding

3 - nipple beginning to crack, involuntary gasp of pain when baby starts feeding

4 - nipple cracked, feels sore "down to my toes" when baby starts feeding

APPENDIX C

Participant #: _____

**DEMOGRAPHIC DATA SHEET**

Mother

Age, in years:_____

Delivery Date: _____ Delivery Time: _____

Discharge Date: _____ Discharge Time: _____

Education:

Some high school: _____ Completed high school: _____

Some university: _____ Completed university: _____

Some community college: _____ Completed community college: __

Other: _____

Family Income:

Under $15,000: _____

$15,001 - $20,000: _____

$20,001 - $30,000: _____

$30,001 - $40,000: _____

$40,001 - $50,000: _____

Over $50,000: _____

Living: alone _____

with husband/partner _____

with other support people _____

Type of analgesia during labour _____

Type of episiotomy _____

Type of delivery _____

When did you make the decision to breastfeed your baby?

_____

General health since baby's birth: _____

_____

Baby

Birth weight: _____grams Sex: _____

General health since birth: _____

_____

Any abnormalities: _____

APPENDIX D

## OBJECTIVE NIPPLE ASSESSMENT SCALE

**MOTHER'S IDENTIFICATION NUMBER**_____

POSTPARTUM DAY_____

The investigator will follow this scale on the two occasions she assesses the subjects nipples.

| **LEFT:** | **RIGHT:** |
|---|---|
| 0; normal colour | 0; normal colour |
| 1; reddened | 1; reddened |
| 2; cracks visible | 2; cracks visible |

==========

## OBJECTIVE NIPPLE ASSESSMENT SCALE

**MOTHER'S IDENTIFICATION NUMBER**_____

POSTPARTUM DAY_____

| **LEFT:** | **RIGHT:** |
|---|---|
| 0; normal colour | 0; normal colour |
| 1; reddened | 1; reddened |
| 2; cracks visible | 2; cracks visible |

APPENDIX E

## INSTRUCTION SHEET A

Each time after you breastfeed your baby, follow the steps below. Follow these instructions even if your baby fed only from one side.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **left** nipple.

3) Place the Red Rose tea bag in the same cup of warm water, until it is wet. Squeeze out the extra water and apply the wet tea bag to your **right** nipple.

4) Remove the tea bag and breast pad from your nipples after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET B

Each time after you breastfeed your baby, follow the staps below. Follow these instructions even if your baby fed only from one side.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **right** nipple.

3) Place the Red Rose tea bag in the same cup of warm water, until it is wet. Squeeze out the extra water and apply the wet tea bag to your **left** nipple.

4) Remove the tea bag and breast pad from your nipples after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET C

Each time after you breastfeed your baby, follow the steps below. Follow these instructions even if your baby fed only from one side.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **right** nipple.

3) Do not apply anything to your **left** nipple.

4) Remove the breast pad from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET D

Each time after you breastfeed your baby, follow the steps below. Follow these instructions even if your baby fed only from one side.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **left** nipple.

3) Do not apply anything to your **right** nipple.

4) Remove the breast pad from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET E

Each time after you breastfeed your baby, follow the steps below. Follow these instructions even if your baby fed only from one side.

1) Fill a cup with warm water.

2) Place a Red Rose tea bag in the warm water until the bag is wet. Squeeze out the extra water and apply this wet tea bag to your **right** nipple.

3) Do not apply anything to your **left** nipple.

4) Remove the tea bag from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET F

Each time after you breastfeed your baby, follow the steps below. Follow these instructions even if your baby fed only from one side.

1) Fill a cup with warm water.

2) Place a Red Rose tea bag in the warm water until the bag is wet. Squeeze out the extra water and apply this wet tea bag to your **left** nipple.

3) Do not apply anything to your **right** nipple.

4) Remove the tea bag from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

# APPENDIX F

## TREATMENT FOR SORE NIPPLES

### Invitation to Participate & Consent Form

Dear

This letter is to invite you to take part in a study being done as part of my Master's thesis. I work at St. Boniface Hospital as a nurse educator, but my role here has no bearing on this study. This study will measure the effect of two treatments for sore nipples in breastfeeding women. The two treatments are wet tea bags, and wet compresses. We know that some breastfeeding women suffer from sore nipples. We would like to find out which treatment makes nipples feel better.

Should you agree to participate in this study, you will be asked to pick at random an envelope which will give you the directions to follow. You will be asked to apply a tea bag, a warm compress, or nothing, to each nipple after feeding, at least four times a day. After feeding, you will be asked to record the soreness on each nipple, as well as how long you fed the baby on each breast. The treatment will take you about 20 minutes (during which you can resume most normal activities), at least four times a day, for the first five days postpartum. Rating your nipple soreness will take you less then 5 minutes after every feed. You will start the treatments 36 hours after the birth of your baby and continue them for 5 days. You will be given the items you

need to carry on the treatments at home. The investigator will look at your nipples twice during your hospital stay to assess their condition. You will also be asked for some information about yourself and your baby. This interview will take 5-10 minutes of your time. The investigator may need to look at your chart (or baby's chart) for other information. The investigator will phone you after you leave the hospital to make sure you do not have any questions. If you have any allergies to tea or tannic acid, or any skin sensitivities, you may not want to participate. This research has been approved by an Ethical Review Committee.

To ensure confidentiality, none of the information will have your name on it. You will be assigned a participant number. This number will be on all the forms you complete. The information gathered will be shared with members of my committee, Dr. Janet Beaton, Annette Gupton, and Dr. Philip Hall, but only after it has been grouped with other participants, and anonymity has been provided. The results of the study may be published.

Your participation in this project is completely voluntary. There is no known risk to you or your baby. You may refuse to participate, refuse to answer certain questions, or drop out of the study at any time. Your care will not be affected by your decision to participate or drop out. If you agree to participate in this study, please complete the

consent below.

Women who choose to breastfeed their infants in the future, may benefit from the results of this study. If you have any questions about the study, feel free to contact myself or my advisor.

I consent to take part in this study as explained. I understand that my rights as an individual will be protected. I understand that my participation is voluntary and that I may drop out of the study at any time. Refusing to take part or dropping out will not affect my care at any time.

NAME:_____ SIGNATURE:_____

ADDRESS:_____

_____

PHONE NUMBER:_____ DATE: _____

Sincerely,

Noelie A. Lavergne, RN, BN
Graduate Nursing Student
University of Manitoba
Phone # (B):
Beeper # (24 Hours):

Dr. Janet Beaton
Dean, Faculty of Nursing
University of Manitoba
Phone # (B):

APPENDIX G

**INSTRUCTION SHEET A**

At least **four times a day** after you breastfeed your baby, follow the steps below.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **left** nipple.

3) Place the Red Rose tea bag in the same cup of warm water, until it is wet. Squeeze out the extra water and apply the wet tea bag to your **right** nipple.

4) Remove the tea bag and breast pad from your nipples after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET B

At least **four times a day** after you breastfeed your baby, follow the steps below.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **right** nipple.

3) Place the Red Rose tea bag in the same cup of warm water, until it is wet. Squeeze out the extra water and apply the wet tea bag to your **left** nipple.

4) Remove the tea bag and breast pad from your nipples after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET C

At least **four times a day** after you breastfeed your baby, follow the steps below.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **right** nipple.

3) Do not apply anything to your **left** nipple.

4) Remove the breast pad from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET D

At least **four times a day** after you breastfeed your baby, follow the steps below.

1) Fill a cup with warm water.

2) Place a clean breast pad in the warm water until the pad is wet. Squeeze out the extra water and apply this wet breast pad to your **left** nipple.

3) Do not apply anything to your **right** nipple.

4) Remove the breast pad from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET E

At least **four times a day** after you breastfeed your baby, follow the steps below.

1) Fill a cup with warm water.

2) Place a Red Rose tea bag in the warm water until the bag is wet. Squeeze out the extra water and apply this wet tea bag to your **right** nipple.

3) Do not apply anything to your **left** nipple.

4) Remove the tea bag from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

## INSTRUCTION SHEET F

At least **four times a day** after you breastfeed your baby, follow the steps below.

1) Fill a cup with warm water.

2) Place a Red Rose tea bag in the warm water until the bag is wet. Squeeze out the extra water and apply this wet tea bag to your **left** nipple.

3) Do not apply anything to your **right** nipple.

4) Remove the tea bag from your nipple after 15 minutes.

5) Leave your bra open under your clothes for another 15 minutes to allow the nipples to air dry.

6) Complete your nipple soreness rating scale.

APPENDIX H

## NIPPLE SORENESS RATING SCALE

MOTHER'S IDENTIFICATION NUMBER_____

POSTPARTUM DAY _____

| FEEDING TIME | | DURATION/MIN | TREATMENT | NIPPLE SORENESS |
|---|---|---|---|---|
| #1 | R | | | |
| | L | | | |
| #2 | R | | | |
| | L | | | |
| #3 | R | | | |
| | L | | | |
| #4 | R | | | |
| | L | | | |
| #5 | R | | | |
| | L | | | |
| #6 | R | | | |
| | L | | | |
| #7 | R | | | |
| | L | | | |
| #8 | R | | | |
| | L | | | |
| #9 | R | | | |
| | L | | | |
| #10 | R | | | |
| | L | | | |

INSTRUCTION FOR USE

Feeding/Time: Indicate the time of feeding

R: right breast

L: left breast

Duration/Minutes: Note number of minutes baby breastfed on each side for each feeding.

Treatment: place a check mark when you do the treatment assigned to your right and left nipples.

Nipple Soreness: Score nipple soreness 0, 1, 2, 3, 4, 5, after you have finished feeding or completed the treatment, according to the explanation below:

0 - normal colour, no tenderness

1 - nipple slightly red and/or tender for first 5 to 10 seconds of feeding

2 - nipple red and tender for longer than first 5 to 10 seconds of feeding

3 - tender between feedings, makes me grimace when baby starts feeding

4 - nipple beginning to crack, involuntary gasp of pain when baby starts feeding

5 - nipple cracked, feels sore "down to my toes" when baby starts feeding

APPENDIX I

## OBJECTIVE NIPPLE ASSESSMENT SCALE

**MOTHER'S IDENTIFICATION NUMBER**_____

POSTPARTUM DAY_____

The investigator will follow this scale on the two occasions she assesses the subjects nipples.

| **LEFT:** | **RIGHT:** |
|---|---|
| 0; normal colour | 0; normal colour |
| 1; slightly red | 1; slightly red |
| 2; entire nipple red | 2; entire nipple red |
| +/or blistered | +/or blistered |
| 3; cracks visible | 3; cracks visible |

==========

## OBJECTIVE NIPPLE ASSESSMENT SCALE

**MOTHER'S IDENTIFICATION NUMBER**_____

POSTPARTUM DAY_____

| **LEFT:** | **RIGHT:** |
|---|---|
| 0; normal colour | 0; normal colour |
| 1; slightly red | 1; slightly red |
| 2; entire nipple red | 2; entire nipple red |
| +/or blistered | +/or blistered |
| 3; cracks visible | 3; cracks visible |

# APPENDIX J

# ETHICAL APPROVAL

The University of Manitoba

FACULTY OF NURSING
ETHICAL REVIEW COMMITTEE

# APPROVAL FORM

Proposal Number N#93/29

Proposal Title: "Evaluation of the Application of Tea Bags to Sore Nipples in Breastfeeding Women."

Name and Title of Researcher(s): NOELIE A. LAVERGNE
M.N. GRADUATE STUDENT
FACULTY OF NURSING UNIVERSITY OF MANITOBA

Date of Review: October 04, 1993

APPROVED BY THE COMMITTEE: October 4, 1993

Comments: APPROVED WITH SUBMITTED CLARIFICATIONS/REVISIONS RECEIVED OCTOBER 12, 1993.

Date: October 13, 1993

Linda J. Kristjanson, PhD, RN — Chairperson
Associate Professor
University of Manitoba Faculty of Nursing

Position

NOTE:
Any significant changes in the proposal should be reported to the Chairperson for the Ethical Review Committee's consideration, in advance of implementation of such changes.

Revised: 92/05/08/se

# APPENDIX K

## APPROVAL FOR ACCESS

Hôpital général St-Boniface General Hospital

October 19, 1993

Noellie Lavergne
Dept. Mat Child Nursing
St. Boniface General Hospital

**Re: Access to SBGH for Study Entitled:**
**EVALUATION OF THE APPLICATION OF TEA BAGS TO SORE NIPPLES IN BREASTFEEDING WOMEN**

Dear Noellie Lavergne:

I am pleased to inform you that your research access request has been approved. You may proceed with your study on the understanding that:

1) any significant changes in your proposal will be submitted to my attention prior to implementation;
2) you review the enclosed policy on confidential information;
3) you inform us when your data collection is complete. This information helps us coordinate research access requests and minimize competing demands of research study protocols on patients and nursing staff time.

We encourage you to make presentations to hospital staff about your research. Also, please consider writing a short story about some aspect of your research project for our Nursing Division newsletter, Nursing Dialogue. Upon completion of your study, we request that you provide us with a brief summary of your final report.

Thank you for selecting St. Boniface as the site for recruiting participants for your study. Please feel free to contact me with your questions or concerns. Should you encounter any site-related difficulties during the course of your study, I would appreciate being notified of these.

All the best with the completion of your study.

Sincerely,

Kaaren Neufeld, R.N., M.N.
Director of Nursing Education and Research
Tel.

KN/mj

cc/Tanya Benoit

409 Taché, Winnipeg, Manitoba, Canada R2H 2A6
Tel (204) Fax (204)