Preventing nipple pain/trauma in breastfeeding women: a best practice implementation project at the XX XX University Hospital (Spain)

Abstract

Objectives: To assess compliance with recommendations to alleviate nipple pain and/or trauma (NPT) and to reduce the rate of breastfeeding abandonment for this reason.

Introduction: As a fundamental priority, health programmes encourage mothers to breastfeed exclusively for the first six months of the baby's life and to supplement breast milk with other foods up to the age of two years. However, the presence of NPT can reduce or prevent compliance with this recommendation.

Methods: The project was designed and carried out using a framework based on the Joanna Briggs Institute Practical Application of Clinical Evidence System (JBI-PACES). Six audit criteria were used in pre- and post-audits to observe any changes in compliance with the recommendations. Between audits, the Getting Research into Practice (GRiP) tool was used to identify stakeholders, barriers and facilitators of the project.

Results: 267 breastfeeding women were studied in the baseline phase and 275 during follow up. Compliance in four criteria improved, and the rates of NPT decreased (pain: from 63.3% to 53.5%; p=0.02; trauma: from 37.8% to 24.7%; p=0.01). The proportion of women advised by qualified personnel increased from 63% to 88%, while those who cited pain as the reason for abandoning exclusive breastfeeding decreased from 1.5% to 1.1%.

Conclusions: The evidence-based implementation project we describe significantly improved compliance rates in most of the evidence-based criteria considered. In consequence, the prevalence of NPT fell significantly. Nevertheless, there was no significant impact on the proportion of mothers abandoning breastfeeding for this reason.

Keywords: Best practice analysis; Breastfeeding; Clinical audit; Evidence-based practice; Painful nipple.

Abstract word count: 245

What is already known

There is no robust evidence for the use of any given strategy to treat breastfeeding-related nipple pain and/or trauma (NPT). However, it has been suggested that the best intervention is to provide comprehensive breastfeeding education, including advice on proper positioning and attachment, together with appropriate assessment of the mother and newborn. Therefore, it is important to incorporate and monitor clinical practices in this respect.

What this paper adds

This study shows that it is essential to evaluate the clinical practices carried out, often routinely, analysing the care provided and the protocols applied, and identifying possible barriers. This analysis should be conducted by a multidisciplinary team, including all those involved in caring for the mother and her child, in order to ensure the protocols used are up to date and that evidence-based quality standards are applied.

Introduction

According to scientific evidence, breast milk is the preferred option for feeding the newborn, since breastfeeding provides short and long-term health benefits both for the mother and for the child[1]. Therefore, promoting exclusive breastfeeding during the first six months of life, followed by supplementation with other foods up to the age of two years, is a fundamental priority in healthcare programmes[2]. Newborns who receive long-term breastfeeding (more than 12 months) have lower rates of morbidity and mortality associated with infectious complications and diseases such as asthma, atopic dermatitis and gastrointestinal disease[2]. Breastfeeding is also associated with a reduced incidence of metabolic disease (for example, diabetes, overweight and obesity) during childhood and adolescence[3,4]. Among benefits for the mother, breastfeeding can reduce the risk of cancer (breast, ovary and endometrium), diabetes and cardiovascular disease[5].

The reasons for discontinuing breastfeeding are many and varied, but a major factor is the presence of nipple pain and/or trauma (NPT). Vieria et al.[6] defined breast fissure as a macroscopic cutaneous lesion in the breast tip and areola, which may take the form of a cleft, loss of skin, wound or clinical evidence of erythema, oedema or blister. Studies report that 80-

90% of breastfeeding women experience NPT[7]. This normally appears between the third and seventh day postpartum and can last until the tenth day postpartum[8]. Therefore, it is of crucial importance to intervene to prevent and/or treat NPT during the immediate postpartum period.

Among studies of this question, one systematic review[8] evaluated five different interventions: glycerine pads, lanolin with or without nipple shield, expressed breast milk and a general purpose nipple ointment. This review found insufficient evidence to recommend any specific intervention, but concluded that, regardless of the treatment used, pain decreased to mild levels at approximately 7-10 days postpartum. However, another study examined the joint use of highly purified anhydrous (HPA) lanolin with expressed breast milk and observed a reduction in pain between days 2 and 7 postpartum in the treatment group, while pain levels remained unchanged ($p<0.001$) in a control (breastfeeding) group over the same period[9]. The extent and depth of trauma was also relieved in the HPA lanolin group after the first week postpartum; this improvement was greater in the HPA lanolin group than in the control group ($p=0.025$)[10]. Another novel treatment, based on photomodulation using a low level laser, was considered in a randomised controlled trial, but the authors concluded that although perceived pain decreased by one point, the use of this approach alone was not effective[11].

Although the literature reflects considerable variability in treatment strategies and in results achieved, the current scientific consensus is that the management of this condition should include an assessment of positioning and attachment during breastfeeding by a trained healthcare professional (Grade A)[9,12], together with investigation to determine the cause of persistent nipple pain (Grade A)[9,12]. NICE postnatal care guidelines recommend that a practitioner with skills and competencies in breastfeeding support should assess individual circumstances to identify and address concerns[13]. As part of the breastfeeding assessment, the practitioner should observe a feed within the first 24 hours after the birth, and at least one more during the first week[13]. Treatment options for NPT include breastfeeding support, antibiotics, antifungal treatments and/or warm compresses, depending on the circumstances and clinical judgement (Grade of evidence B)[11].

Context

The XX XX University Hospital (MVUH) in Santander (Spain) is a public, tertiary care hospital with 906 beds, serving the regional community of Cantabria, which has around 580,000 inhabitants. In 2020, the hospital attended 2,830 deliveries (20% caesarean, with 10 delivery rooms), which represents 82% of births in the community[14]. Its obstetric hospitalisation area has 30 individual rooms where mothers and their infants can remain together. MVUH has a lactation coordinator (a nurse specialist in paediatrics, with International Board Certified Lactation Consultant certification, who advises and trains health personnel on breastfeeding issues. In addition, there is a Lactation Clinic staffed by the lactation coordinator, a neonatologist and, occasionally, a gynaecologist. The maternity unit employs 17 registered nurses and 1 midwife. Postpartum hospitalisation normally lasts 48–72 h, depending on whether the patient had a vaginal or caesarean delivery, respectively.

According to the latest data obtained, 83% of the mothers admitted to the hospital unit begin breastfeeding, but only 54% continue until discharge[15]. One of the reasons for abandoning breastfeeding is the presence of NPT[7]. Moreover, there is a lack of objective data on the percentage of women who experience NPT during their hospital stay. Accordingly, we consider it important to study the prevention and/or management of this problem, to ensure that breastfeeding is not only initiated but also maintained. The completion of an evidence-based care implementation project at the MVUH provided a suitable opportunity to determine the prevalence of NPT in our unit, assuming this to be a cause of breastfeeding being abandoned. The aim of this project was to enhance NPT prevention and management and thus increase the rate and persistence of breastfeeding. Although a wide range of treatments have been prescribed for NPT, including lanolin ointment, silicone dressings, expressed milk or the use of a nipple shield or breast pump, for many women prevention and/or early management of this condition are essential for breastfeeding to be not only started but continued.

Objective

To assess compliance with evidence-based criteria for preventing and managing NPT, among mothers who wish to breastfeed at the maternity unit of the MVUH. Specifically, we aim to:

- Determine the prevalence of NPT in this hospital, before and after the implementation of evidence-based care.
- Identify the barriers and facilitators to achieving compliance with evidence-based criteria for preventing and managing NPT.
- To improve this compliance.
- To reduce the rate of abandonment of breastfeeding due to NPT.

Methods

The evidence-implementation project applied at the MVUH used the JBI Practical Application of Clinical Evidence System (JBI-PACES) and the Getting Research into Practice (GRiP) audit and feedback tool. These instruments for promoting evidence-based healthcare are used to identify knowledge gaps, to develop an appropriate action plan and to perform follow-up audits, thus raising standards in clinical practice[16]. The project was structured into three phases, implemented over a six-month period from December 2019 to May 2020.

Phase 1. Stakeholder engagement and baseline audit

During phase 1, the project team was assembled, the JBI-PACES and audit criteria were established, the setting and sample size determined and the baseline audit executed.

Establishing the project team

A registered nurse from the maternity unit (the project leader) presented the audit project to the key stakeholders: two doctors (a gynaecologist and a paediatrician), two nursing supervisors from the maternity wards, a lactation coordinator, two care nurses from the hospital areas involved, a midwife and a nurse from the hospital research support unit. All expressed interest in the project and the project team was formed.

Setting up the JBI Practical Application of Clinical Evidence System and identifying audit criteria

The JBI-PACES programme supplied the six evidence-based audit criteria used to evaluate compliance with best-practice recommendations for preventing and managing NPT caused by breastfeeding (**Table 1)**.

Identifying the setting and sample size

The following study inclusion criteria were applied: postpartum women, with their newborns, admitted to the obstetric hospitalisation unit, in December 2019, and who on admission expressed the wish to breastfeed. Those who expressed the wish not to breastfeed, or whose infant was admitted to the neonatal care unit or who lacked the ability to use and understand Spanish were excluded.

The sample size was calculated assuming a reference population of 240 births per month. A random sample of 154 individuals was considered a sufficient size with which to estimate, with 95% confidence and ±5% precision, a population percentage of around 50%, with a predicted replacement rate of 10%. Data were collected consecutively over several days until the sample size was completed.

Conducting the baseline audit

A baseline audit was conducted in December 2019 to collect information about compliance with the audit criteria before any intervention was made. A convenience sample of 267 women were contacted on the day of their hospital discharge (48–72 h postpartum) and invited to participate. On provision of informed consent, the mothers were asked to complete an ad-hoc questionnaire developed by the project team to assess audit criteria 1, 2 and 5. The questionnaire contained nine dichotomous questions, divided into two blocks. The first block (questions 1-3) concerned knowledge of breastfeeding and the advice received in this respect. The second block (questions 4-9) asked whether the mother had experienced NPT, her opinion of the counselling received, and the effectiveness of the pain relief methods used (**Appendix I**). To assess audit criteria 3, 4 and 6, the medical histories of the mother and her infant were reviewed and a physical examination of both was performed (see **Table 1**). The compliance rates for each criterion were calculated and presented to the project team during a subsequent briefing session.

Phase 2: Design and implementation of GRiP strategies

During this phase, which took place from January to March 2020, the project team reflected upon the results of the baseline audit. The project team discussed these differences between clinical practice and best practice according to available evidence, and identified barriers to compliance. The GRiP tool was used to document these barriers and to identify appropriate strategies and resources to overcome them. On this basis, interventions were designed to improve compliance with the best-practice criteria for preventing and managing NPT related to breastfeeding and an institutional protocol was developed to apply the strategies proposed. A follow-up audit was then performed to evaluate the strategies adopted.

Phase 3: Follow-up audit after implementation of the compliance improvement strategy

The follow-up audit was conducted during April-May 2020 on a sample of 275 women, using the same criteria as in the baseline audit, except that the puerperal women who had tested positive for COVID-19 and had been admitted to another hospital unit were also excluded. The audit results were analysed to assess the effectiveness of the implementation and then presented to the key stakeholders.

Ethical considerations

The project was registered as a quality improvement activity within the participating hospital, and therefore did not require ethical approval. The patients concerned were given an information sheet describing the project aims, and their verbal consent was requested and obtained in every case. The data collected were anonymised before inclusion in the project database, in accordance with current legislation.

Data analysis

The findings of the baseline and follow-up audits for the six criteria were analysed descriptively and graphically using the JBI-PACES program (version 2, 2019) (JBI, Adelaide, Australia). All

data were subjected to a descriptive and inferential analysis (95% CI and z-test), using the Epidat 4.2 statistical package.

Results

A sample of 267 puerperal women was obtained for the baseline audit while 275 puerperal women were included in the six-month post-audit study. **Table 2** shows the socio-clinical characteristics of the participants and their newborns, for both audits. 39.3% of the women had breastfed prior to the baseline audit, compared to 42.5% in the follow-up. **Figure 1** shows the results of the baseline and follow-up audits, including the rate of compliance with each criterion according to the JBI-PACES program.

These audits identified ten obstacles to compliance with best practices, and remedial strategies were then implemented. One of the barriers related to criterion 1 (knowledge) was the lack of maternal education provided to women hospitalised for pregnancy complications. Moreover, during the COVID-19 pandemic, maternal on-site training was suspended in primary care clinics. Criterion 2 (training) was fully met in both periods. Barriers related to criteria 3 (detailed assessment), 4 (the use of a specific pain-assessment instrument), 5 (assessment of breastfeeding position and attachment by a qualified health professional) and 6 (assessment for ankyloglossia) were related to deficiencies in the electronic medical record (which had no provision for such assessments) and its use by professionals, together with insufficient or deficient training in the prevention and management of NPT.

Knowledge-related barriers to compliance (criterion 1) were addressed by new strategies to improve maternal education. Thus, women hospitalised for pregnancy complications were offered one-hour individual or group sessions, twice weekly, as part of the Cantabria Health Service pre-maternity programme, adapted to the patient's clinical situation and to the hospital environment. Unfortunately, these sessions had to be suspended due to the Covid-19 pandemic, but they were replaced with online sessions provided via the Facebook page "Matronas Cantabria".

Strategies related to criteria 3, 4, 5 and 6 included changes in the electronic medical history records and improvements to the communication of best practices in the prevention and

management of NPT, via focused training for nurses, midwives, paediatricians and gynaecologists. The electronic medical record system was enhanced by the inclusion of a standardised method for breastfeeding observation and assessment, including the mother's clinical history and relevant data on the newborn. The method included objective criteria for the correct observation of breastfeeding, for recording nipple pain (on a visual analogue scale, VAS), on the use or otherwise of nipple shields, on breast and nipple anatomy and on the mouth anatomy of the newborn. The presence or absence of ankyloglossia was also noted. This record was developed by the project team and approved by the department heads for paediatrics and gynaecology, as well as by the hospital's clinical records commission. These records were introduced in two phases, as follows:

1. Appropriate training was provided for all maternity nurses in the use of the new lactation record system, via theoretical and practical presentations, with real observation of breastfeeding, followed by data recording and the resolution of doubts that might arise.
2. The new tool was piloted for 15 days, before definitive implementation.

The certified training programmes included:

- A 17-hour in-person training course in breastfeeding, offered twice yearly, for staff with direct involvement in mother-child care.
- A one-hour practical workshop on expressing and storing breast milk, observation of feeding, and counselling on breastfeeding, provided every Monday.
- A summer initiation course for newly-hired staff (1.5 hours specific to breastfeeding topics).
- 2020 Update (Cantabria Health Service online training course. January 2020 subject: Breastfeeding): A 3.5 hour training activity on breastfeeding procedures, with a 10-item test questionnaire (pass mark: 80% correct responses).

In addition to the above, a NPT prevention and management procedure was developed, with referral to qualified personnel. This procedure was developed by the project team, based on evidence[16,18] and approved by the hospital's management commission and quality service. The

content of the procedure was distributed by e-mail, described in training sessions for health practitioners and made available on the hospital's intranet.

The results of the GRiP process are presented in **Table 3.**

Following application of the evidence-based project, these changes were observed in the audit criteria:

- Criterion 1. Premiparous breastfeeding women receive comprehensive breastfeeding education including proper positioning and attachment: baseline 69%, post-audit 34%; p<0.01 (95% CI 0.272 to 0.430).
- Criterion 2. Women receive one-to-one breastfeeding training: 100% in both audits; p=n/s.
- Criterion 3. In women experiencing NPT, a detailed assessment (including clinical history and physical examination) of the mother and infant is conducted: baseline 0%, post-audit 98%; p<0.01 (95% CI -0.993 to -0.956).
- Criterion 4. In women experiencing NPT, pain is assessed using an appropriate measuring instrument, such as the visual analogue scale: baseline 0%, post-audit 94%; p<0.01 (95% CI -0.964 to -0.905).
- Criterion 5. In women experiencing NPT, a qualified health professional assesses breastfeeding position and attachment: baseline 63%, post-audit 88%; p<0.01 (95% CI -0.32 to -0.181).
- Criterion 6. If pain persists after the health professional's review of position and attachment, the infant is assessed for ankyloglossia: baseline 9%, post-audit 97%; p<0.01 (95% CI -0.921 to -0.841).

The following outcomes were recorded:

- Nipple pain: baseline 63.3%, post-audit 53.5%; p = 0.02 (95% CI 0.016 to 0.181).
- Pain as the exclusive cause of breastfeeding abandonment: baseline 1.5%, post-audit 1.1%; p= ns.
- Nipple trauma: baseline 37.8%, post-audit 24.7%; p = 0.01 (95% CI 0.054 to 0.208).

- Trauma as the exclusive cause of breastfeeding abandonment: baseline 0.4%, post-audit 0%; p= ns.

Discussion

This evidence-based implementation project was conducted at the maternity unit of the MVUH to assess compliance with evidence-based criteria for preventing and managing NPT, among mothers who wished to breastfeed. The baseline audit revealed poor compliance in NPT management practice with all of the criteria considered, except training (criterion 2), which was fully met in both periods. Significant improvements were achieved in the other five criteria. The project achieved a significant reduction in the rates of NPT but did not produce a major impact on the level of BF abandonment for this reason. Although we have not studied it, we believe that the decision to abandon exclusive breastfeeding in the immediate puerperium may be due to other non-clinical reasons. In a previous prospective cohort study conducted in our hospital in 970 infants, we studied the main reasons for cessation of breastfeeding reported by mothers during the first year of life[17]. Main reasons for cessation of breastfeeding were: maternal desire 15,83%, low milk supply 15,44% and work-related causes 9,85%. Morrison et al[18] in their revision about maternal explanations for early breastfeeding cessation in economically developed countries found the most common themes were perceived inadequate supply and breast or nipple pain. It would be necessary to carry out research to analyze the motivations of mothers to abandon breastfeeding in the immediate postoperative period, distinguishing between the clinical and non-clinical causes that lead them to make this decision. On the other hand, we consider that the COVID-19 pandemic also influenced exclusive breastfeeding rates at discharge, since positive mothers were excluded from the follow-up period.

Breastfeeding education for mothers

It is important to provide mothers with antenatal education on breastfeeding at an early stage, during the pregnancy, because one of the reasons why women are unable or unwilling to breastfeed concerns a lack of education and knowledge about how to do so. Prenatal education for all mothers-to-be on the importance and management of BF is a key aspect of success. Unfortunately, the COVID-19 pandemic had a negative impact on the project we describe;

according to the baseline audit, 69% of mothers had received comprehensive breastfeeding education, including positioning and attachment, but in the follow-up audit, this figure fell to just 34%.

Detailed assessment in women experiencing NPT

According to available scientific evidence, the correct positioning and attachment of the newborn to the breast is the most important factor in preventing NPT, which is why observation of feeding and measurement with a validated scale are so essential[19]. Among the feeding assessment scales that have been proposed, the best known are the LATCH[20] scale and the WHO feeding observation sheet. The MVUH unit uses the WHO scale[21], which is included in the newborn's electronic medical history record. The observation and support of breastfeeding (criterion 2) was correctly and fully performed, in both audits. In our opinion, in addition to the computer support, the use of a specific protocol probably helped the unit achieve this objective.

Nipple pain assessed using a purpose-built measurement instrument

To improve breastfeeding recording and assessment, a new questionnaire was developed, which included NPT-related data on the mother and the newborn, scored on a visual analogue scale (VAS), an approach that is practical and easy to interpret. The use of this instrument dramatically improved the results obtained, with the compliance rate for pain record registration (criterion 3) increasing from 0% in the baseline audit (when no such record was maintained) to 98% in the post-audit. Moreover, in 94% of cases, the medical history of postpartum women with NPT was assessed, and a physical examination of mother and baby was performed (criterion 4).

In a similar implementation project, described by Yang et al.[22], compliance with criterion 4 increased from 85% to 100%, with the use of a Numerical Rating Scale (NRS) and the Tongue-tie and Breastfed Babies (TABBY) assessment tool. Like ours, this project consisted of multidisciplinary team members working towards a common goal and using a common approach. In other studies, Avignon used the VAS[4] and Shimoda et al.[23] evaluated pain, but neither indicated the use of a specific measurement instrument, nor employed the audit criteria we describe.

In the MVUH unit, the VAS is now routinely used to assess nipple pain intensity. Various scales can be used for this purpose, but for acute pain, the most appropriate single-dimension intensity

scales are the VAS and the NRS. These can be incorporated into physical examinations and effectively complement other assessments of NPT in breastfeeding women[24].

Assessment of breastfeeding position and attachment by qualified health professionals

The long-standing presence in the unit of an International Board Certified Lactation Consultant means that specialised support is available for puerperal women who have difficulties with breastfeeding. In our sample, 63% of the puerperal women suffering from NPT were already receiving counselling. However, this service is only available in the mornings, and not at all at weekends. The nurses who work directly with the mothers and their babies have specific training in breastfeeding counselling. Their knowledge in this field was assessed using the ECOLAE[25] questionnaire. The results obtained were similar to those of related professionals such as midwives. Therefore, considering the unit's nurses to be qualified in this field, 88% of the postpartum women with NPT had access to qualified counselling (criterion 5).

Ankyloglossia assessment

In relation to criterion 6, implementation of the project significantly improved the recording of sublingual frenulum, which rose from 9% at baseline to 97% in the post-audit. If ankyloglossia was detected, together with persistent breastfeeding difficulties such as poor milk transfer and/or painful latch-on, initial consultation with a lactation specialist was recommended. If problems persisted, lingual frenotomy, which can be performed without general anaesthesia, might be considered. Results from previous clinical trials are mixed, but generally suggest that frenotomy helps relieve maternal pain during and after breastfeeding[26,27]. A recent meta-analysis by Shekher et al. concluded that frenectomy is associated with improvements in breastfeeding that may be significant if ankyloglossia is addressed as early as possible. The quality criterion is that the presence of a sublingual frenulum should be detected within the first 48 hours of life[28].

Limitations

This implementation project had several limitations. Firstly, only patients who spoke and understood Spanish participated in the audit. Secondly, implementation of the GRiP phase and the follow-up audit took place at the outset of the COVID-19 pandemic. During this period, puerperal women who had tested positive for the disease were excluded from the sample. Finally,

the project was conducted over a short span (six months) and the sustainability of the implementation has yet to be established.

Conclusions

The evidence-based implementation project we describe significantly improved compliance rates with most of the evidence-based criteria considered. The project was designed to help prevent and/or manage NPT, among mothers who wished to breastfeed at the maternity unit of the MVUH. This improvement was achieved via several strategies, which were accepted and implemented by all the health practitioners involved. The strategies included improving the mothers' understanding of the issues involved, with particular regard to NPT, including an assessment of this condition in the electronic clinical history, making use of a specialised instrument for assessing NPT, ensuring the availability of a qualified health professional to assess and advise on correct breastfeeding position and attachment, and considering the possible presence of ankyloglossia in cases of persistent pain. Future audits are planned to ensure the sustainability of the project.

Although this project achieved a significant reduction in rates of NPT, it did not have a significant impact on the numbers of women abandoning breastfeeding due to NPT. This low impact was probably influenced by the exclusion from the sample of mothers who tested positive for COVID-19 during the follow-up audit.

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Conflict of interest

There is no conflict of interest to declare for this project.

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Appendix I: NPT questionnaire

1. Did you receive information on latch-on and proper breastfeeding posture during the preparation for childbirth with the midwife at your health centre?

□Yes □No

2. Did any health professional observe a breastfeeding feeding during your hospital admission?

□Yes □No

3. Did you receive any help/advice on latch-on and feeding posture during your admission?

□Yes □No

If you experienced nipple pain/trauma, please answer the following questions:

4. Have you been assessed by a midwife / paediatrician / lactation coordinator due to pain?

□Yes □No

5. Have you been advised to apply expressed milk (colostrum) to the nipple?

□Yes □No

6. Have you been advised to apply a dressing (Mepitel) to the nipple?

□Yes □No

7. Have you been advised to apply an ointment (Lanolin) to the nipple?

□Yes □No

8. Have you used a nipple shield for nipple pain/trauma?

□Yes □No

9. Have you used a breast pump as an alternative to suffering nipple pain/trauma?

□Yes □No