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An evaluation of the signs of nipple trauma associated with breastfeeding: A Delphi Study

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Key Messages

- There is no consensus on the definitions of nipple trauma, so that identical events are assessed inconsistently by different observers.
- Based on the responses of multiple experts consensus was reached on 48 definitions for the seven signs of nipple trauma related to breastfeeding.
- We developed an observation tool “seven signs of nipple trauma associated with breastfeeding” by combining 48 definitions and case images.
- Further research will be required to determine if the application of this tool can improve objectivity in monitoring and evaluating nipple trauma.

An evaluation of the signs of nipple trauma associated with breastfeeding: A Delphi study

Abstract

Background: No consensus on the definitions of nipple trauma has been reported. Thus, different individuals assess identical events inconsistently.

Research Aim: To establish clear definitions for the seven signs of nipple trauma related to breastfeeding—erythema, swelling, scabbing, blistering, fissure, purpura, and peeling—and to reach consensus among multiple specialists.

Methods: We implemented a longitudinal, prospective survey design using a three-step Delphi method. In the first survey we targeted specialists in breastfeeding, dermatology, and cosmetics, and we presented images as representative cases during a set of semi-structured interviews. In the second and third surveys, we questioned midwives who were certified as “advanced midwives” through mail using a questionnaire prepared based on results of the first survey. The agreement criteria of this study were as follows: (1) a median of 2.0 or below, (2) an interquartile range of 1.0 or below, and (3) at least 51% showing responses of either “strongly agree” or “agree.”

Results: Based on responses of the 42 experts, we reached a consensus on 48 items: eight related to erythema, 10 to swelling, nine to scabbing, seven to blistering, seven to fissure, four to purpura, and three related to peeling. Then we classified these items based on the condition or possible mechanism of the wound. Finally, we developed an observation tool “seven signs of nipple trauma associated with breastfeeding” along with the images.

Conclusions: Application of this tool for breastfeeding support could improve objectivity in observing and evaluating nipple trauma.

Background

Breastfeeding is an innate, and biologically stable behavior. However, many women abandon breastfeeding early due to nipple trauma, as the major contributing factor (Ruth et al., 2019). Azin et al. (2018) reported that on average 80%–90% of breastfeeding women experience nipple trauma. A similar trend has been reported in Japan, with a nipple trauma rate of 100% within nine days after delivery (Nakamura & Asaka, 2019). Therefore, the prevention and treatment of nipple trauma during the early puerperium period is essential for the success of breastfeeding.

Physical stimulation of the skin and poor latch on techniques during breastfeeding may contribute to nipple trauma (Riordan, 2019), with signs of trauma changing over time through repeated breastfeeding behaviors (Nakamura & Asaka, 2019). Midwives macroscopically observe and assess these signs. However, identical events are assessed inconsistently by different observers (Cirico et al., 2017). In previous studies authors have reported only moderate inter-rater reliability for both erythema and swelling, revealing differences in clinical judgment (Nakamura et al., 2018). These inconsistencies have caused a lack of consensus about treatments that are most effective for nipple trauma (Mariani et al., 2018). Therefore, explicit definitions of nipple trauma are urgently needed to advance nipple trauma treatments.

Erythema, swelling, scabbing, blistering, fissure, purpura, and peeling are the seven signs of nipple trauma that have been identified by researchers and their reliability for diagnosing nipple trauma has been confirmed (Nakamura et al., 2018). These medical terms are used primarily in the fields of dermatology and wound repair. However, no definitions have been established that focus on nipples and breastfeeding. In this study, breastfeeding has been defined as the condition in which mother’s own milk is given to a baby regardless of the duration,

amount, or method. Thus, our aim was to establish clear definitions for the seven signs of nipple trauma related to breastfeeding—erythema, swelling, scabbing, blistering, fissure, purpura, and peeling—and reach a consensus among multiple specialists.

Methods

Research Design

This was a longitudinal, prospective survey design using a three-step Delphi method with each step informing the next one. The Delphi method is a technique used for reaching consensus and involves presenting surveyed results through an estimate-talk-estimate process. We created a questionnaire about a case of nipple trauma, following which opinions were consolidated (Marlen & Julia, 2020). This method has previously been employed in the field of dermatology and breastfeeding (Maverakis et al., 2018; Shawahna et al., 2018) to establish diagnostic and therapeutic techniques. Our study protocol was approved by the Ethical Review Board of the Department of Health Sciences of Hokkaido University (Approval number: 19-27, 19-85-1).

Setting and Relevant Context

Our study was conducted in Japan. The number of births in Japan has continued to decline since 1973, with about 840,000 births in 2020. According to the *Japanese National Nutrition Survey* of preschool children in 2015, 96.0% pregnant Japanese women hoped to breastfeed their babies, and 96.5% actually breastfed their babies for the first month (Ministry of Health, Labour and Welfare, Japan., 2016).

In Japan, breastfeeding support is mainly provided by midwives. Hence, the ability of Japanese midwives to accurately observe nipples is beneficial for supporting breastfeeding. When mothers have trouble with nipple pain or mastitis, they access midwifery centers. The cost is

approximately \$45 per hour for a consultation and breast massage.

Advanced midwives play a particularly important role in supporting breastfeeding in Japan. The *Japan Institute of Midwifery Evaluation* is the body that certifies advanced midwives as being capable of providing midwifery care in clinical practice. By 2020, approximately 1/4 of employed Japanese midwives were certified as advanced midwives. Similarly, since 2018, advanced midwives also made insurance available for breast care to prevent mastitis. As a result, the role of advanced midwives has been emphasized in Japan.

Sample

For the first survey, the inclusion criterion was that participants would be specialists in the field of breastfeeding, dermatology, and cosmetics who observe either nipples or skin issues daily. Participants were also selected using a non-probability sampling technique, in addition to referrals from acquaintances or appointments made through websites. Consequently, five specialists from different fields consented to participate in the survey, including a midwife, a pediatrician providing breastfeeding outpatient services, a cosmetic surgeon, a dermatologist, and a certified nurse specializing in breast cancer nursing. To allow for a wide spectrum of opinions, the first survey was not limited to a specific occupation.

For the second and third survey, the inclusion criteria was that participants would be midwives working at midwifery centers who had been certified as advanced midwives from 2016 to 2017. In the second survey of advanced midwives ($n = 265$) whose names and affiliations were listed in the official register and whose addresses were identified, 60 people who responded to the questionnaire became participants (response rate: 22.6%). For the third survey, 42 (85.7%) of the second survey participants replied were included. The number of panelists finally included in this study (Table 1) was sufficient based on a previous study

(Marlen & Julia, 2020), which reported that requiring panelists were in the low double-digit range, following the Delphi method.

Measurement

This study was conducted in Japan. Therefore, we also ensured that the words/phrases used during the study had English subtitles. Similarly, we conducted a literature review of nipple trauma and obtained translation advice from medical English experts.

There were three steps in our process (creating the survey, 1st survey and 2nd survey), during each step data were collected that informed the subsequent step. During the first step, face-to-face semi-structured interviews were conducted to create the questionnaire for the second step. During each interview, the interviewer presented representative cases of each of the signs of trauma (Figure.1). Participants were asked to talk freely about the “characteristic of the each sign of trauma” in accordance with the interview guide (Supplementary File.1). The images of each sign of trauma were obtained during our previous study (Nakamura et al., 2018) at an Obstetrics and Gynecology facility in Sapporo, Japan. Each interview session lasted 30 to 60 minutes. The content of the interviews were recorded using a digital voice recorder, after consent was obtained from the participants. Incentive gift cards worth \$45 were subsequently given to participants after the interview.

The second step was conducted using the created questionnaire (Supplementary File.2), based of results of the first step. In the questionnaire, representative cases were presented, and participants were asked how strongly they agreed with the characteristics being associated with nipple trauma. We used a five-point Likert scale (“strongly agree” to “strongly disagree”). Additionally, a free description field was added to the questionnaire, where participants were asked to write descriptions of nipple trauma signs, along with the characteristics that they had

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previously observed, which were different from those on the questionnaire. We also asked participants to return the questionnaire within 2 weeks. Notably, we explained in writing that a third survey and a feedback phase would be conducted, and participants were asked to return an enclosed consent form stating whether they were willing to receive the third survey.

The third survey included 13 items that participants commonly cited in the free description field of the second survey (Supplementary File.3). It is recommended when using the Delphi method that the results of the previous steps be presented after each round to inform participants of their position relative to other members of the group (Marlen & Julia, 2020). Therefore, a report listing the number of respondents, each option selected, and the rate of agreement as obtained during the second survey was enclosed for reference with the third survey questionnaire. We explained to the participants that the report was intended solely for helping them understand their position relative to the overall trend and not for encouraging them to agree with certain opinions. We also requested that participants return the questionnaire within two weeks. Additionally, we explained that a feedback phase would be conducted afterwards, and asked participants to respond in an enclosed consent form whether they wanted to receive the feedback. Finally, results of the third survey and incentive gift cards worth \$9 were mailed with the feedback.

The agreement criteria adopted for this study were the selection of factors that meet all of the following three criteria ; (1) a median of 2.0 or below, (2) an interquartile range of 1.0 or below, and (3) at least 51% of the responses of either “strongly agree” or “agree”. Although no established standards were available for setting an agreement rate representing the final consensus, we set this agreement criteria based on what researchers have previously reported. We considered that this was appropriate for an exploratory study (Halvorsrud et al., 2018).

Data Collection

The first survey was administered between July and October 2019, the second survey was conducted in February 2020, and the third survey was in March 2020. Written informed consent was obtained from all participants. Participation in the study was voluntary, and no disadvantage was involved when participation was refused. The withdrawal of consent for participation was also guaranteed at any time during the research. Collected data were managed using a dedicated personal computer and stored in a lockable location; it will be stored for five years after completion of the study.

Data Analysis

Descriptive statistics were used to analyze demographic variables. First, the characteristic of each sign was extracted verbatim from the records obtained from interviews. These records were encoded as single units. Next, all codes were categorized based on the similarity of the semantic content, after which a representative label was given to each semantic category. Afterward, it was determined whether each category was appropriate as a questionnaire item, following text editing based on conclusions. Two researchers conducted each analysis, with several discussion sessions held before reaching consensus. Content validity was also confirmed by a preliminary test in which three midwives checked the contents of the questionnaire.

Similarly, for the second and third surveys, descriptive statistics were also used to calculate the agreement rate between each item. We calculated the median and interquartile range of the five-point scale for each item. Meanwhile, researchers considered contents of the free description field in the second survey and included these contents in the modified draft items of the third survey. Results obtained from the third survey were subsequently treated as the consensus of this study.

Results

Characteristic of the Sample

Demographic characteristics of participants are shown in Table 2. The average age of the participants in each survey exceeded 50 years. Additionally, the average professional experience exceeded 25 years.

Delphi Steps

During the first step, a total of 72 items were extracted from the structured interviews. These were 9 items for erythema, 12 for swelling, 11 for scabbing, 11 for blistering, 10 for fissure, nine for purpura, and 10 for peeling (Table 3).

Consensus was reached during step two on 36 (50%) of the 72 items from step one (Table 4). A response rate of 22.6% was obtained. From the analysis of the write in descriptions, one item was removed, and 13 items were added to the step three questionnaire (Table 5). Some descriptions suggested that frequent breastfeeding immediately after childbirth caused erythema despite non-shallow sucking. Accordingly, we removed one item that included two factors (frequent breastfeeding and shallow sucking), “caused by frequent shallow sucking by the child” (erythema No. 9), then divided it into two items, “caused by frequent breastfeeding” (erythema No. 10) and “caused by shallow latching” (erythema No. 11). Based on these changes, the signs of trauma might appear immediately after childbirth during the early breastfeeding period (3–4 days after the start of sucking). Accordingly, a new item “sign observed in early breastfeeding stage” was added (erythema No. 12).

According to the description that prolonged non-nutritional sucking caused swelling, we added “caused by prolonged non-nutritional sucking” (swelling No. 13). Also, given the description that concomitantly occurring breast engorgement was troublesome we added

“accompanied by breast engorgement” (swelling No. 14). Moreover, given the description of selective drinking by the child or galactostasis due to congestion of milk secretion, we added “accompanied by galactostasis” (swelling No. 15).

Similarly, based on the description that scabbing occurred shortly after childbirth or during hospitalization, we added “a sign that occurs in the early breastfeeding period” (scabbing No. 12). Regarding the description that the condition was chronic or prolonged, researchers deliberated and determined that time had elapsed after damage was inflicted and wound experienced becomes chronic. Therefore, we added “time elapsed after damage, and the wound became chronic” (scabbing No. 13). Likewise, based on the description that too much negative pressure was partially responsible for blistering, we added “caused by a localized negative pressure” (blistering No. 12).

Due to the description that a fissure occurs when the child grabs the nipple hard between tooth ridges, we added “caused when the latched mouth was removed” (fissure No. 11). However, based on observations that the maxillary sinus formed by the tongue and palate was shallow, we added “generated in association with the shapes of the tongue and palate of the child” (fissure No. 12). Moreover, due to the description that a fissure was caused by galactostasis, we added “caused by galactostasis” (fissure No. 13). Finally, based on the description that the purpura was caused due to use of nipple shields, we added “caused by inappropriate use of nipple shields” (purpura No. 10). No new items were added regarding nipple peeling.

During the third survey, 48 (57.1%) of 84 items reached consensus (Table 5). All 36 items that reached consensus during the second survey were also agreed on in the third survey, along with 12 items that were newly agreed-upon in this survey. These included seven items

based on the contents of free descriptions obtained from the second survey. For the 84 items presented, no descriptions required modifications. No opinions or queries about results were received after the results of the third survey.

Discussion

Participants included in this study were critical to achieving the research aim. To ensure the reliability of the Delphi method, it was important to ensure that specialists within a relevant field of study were selected as panelists (McMillan et al., 2016). During the first survey, it was useful to obtain information through interviews with experienced specialists to extract definitions for each sign of nipple trauma. However, for the second survey, participants were highly experienced specialists. Moreover, among the participants, the advanced midwives were more interested in nipple trauma. As a result, we were successful in obtaining the opinions of more expert participants.

For reliable consensus indicators, despite limitations of the approach, results reflected expert consensus. Some would argue that a stability of consensus can be reached if the between round group responses varied by $\leq 10\%$ or showed 70–80% agreement. In this study, 15 (36.5%) of the 41 items were between round group responses, which varied by $\leq 10\%$. However, with the 37 (90.2%) items, the agreement rate was higher in the third survey than in the second survey; whereas, with the 38 (79.1%) of 48 items for which consensus was obtained, the agreement rate was 70% or higher. Therefore, results obtained from this study are reliable.

Based on the results from this study, we identified seven signs of nipple trauma associated with breastfeeding (Figure 1). Although further clinical research will be required, we propose that using this tool will improve objectivity in the observation and evaluation of nipple trauma.

The 48 agreed items were classified into wound conditions, possible mechanism and

assessment. Items indicating wound conditions were similar to literature definitions used in the dermatology field (Wolff & Johnson, 2017). The wording was also based on the wound occurred on the nipple's skin. Additionally, some figurative expressions, e.g., "looks like a mulberry" (swelling No. 4), and onomatopoeic expressions, "bumpy" (swelling No. 7) and "puffy" (blistering No. 3) were used to describe extent of cases. We propose that these expressions will help evaluators understand the condition being referred to more clinically and help them reach a common perception.

For items related to the possible mechanism of the wound, specific expressions relating to the nipple tissue were used. For purpura, "caused by strong sucking pressure," was consistent with those of previously reported that breast pumps generated nipple bruising (Berens et al., 2016). Major items related to the possible mechanism of these factors were also added in the free description field. Furthermore, since these items were based on opinions of highly experienced midwives, we expected that they will provide critical insights for observing and assessing nipple trauma.

With the consensus of fissure (No. 9), "when this case is observed, it should be expressed as "fissure", the term "fissure" referred to one sign of nipple trauma. In previous reports, the term "fissure" has been used in two ways. One was a general term for nipple injuries in the same way as "nipple trauma" is used (Maryam et al., 2020; Azin et al., 2018). The other was used as a sign of nipple trauma, similar to our findings. Therefore, the determination of the definition of fissure in this study will help to unify the view of fissure.

Additionally, differences between swelling and blister were noted. Some considered swelling and blistering in nipple tissues as edema of the skin. However, swelling and blistering are separate signs within the dermatology field. This study revealed that although both swelling

and blistering were observed as edematous, their mechanisms of occurrence were different; swelling appeared throughout the nipple, while blistering appeared locally.

A strength of this study was our collaboration with various specialists, who had many years of clinical experience, providing definitions for nipple trauma, which had not been agreed on previously. In future research, multiple experts would have to observe nipples using the seven signs of nipple trauma associated with breastfeeding and examine the reliability and validity of this tool. We expect that in the future, objectivity will be improved leading to better continuous support for breastfeeding.

Limitations

One of the limitations of this study was that observation conditions were different than the usual clinical conditions since images used were limited to the nipple area. We also only focused on visual inspection of representative cases. Another limitation is the low response rate for the second survey. However, from the viewpoint of selection bias, measures to enhance the response rate should have been implemented.

Conclusion

We are the first to describe each type of nipple trauma using case images with objective criteria for evaluation of nipple trauma. This is a first step in developing an observational tool. The application of “seven signs of nipple trauma associated with breastfeeding” to breastfeeding support is expected to improve objectivity in monitoring and evaluating nipple trauma in women with these cases.

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References

- Azin, N., Vafa Baradaran, R., Sina, S., Nafiseh, A., Pouria, R., Zahra, S., Amirhossein, S., Hassan, R., & Vahid, R. A. (2018). A Systematic Review on Prevention and Treatment of Nipple Pain and Fissure: Are They Curable?. *Journal of Pharmacopuncture*, 21(3), 139-150. <https://doi.org/10.3831/KPI.2018.21.017>
- Berens, P., Eglash, A., Malloy, M., & Steube, A. M. (2016). ABM clinical protocol #26: Persistent pain with breastfeeding. *Breastfeeding Medicine*, 11(2), 46-53. <https://doi.org/10.1089/bfm.2016.29002.pjb>
- Cirico, M. O., Shimoda, G. T., & Oliveira, R. N. (2017). Healthcare quality in breastfeeding: Implementation of the nipple trauma index. *Revista Gaucha de Enfermagem [Journal of Rio Grande do Sul Federal University]*, 37(4), e60546. <https://doi.org/10.1590/1983-1447.2016.04.60546>
- Halvorsrud, K., Flynn, D., Ford, G. A., McMeekin, P., Bhalla, A., Balami, J., Craig, D., & White, P. (2018). A Delphi study and ranking exercise to support commissioning services: future delivery of thrombectomy services in England. *BMC Health Services Research*, 18(1), 135. <https://doi.org/10.1186/s12913-018-2922-3>
- Labour and Welfare. (2016, August). The National Nutrition Survey on Preschool Children, 2015. Ministry of Health. <http://www.mhlw.go.jp/file/06-Seisakujouhou-11900000-Koyoukintoujidoukateikyoku/0000134458.pdf>
- Mariani Neto, C., de Albuquerque, R. S., de Souza, S. C., Giesta, R. O., Fernandes, A. P. S., &

- Mondin, B. (2018). Comparative study of the use of HPA lanolin and breast milk for treating pain associated with nipple trauma. *Revista Brasileira de Ginecologia e Obstetricia: Revista da Federacao Brasileira das Sociedades de Ginecologia e Obstetricia [RBGO Gynecology & Obstetrics]*, 40(11), 664-672.
<https://doi.org/10.1055/s-0038-1675180>
- Marlen, N., & Julia, S. (2020). Delphi Technique in Health Sciences: A Map. *Frontiers in Public Health*, 8, 457. <https://doi.org/10.3389/fpubh.2020.00457>
- Maryam, F., Naimeh, P., & Mohadeseh, B. (2020). Comparing the Effects of Yarrow, Honey, and Breast Milk for Healing Nipple Fissure. *Iranian journal of nursing and midwifery research*, 25(4), 282-285. https://doi.org/10.4103/ijnmr.IJNMR_133_19
- Maverakis, E., Ma, C., Shinkai, K., Fiorentino, D., Callen, J. P., Wollina, U., Marzano, A. V., Wallach, D., Kim, K., Schadt, C., Ormerod, A., Fung, M. A., Steel, A., Patel, F., Qin, R., Craig, F., Williams, H. C., Powell, F., Merleev, A., ... Cheng, M. Y. (2018). Diagnostic criteria of ulcerative pyoderma gangrenosum: A Delphi consensus of international experts. *JAMA Dermatology*, 154(4), 461-466.
<https://doi.org/10.1001/jamadermatol.2017.5980>
- McMillan, S. S., King, M., & Tully, M. P. (2016). How to use the nominal group and Delphi techniques. *International Journal of Clinical Pharmacy*, 38(3), 655-662.
<https://doi.org/10.1007/s11096-016-0257-x>
- Nakamura, M., Asaka, Y., Ogawara, T., & Yorozu, Y. (2018). Nipple skin trauma in breastfeeding women during postpartum week one. *Breastfeeding Medicine*, 13(7), 479-484. <https://doi.org/10.1089/bfm.2017.0217>
- Nakamura, M., & Asaka, Y. (2019). Change process of nipple tissue after initiating

breastfeeding. *Journal of Japan Academy of Midwifery*, 33(2), 173-184.

<https://doi.org/10.3418/jjam.JJAM-2018-0032>

Riordan, J. (2019). *Breastfeeding and Human Lactation* (6th ed.). Sudbury, MA: Jones and Bartlett Publishers, Inc.

Ruth, L., Katherine, B., Mallory, P., Heather, E., Divya, R., Erin, Y., Stephen, W., Angela, S. (2019). Promoting self-management of breast and nipple pain in breastfeeding women: Protocol of a pilot randomized controlled trial. *Research in Nursing & Health*, 42(3), 176-188. <https://doi.org/10.1002/nur.21938>.

Shawahna, R., Qiblawi, S., & Ghanayem, H. (2018). Which Benefits and Harms of Using Fenugreek as a Galactagogue Need to Be Discussed during Clinical Consultations? A Delphi Study among Breastfeeding Women, Gynecologists, Pediatricians, Family Physicians, Lactation Consultants, and Pharmacists. *Evidence-Based Complementary and Alternative Medicine*, 1-13. <https://doi.org/10.1155/2018/2418673>

Wolff, K., & Johnson, R. A. (2009). *Fitzpatrick's Color Atlas and Synopsis of Clinical Dermatology* (6th ed.). McGraw-Hill, Medical Pub Division.

Table 1.
The Delphi process as followed for this study

Step		<i>n</i> (%)	Process	Data collected	Modification
Step 1	Recruited	5	Interviews conducted	Characteristics of observed sign	2 nd survey questionnaire created
	Consented	5 (100)			
Step 2	Mailed	256	Questionnaire (72 items + free description) mailed	Degree of agreement on 72 items	1 item removed; 13 items added
	Returned	60 (23.4)			
	Consent to 3 rd survey	49 (81.6)	Intention of 3 rd investigation confirmed	Additional opinions	Revised questionnaire (84 items) created
Step 3	Mailed	49	Revised questionnaire (84 items) mailed	Degree of agreement 84 items	No modification
	Returned	42 (85.7)	Results of 2 nd survey mailed		
	Consented	41 (97.6)	Intention to provide feedback confirmed		
Feedback	Mailed	41	Results of 3 rd survey & incentive gift cards mailed	Not Applicable	No modification

Table 2.*Demographic characteristics of the participants in each of the three surveys*

Characteristic	First survey <i>n</i> = 5 <i>M</i> (<i>SD</i>)	Second survey <i>n</i> = 60 <i>M</i> (<i>SD</i>)	Third survey <i>n</i> = 42 <i>M</i> (<i>SD</i>)
Age (years)	54.20 (13.10)	50.51 (11.56)	51.38 (8.90)
Professional experience (years)	27.40 (12.04)	26.55 (10.26)	25.93 (10.37)
Number of breastfeeding supports per week	N/A	9.75 (9.78)	9.04 (9.04)

Note: N/A = Not Applicable

Table 3.

Parameters of Nipple Trauma Explored in The First Survey

No		Parameter	No		Parameter	No		Parameter	No		Parameter
Erythema		1 Red-colored	Scabbing		1 Injury reaching dermis	Fissure		1 Caused by stretched skin	Purpura		1 Caused by strong sucking pressure
		2 Light pink-colored			2 Blood coagulated			2 Thin skin			2 Looks like a bruise
		3 Dark red-colored			3 Exudate solidified			3 Skin is scarred or separated			3 Internal hemorrhage
		4 Redder than the surrounding skin			4 Some dried secreted materials			4 Minor wound			4 Red-colored
		5 Dilated capillaries			5 Hardened			5 Shallow wound			5 Purple-colored
		6 Erosion			6 Peels on touch			6 Straight wound			6 Does not disappear when pressed
		7 Thin skin			7 Crust formed			7 Scarred after healing			7 Blood is leaking
		8 Wound on peeled or scabbing skin			8 Formed after blistering			8 On border of nipple and areola			8 Caused by inappropriate use of breast pump
		9 Caused by frequent shallow sucking by child			9 Reddish-black			9 When this case is observed, it should be expressed as “fissure”			9 Looks like a love bite

No	Parameter	No	Parameter	No	Parameter	No	Parameter
		10	Black-colored	10	Occurs when bitten by child with erupted teeth		
		11	Yellow-colored				
Swelling	1 Entire nipple swollen	Blistering	1 Caused by friction injury mechanism			Peeling	1 Dry
	2 Entire nipple edematous		2 Caused by scraping of tongue				2 Coarse
	3 Fresh		3 Puffy				3 Epidermis of nipple is slightly exfoliated
	4 Looks like a mulberry		4 Looks like salmon roe				4 Hangnail-like
	5 Looks like a turtle shell		5 Blister				5 Inflammation-like
	6 Looks like a wart		6 Sub-epidermal inflammation				6 Also expressed as desquamation
	7 Bumpy		7 Accumulated exudate				7 Unnecessary skin is peeled
	8 Partially swollen		8 Accumulated blood				8 Firm skin is formed after old skin is peeled
	9 Swollen		9 Purulent rash-like				9 Itchy
	10 Inflammatory		10 Red				10 Caused by scratching

No	Parameter	No	Parameter	No	Parameter	No	Parameter
	Characteristic of	11	Yellow ocher-colored				
11	breastfeeding						
	period						
	Caused by sucking						
12	pressure of shallow						
	sucking						

Note: No = number.

Table 4.*Degree of Agreement of the Items on the Second Survey (n=60)*

Sign	Item No	Parameters	Degree of Agreement								% Agreement
			1	2	3	4	5	Missing	Mdn	IQR	
Erythema	1	Red-colored	17	33	8	0	0	2	2	1	83.3
	2	Light pink-colored	5	19	18	12	4	2	3	2	40.0
	3	Dark red-colored	3	11	23	16	3	4	3	1.25	23.3
	4	Redder surrounding skin	29	26	4	0	0	1	2	1	91.7
	5	Dilated capillaries	3	9	27	13	6	2	3	1	20.0
	6	Erosion	3	21	13	10	10	2	3	2	41.7
	7	Thin skin	12	34	9	2	1	2	2	0	76.7
	8	Peeled skin or scabbing	11	29	8	7	2	3	2	1	66.7
	9	Frequent shallow sucking	19	32	7	2	0	0	2	1	85.0
Swelling	1	Entire nipple is swollen	19	21	12	3	0	5	2	2	67.0
	2	Entire nipple is edematous	22	21	10	2	0	5	2	1	72.0
	3	Fresh	13	23	6	6	6	6	2	1	60.0
	4	Looks like a mulberry	7	32	9	5	1	6	2	1	65.0
	5	Looks like a turtle shell	5	13	18	16	2	6	3	2	30.0
	6	Looks like a wart	2	9	16	17	9	7	3	1	18.0
	7	Bumpy	4	31	7	8	4	6	2	1	58.0
	8	Partially swollen	15	28	9	2	0	6	2	1	72.0
	9	Swollen	9	26	13	5	0	6	2	1	58.0

1		10	Inflammatory	11	24	17	3	1	4	2	2	58.0
2		11	Characteristic of BF period	4	22	15	11	2	6	3	1	43.0
3		12	Sucking of shallow sucking	17	27	10	2	0	4	2	1	73.0
4												
5												
6	Scabbing	1	Injury reaching dermis	8	25	15	9	0	3	2	1	55.0
7		2	Blood coagulated	7	23	17	9	2	2	2	1	50.0
8		3	Exudate solidified	5	26	15	12	0	2	2	1	51.7
9		4	Dried secreted materials	3	23	16	11	2	5	3	1	43.3
10		5	Hardened	10	35	10	2	0	3	2	0	75.0
11		6	Peels on touch	4	14	23	15	1	3	3	2	30.0
12		7	Crust has formed	18	37	3	0	0	2	2	1	91.7
13		8	Formed after blistering	7	31	17	3	0	2	2	1	63.3
14		9	Reddish-black	13	34	9	0	0	4	2	0	78.3
15		10	Black-colored	5	22	18	10	1	4	3	2	45.0
16		11	Yellow-colored	1	10	22	17	6	4	3	1.25	18.3
17												
18	Blistering	1	Friction injury mechanism	6	21	14	13	0	6	2.5	1	45.0
19		2	Caused by scraped tongue	6	11	26	12	0	5	3	1	28.3
20		3	Puffy	12	38	3	2	0	5	2	0	83.3
21		4	Looks like salmon roe	7	16	21	8	2	5	3	1	38.3
22		5	Blister	23	30	2	0	0	5	2	1	88.3
23		6	Subepidermal Inflammatory	9	28	14	4	0	5	2	1	61.7
24		7	Accumulated exudate	15	32	6	2	0	5	2	1	78.3
25		8	Accumulated blood	2	6	19	25	3	5	4	1	13.3
26		9	Purulent rash-like	2	5	18	21	11	3	4	1	11.7
27		10	Red-colored	5	32	11	4	0	8	2	0	61.7
28		11	Yellow ocher-colored	2	13	21	15	3	6	3	2	25.0

Fissure	1	Caused by stretched skin	25	28	5	1	0	1	2	1	88.3
	2	Thin skin	20	33	3	1	1	2	2	1	88.3
	3	Skin is scarred or separated	17	28	12	2	0	1	2	1	75.0
	4	Minor wound	2	9	26	19	1	3	3	1	18.3
	5	Shallow wound	4	22	17	13	1	2	3	1	43.3
	6	Straight wound	1	11	31	14	2	1	3	1	20.0
	7	Scar left after healed	1	12	25	15	3	4	3	1	21.7
	8	Border of the nipple & areola	24	30	5	0	0	1	2	1	90.0
	9	Expressed as “fissure”	21	27	7	4	0	1	2	1	80.0
	10	Bitten by newborn	4	9	29	10	6	2	3	0.75	21.7
Purpura	1	Strong sucking pressure	11	32	11	1	0	5	2	0	71.7
	2	Looks like a bruise	1	7	23	17	6	6	3	1	13.3
	3	Internal hemorrhage	5	27	17	5	0	6	2	1	53.3
	4	Red-colored	2	15	21	15	1	6	3	2	28.3
	5	Purple-colored	6	40	8	1	0	5	2	0	76.7
	6	Does not disappear pressed	7	32	9	4	0	8	2	0	65.0
	7	Blood is leaking	1	8	31	11	2	7	3	0	15.0
	8	Inappropriate breast pump use	4	17	28	3	1	6	3	1	35.0
Peeling	9	Looks like a love bite	2	9	21	17	6	5	3	2	18.3
	1	Dry	12	43	4	0	0	1	2	0	91.7
	2	Coarse	7	34	10	7	0	2	2	1	68.3
	3	Epidermis slightly exfoliated	8	38	7	3	1	3	2	0	76.7
	4	Hangnail-like	3	17	25	10	2	3	3	1	33.3
	5	Inflammation-like	7	11	23	17	0	2	3	2	30.0
	6	Expressed as desquamation	3	16	24	12	2	3	3	1	31.7

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7	Unnecessary skin is peeled	1	15	27	12	3	2	3	1.75	26.7
8	Firm skin after old peeled	1	16	28	10	1	4	3	1	28.3
9	Itchy	2	14	31	9	2	2	3	1	26.7
10	Caused by scratching	1	5	32	16	3	3	3	1	10.0

Note: Scale ratings: 1 = Strongly agree; 2 = Agree; 3 = Neither; 4 = Disagree; 5 = Strongly disagree.

For Peer Review

Table 5.*Degree of Agreement for Items on the Third Survey (n =42)*

Signs	Item No	Parameter	Degree of Agreement								% Agreement
			1	2	3	4	5	Missing	Mdn	IQR	
Erythema	1	Red-colored ^c	8	33	0	0	0	1	2	0	97.6
	2	Light pink-colored ^d	3	21	13	2	2	1	2	1	57.1
	3	Dark red-colored	3	9	19	8	1	2	3	1	28.6
	4	Redder than the surrounding skin ^c	15	22	3	0	0	2	2	1	88.1
	5	Dilated capillaries	1	6	22	11	1	1	3	1	16.7
	6	Erosion	1	16	16	7	1	1	3	1	40.5
	7	Thin skin ^c	9	28	3	0	1	1	2	0	88.1
	8	Wound is on peeled skin or scabbing ^c	4	30	6	1	0	1	2	0	81.0
	10	Caused by frequent breastfeeding ^{d, f}	7	18	11	4	1	1	2	1	59.5
	11	Caused by shallow latching ^{d, f}	21	18	2	0	0	1	1	1	92.9
	12	Sign observed in early breastfeeding stage ^{d, f}	13	21	7	0	0	1	2	1	81.0
Swelling	1	Entire nipple is swollen ^d	8	26	6	2	0	0	2	0	81.0
	2	Entire nipple is edematous ^c	7	29	5	1	0	0	2	0	85.7
	3	Fresh ^c	6	29	3	3	1	0	2	0	83.3
	4	Looks like a mulberry ^c	2	31	4	3	1	1	2	0	78.6
	5	Looks like a turtle shell	1	13	21	5	1	1	3	1	33.3
	6	Looks like a wart	1	3	18	15	5	0	3	1	9.5
	7	Bumpy ^c	2	31	6	2	1	0	2	0	78.6
	8	Partially swollen ^c	3	31	8	0	0	0	2	0	81.0
	9	Swollen ^c	2	31	8	1	0	0	2	0	78.6

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Scabbing	10	Inflammatory ^c	3	31	7	1	0	0	2	0	81.0
	11	Characteristic of breastfeeding period ^d	4	23	12	3	0	0	2	1	64.3
	12	Caused by pressure of shallow sucking ^d	7	31	3	0	0	1	2	0	90.5
	13	Caused by prolonged non-nutritional sucking ^f	5	11	22	4	0	0	3	1	38.1
	14	Accompanied by breast engorgement ^f	1	10	20	7	3	1	3	1	26.2
	15	Accompanied by galactostasis ^f	1	10	20	8	3	0	3	1.5	19.0
	1	Injury reaching dermis ^c	3	25	12	2	0	0	2	1	66.7
	2	Blood coagulated ^c	3	30	6	3	0	0	2	0	78.6
	3	Exudate solidified ^c	1	30	9	2	0	0	2	0.75	73.8
	4	Dried secreted materials ^d	1	30	8	3	0	0	2	0.75	73.8
	5	Hardened ^c	3	31	7	1	0	0	2	0	81.0
	6	Peels on touch	2	13	22	5	0	0	3	1	35.7
	7	Crust has formed ^c	8	32	1	1	0	0	2	0	95.2
	8	Formed after blistering ^c	3	23	15	1	0	0	2	1	61.9
	9	Reddish-black ^c	6	33	2	1	0	0	2	0	92.9
Blistering	10	Black-colored	3	14	16	8	1	0	3	1	40.5
	11	Yellow-colored	1	3	26	9	3	0	3	1	9.5
	12	Occurs in the early breastfeeding period ^{d, f}	5	19	15	3	0	0	2	1	57.1
	13	Time elapsed after damage, became chronic ^f	1	15	16	9	1	0	3	1	38.1
	1	Caused by friction injury-like mechanism ^c	4	19	14	2	1	2	2	1	54.8
	2	Caused by scraped tongue	1	13	22	4	1	1	3	1	33.3
	3	Puffy ^c	8	31	1	0	1	1	2	0	92.9
	4	Looks like salmon roe	1	14	24	1	1	1	3	1	35.7
	5	Blister ^c	10	29	2	0	0	1	2	0	92.9
	6	Subepidermal Inflammatory ^c	2	30	7	2	0	1	2	0	76.2

Fissure	7	Accumulated exudate ^c	6	33	2	0	0	1	2	0	92.9
	8	Accumulated blood	1	0	21	19	0	1	3	1	2.4
	9	Purulent rash-like	1	5	12	19	4	1	4	1	14.3
	10	Red-colored ^c	2	23	10	6	0	1	2	1	59.5
	11	Yellow ocher-colored	2	7	23	6	2	2	3	0	21.4
	12	Caused by a localized negative pressure ^{d, f}	14	27	0	0	0	1	2	1	97.6
	1	Caused by stretched skin ^c	12	28	1	0	0	1	2	1	95.2
	2	Thin skin ^c	14	26	0	1	0	1	2	1	95.2
	3	Skin is scarred or separated ^c	8	25	6	2	0	1	2	0	78.6
	4	Minor wound	2	6	25	8	0	1	3	0	19.0
	5	Shallow wound	2	14	16	8	0	2	3	1	38.1
	6	Straight wound	1	12	20	8	0	1	3	1	31.0
	7	Scar is left after healing	1	13	17	9	0	2	3	1	33.3
Purpura	8	On border of nipple and areola ^c	13	24	3	1	0	1	2	1	88.1
	9	This case is observed, expressed as “fissure” ^c	13	23	2	3	0	1	2	1	85.7
	10	Occurs when bitten by newborn	2	13	22	3	1	1	3	1	35.7
	11	Occurred when latching is off ^{d, f}	4	20	14	3	0	1	2	1	57.1
	12	Shapes of the tongue and palate of the child ^{d, f}	4	19	15	3	0	1	2	1	54.8
	13	Caused by galactostasis ^f	2	10	17	11	1	1	3	2	28.6
	1	Caused by strong sucking pressure ^c	6	31	4	1	0	0	2	0	88.1
	2	Looks like a bruise	3	9	18	10	2	0	3	2	28.6
	3	Internal hemorrhage ^c	3	30	9	0	0	0	2	0	78.6
	4	Red-colored	2	11	27	1	1	0	3	1	31.0
	5	Purple-colored ^c	3	35	3	0	1	0	2	0	90.5
	6	Does not disappear when pressed ^c	7	30	2	1	1	1	2	0	88.1

1	Peeling	7	Blood is leaking	1	11	23	5	1	1	3	1	28.6
2		8	Caused by inappropriate use of breast pump	2	8	30	2	0	0	3	0	23.8
3		9	Looks like a love bite	2	6	26	7	1	0	3	0	19.0
4		10	Caused by inappropriate use of nipple shields ^f	2	13	22	4	1	0	3	1	35.7
5		1	Dry ^c	7	32	2	0	0	1	2	0	92.9
6		2	Coarse ^c	4	30	4	3	0	1	2	0	81.0
7		3	Epidermis of nipple is slightly exfoliated ^c	5	32	2	2	0	1	2	0	88.1
8		4	Hangnail-like	3	15	16	7	0	1	3	1	42.9
9		5	Inflammation-like	3	7	20	11	0	1	3	1	23.8
10		6	Also expressed as desquamation	1	9	20	10	1	1	3	1	23.8
11	7	Unnecessary skin is peeled	1	13	23	4	0	1	3	1	33.3	
12	8	Firm skin is formed after old skin is peeled	1	13	24	2	1	1	3	1	33.3	
13	9	Itchy	1	7	28	4	1	1	3	0	19.0	
14	10	Caused by scratching	1	1	27	10	2	1	3	1	4.8	

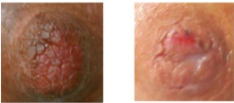
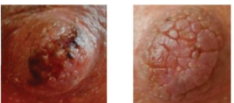
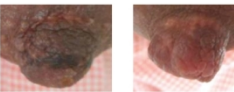
Note: Scale ratings:1 = Strongly agree, 2 = Agree, 3 = Neither, 4 = Disagree, 5 = Strongly disagree. BF = breastfeeding

^c Items agreed in the second and third surveys

^d Items agreed in the third survey

^e Items removed in the third survey

^f Items added in the third survey

Sign	Representative case		Wound condition	Possible mechanism/assessment
[Erythema]			Red-colored Light pink-colored Redder than surrounding skin Thin skin Wound is on peeled skin or scabbing	Caused by frequent breastfeeding Caused by shallow latching Sign observed in early breastfeeding stage
[Swelling]			Entire nipple is swollen Entire nipple is edematous Fresh Looks like a mulberry Bumpy Partially swollen Swollen Inflammatory	Signs characteristics of breastfeeding period Caused by sucking pressure of shallow sucking
[Scabbing]			Reddish black Injury reaching dermis Blood coagulated Exudate solidified Some dried secreted materials Hardened Crust has formed	Formed after blistering A sign that occurs in the early breastfeeding period
[Blistering]			Red-colored Blister Subepidermal Inflammatory Accumulated exudate Puffy	Caused by friction injury-like mechanism Caused by a localized negative pressure
[Fissure]			On border of nipple and areola Skin is scarred or separated Thin skin	Caused by stretched skin Occurred when latching is off Generated in association with the shapes of the tongue and palate of the child
[Purpura]			Purple-colored Internal hemorrhage Does not disappear when pressed	Caused by strong sucking pressure
[Peeling]			Dry Coarse Epidermis of nipple is slightly exfoliated	

The image on the left is a representative case presented to the study participants in each survey, and the text on the right categorizes the consented items into wound conditions and possible mechanism and assessment.

1
2
3 **Supplementary File 1:**
4 *Interview Guide of the first survey*
5
6

7 **Interview Guide**

8 An evaluation of the signs of nipple trauma associated with breastfeeding: A Delphi Study
9

10
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13 **[Interview Scene]**

- 14 • Sit in a quiet and privacy-protected space and speak calmly.
15
16 • Interviews will be suspended when the participant is no longer in a situation where they can speak
17 calmly due to medical treatment, visitors, and so on.
18

19
20 **[Notes]**

- 21 • Interviews will last between 30 and 60 min, and discussions will be recorded on an IC recorder with
22 the research participants' permission.
23
24 • It is important to professionally ask questions but speak freely.
25
26 • To make it easier for participants to imagine the actual nipple observation scene, interviewers are
27 advised to talk while looking at the image.
28

29
30 **[Development]**

31 ●Introduction

32
33 1. During this interview, we would like you to share your thoughts on the characteristic of the seven
34 signs (erythema, swelling, scabbing, blistering, fissure, purpura, and peeling) that can occur in the
35 nipple through breastfeeding.
36

37 During the interview, the seven signs, such as erythema, would be replaced with “sign” during the
38 interview session.
39

40
41 ●Core question

- 42
43 1.Can you describe the characteristic of the “sign” observed in this case?
44
45 2.When you observe this case in clinical practice, can you share what you think about the mechanism
46 of their occurrence and how to deal with them?
47
48 3.How would you share these cases with other professionals?
49
50 4.What kind of nipple condition do you regard as a “sign”?

51 ●Question on Exit

- 52
53 1.Have you felt or noticed anything about your daily observations?
54
55 2.In the future, what do you propose is important about observing the “sign”?
56

57
58 We express our sympathy for what you said you wanted to treasure and end the interview with words
59 of thanks.
60

Supplementary File 2*Questionnaire for the second survey*

An evaluation of the signs of nipple trauma associated with breastfeeding: A Delphi Study

Questionnaire for the Second survey

Explanation of the survey

- Questions begin later on this page.
- The survey has 8 pages, including this page.
- Survey takes about 20 to 30 min.
- We will present a token of our appreciation to those who participated in this survey.

Response deadline: Friday, February 28, 2020

We appreciate your cooperation in responding within the given deadline.

If you wish to participate in the third survey, please mail this survey form together with the letter of consent.

Research manager

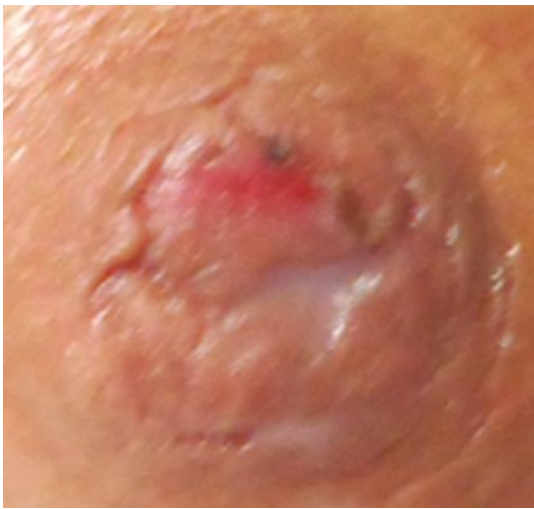
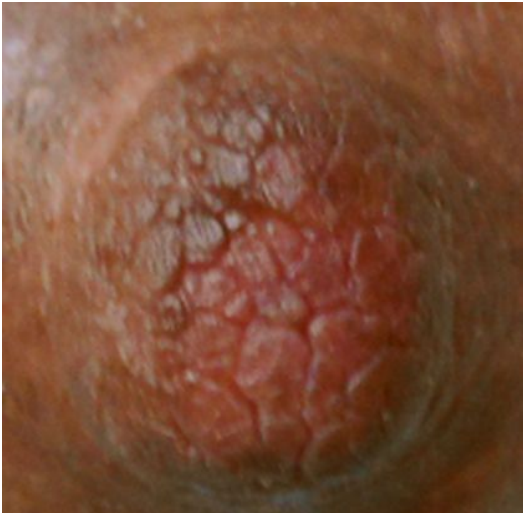
Author affiliation Name of author

The investigation will start from here. Please answer the following questions.

First, please give a brief detail about yourself.

Age (years)	
Professional experience (years)	
Number of breastfeeding supports per week	

【Erythema】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Red-colored	1	2	3	4	5
Light pink-colored	1	2	3	4	5
Dark red-colored	1	2	3	4	5
Redder than the surrounding skin	1	2	3	4	5
Dilated capillaries	1	2	3	4	5
Erosion	1	2	3	4	5
Thin skin	1	2	3	4	5
Wound is on peeled skin or scabbing	1	2	3	4	5
Caused by frequent shallow sucking by the child	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

【Swelling】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Entire nipple is swollen	1	2	3	4	5
Entire nipple is edematous	1	2	3	4	5
Fresh	1	2	3	4	5
Looks like a mulberry	1	2	3	4	5
Looks like a turtle shell	1	2	3	4	5
Looks like a wart	1	2	3	4	5
Bumpy	1	2	3	4	5
Partially swollen	1	2	3	4	5
Swollen	1	2	3	4	5
Inflammatory	1	2	3	4	5
Characteristic of breastfeeding period	1	2	3	4	5
Caused by sucking pressure of shallow sucking	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

【Scabbing】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Injury reaching dermis	1	2	3	4	5
Blood coagulated	1	2	3	4	5
Exudate solidified	1	2	3	4	5
Some dried secreted materials	1	2	3	4	5
Hardened	1	2	3	4	5
Peels on touch	1	2	3	4	5
Crust has formed	1	2	3	4	5
Formed after blistering	1	2	3	4	5
Reddish black	1	2	3	4	5
Black-colored	1	2	3	4	5
Yellow-colored	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

【Blistering】

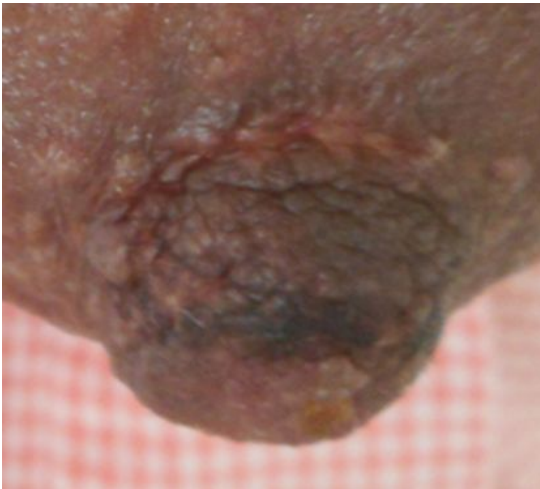


To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Caused by friction injury-like mechanism	1	2	3	4	5
Caused by scraped tongue	1	2	3	4	5
Puffy	1	2	3	4	5
Looks like salmon roe	1	2	3	4	5
Blister	1	2	3	4	5
Subepidermal Inflammatory	1	2	3	4	5
Accumulated exudate	1	2	3	4	5
Accumulated blood	1	2	3	4	5
Purulent rash-like	1	2	3	4	5
Red-colored	1	2	3	4	5
Yellow ocher-colored	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

【Fissure】

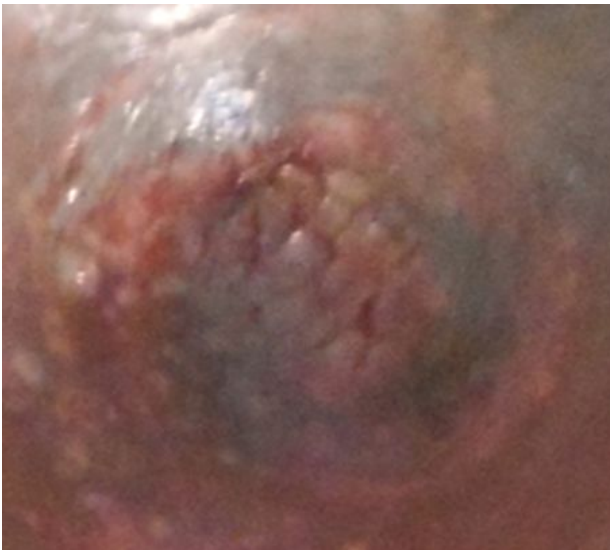


To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Caused by stretched skin	1	2	3	4	5
Thin skin	1	2	3	4	5
Skin is scarred or separated	1	2	3	4	5
Minor wound	1	2	3	4	5
Shallow wound	1	2	3	4	5
Straight wound	1	2	3	4	5
Scar is left after healing	1	2	3	4	5
On border of nipple and areola	1	2	3	4	5
When this case is observed, it should be expressed as “fissure”	1	2	3	4	5
Occurs when bitten by newborn	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

【Purpura】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Caused by strong sucking pressure	1	2	3	4	5
Looks like a bruise	1	2	3	4	5
Internal hemorrhage	1	2	3	4	5
Red-colored	1	2	3	4	5
Purple-colored	1	2	3	4	5
Does not disappear when pressed	1	2	3	4	5
Blood is leaking	1	2	3	4	5
Caused by inappropriate use of breast pump	1	2	3	4	5
Looks like a love bite	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

【Peeling】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Dry	1	2	3	4	5
Coarse	1	2	3	4	5
Epidermis of nipple is slightly exfoliated	1	2	3	4	5
Hangnail-like	1	2	3	4	5
Inflammation-like	1	2	3	4	5
Also expressed as desquamation	1	2	3	4	5
Unnecessary skin is peeled	1	2	3	4	5
Firm skin is formed after old skin is peeled	1	2	3	4	5
Itchy	1	2	3	4	5
Caused by scratching	1	2	3	4	5

Free description field: Please describe the characteristic of the image above if you have other ideas.

This is the end of this survey. Thank you for your cooperation.

Supplementary File 3*Questionnaire for the third survey*

An evaluation of the signs of nipple trauma associated with breastfeeding: A Delphi Study

Questionnaire for the Third survey

Explanation of the survey

- Questions begin later on this page.
- The survey has 8 pages, including this page.
- Please answer all questions on all pages.
- Please reply after confirming the survey result of the enclosed second survey.
- Although the enclosed survey result is to be used as a reference to answer this questionnaire, it does not encourage pandering of opinions.
- Blue boxes represent items that were added or revised based on previous comments.
- The survey takes about 20 to 30 min.
- We will present a token of our appreciation to those who participated in the two surveys.

Response deadline: Tuesday, March 31, 2020

We appreciate your cooperation in responding within the deadline.

Please return this survey form together with the letter of consent through mail.

We will send you feedback of the research results and the thank-you item.

Research manager

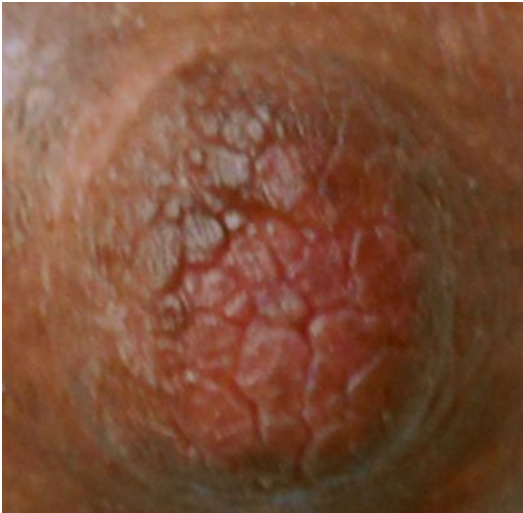
Author affiliation Name of author

The investigation will start from here. Please answer the following questions.

First, please give a brief detail about yourself.

Age (years)	
Professional experience (years)	
Number of breastfeeding supports per week	

【Erythema】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Red-colored	1	2	3	4	5
Light pink-colored	1	2	3	4	5
Dark red-colored	1	2	3	4	5
Redder than the surrounding skin	1	2	3	4	5
Dilated capillaries	1	2	3	4	5
Erosion	1	2	3	4	5
Thin skin	1	2	3	4	5
Wound is on peeled skin or scabbing	1	2	3	4	5
Caused by frequent breastfeeding	1	2	3	4	5
Caused by shallow latching	1	2	3	4	5
Sign observed in early breastfeeding stage	1	2	3	4	5

【Swelling】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Entire nipple is swollen	1	2	3	4	5
Entire nipple is edematous	1	2	3	4	5
Fresh	1	2	3	4	5
Looks like a mulberry	1	2	3	4	5
Looks like a turtle shell	1	2	3	4	5
Looks like a wart	1	2	3	4	5
Bumpy	1	2	3	4	5
Partially swollen	1	2	3	4	5
Swollen	1	2	3	4	5
Inflammatory	1	2	3	4	5
Characteristic of breastfeeding period	1	2	3	4	5
Caused by sucking pressure of shallow sucking	1	2	3	4	5
Caused by prolonged non-nutritional sucking	1	2	3	4	5
Accompanied by breast engorgement	1	2	3	4	5
Accompanied by galactostasis	1	2	3	4	5

【Scabbing】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Injury reaching dermis	1	2	3	4	5
Blood coagulated	1	2	3	4	5
Exudate solidified	1	2	3	4	5
Some dried secreted materials	1	2	3	4	5
Hardened	1	2	3	4	5
Peels on touch	1	2	3	4	5
Crust has formed	1	2	3	4	5
Formed after blistering	1	2	3	4	5
Reddish black	1	2	3	4	5
Black-colored	1	2	3	4	5
Yellow-colored	1	2	3	4	5
A sign that occurs in the early breastfeeding period	1	2	3	4	5
Time elapsed after damage, and the wound became chronic	1	2	3	4	5

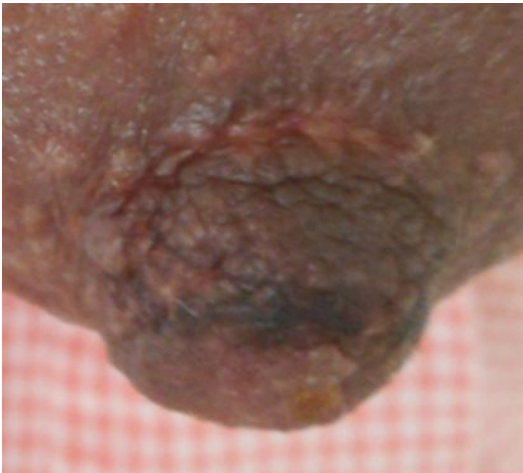
【Blistering】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Caused by friction injury-like mechanism	1	2	3	4	5
Caused by scraped tongue	1	2	3	4	5
Puffy	1	2	3	4	5
Looks like salmon roe	1	2	3	4	5
Blister	1	2	3	4	5
Subepidermal Inflammatory	1	2	3	4	5
Accumulated exudate	1	2	3	4	5
Accumulated blood	1	2	3	4	5
Purulent rash-like	1	2	3	4	5
Red-colored	1	2	3	4	5
Yellow ocher-colored	1	2	3	4	5
Caused by a localized negative pressure	1	2	3	4	5

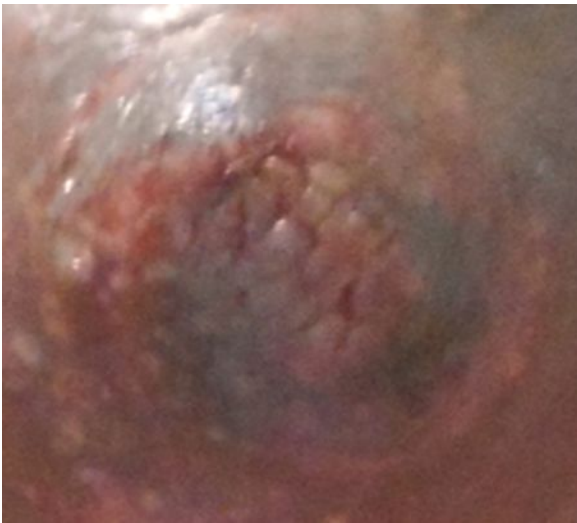
【Fissure】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Caused by stretched skin	1	2	3	4	5
Thin skin	1	2	3	4	5
Skin is scarred or separated	1	2	3	4	5
Minor wound	1	2	3	4	5
Shallow wound	1	2	3	4	5
Straight wound	1	2	3	4	5
Scar is left after healing	1	2	3	4	5
On border of nipple and areola	1	2	3	4	5
When this case is observed, it should be expressed as “fissure”	1	2	3	4	5
Occurs when bitten by newborn	1	2	3	4	5
Occurred when latching is off	1	2	3	4	5
Generated in association with the shapes of the tongue and palate of the child	1	2	3	4	5
Caused by galactostasis	1	2	3	4	5

【Purpura】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Caused by strong sucking pressure	1	2	3	4	5
Looks like a bruise	1	2	3	4	5
Internal hemorrhage	1	2	3	4	5
Red-colored	1	2	3	4	5
Purple-colored	1	2	3	4	5
Does not disappear when pressed	1	2	3	4	5
Blood is leaking	1	2	3	4	5
Caused by inappropriate use of breast pump	1	2	3	4	5
Looks like a love bite	1	2	3	4	5
Caused by inappropriate use of nipple shields	1	2	3	4	5

【Peeling】



To what extent do you agree with the following statements as characteristic of the image above?
Please mark the appropriate number.

Nipple trauma characteristic	Strongly Agree	Agree	Neither	Disagree	Strongly Disagree
Dry	1	2	3	4	5
Coarse	1	2	3	4	5
Epidermis of nipple is slightly exfoliated	1	2	3	4	5
Hangnail-like	1	2	3	4	5
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Also expressed as desquamation	1	2	3	4	5
Unnecessary skin is peeled	1	2	3	4	5
Firm skin is formed after old skin is peeled	1	2	3	4	5
Itchy	1	2	3	4	5
Caused by scratching	1	2	3	4	5

This is the end of this survey. Thank you for your cooperation.