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A Critical Review of the Literature Regarding Positioning for the Treatment of Gastroesophageal Reflux in Neonates

Susan Pfister, RNC, BSN

2/28/2011

Introduction

Premature infants are at risk for many long term health problems. One that can be very distressing to parents and caregivers is gastroesophageal reflux (GER). Infants who are afflicted with GER experience the symptoms within 30 minutes of eating. The common symptoms are regurgitation, crying, irritability and arching. Conflicting data or lack of data on effective interventions can be confusing or misleading to caregivers.

In textbooks and handbooks used within the Neonatal Intensive Care Unit (NICU) there are guidelines on what interventions should be utilized for these infants, often with insufficient supporting evidence to base the recommendations. Specifically, Watson, in *Core Curriculum for Neonatal Intensive Care Nursing, 3rd Ed (2004)* recommends elevating the head of the infant bed to 30 degrees based on a 2002 article by Jadcherla (p. 680). Gomella et al recommend that the caregiver “hold the infant upright in your arms at least 30 minutes after feeding. Head-elevated prone position was preferred in infants with GER but it has become controversial” (Gomella, 2009, p. 257). There is no supporting literature listed for this recommendation. Ellard and Anderson in the *Manual of Neonatal Care, 6th Ed (2008)* recommend elevating the head of the bed and to position the infant prone (p. 134) though they list no supporting literature. Positioning infants prone after 37 weeks corrected gestational age is discouraged due to American Academy of Pediatrics Back to Sleep guidelines (2005) which correlate prone positioning with Sudden Infant Death Syndrome (SIDS). Many caregivers in NICUs position infants with the head of the bed elevated to 30 degrees as an anecdotal remedy based upon recommendations of reference books that offer conflicting advice.

Therefore, this paper demonstrates there is insufficient evidence for these remedies. As stated in Polit and Beck, it is “estimated that 85% of health care practice has not been

scientifically validated” (Polit & Beck, 2008, p. 12). Ideas become habits and these habits then become established practice without research to support them which is not best practice. Head of bed elevation may be one of these practices that are carried out but not validated. After reviewing the literature a best practice will be identified for positioning of infants with GER.

Definition

The process of digestion begins with ingestion of food. The food passes through the esophagus into the stomach via the lower esophageal sphincter which opens and allows the food to enter the stomach. The sphincter then closes to prevent reflux back into the esophagus. In the stomach digestive acidic fluids break down the food (Lawson, 2003). For an infant the mean gastric emptying time from stomach to duodenum is from 34.9 to 91.7 minutes (Omari et al, 2004).

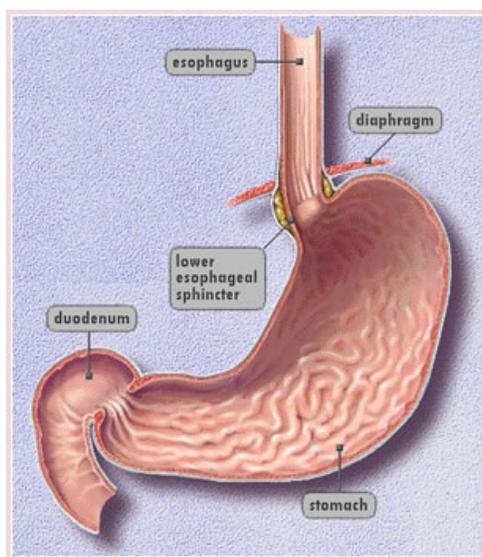


Figure 2. The esophagus, diaphragm, lower esophageal sphincter, stomach and duodenum.
http://www.gerd.com/images/image_stomach_large.jpg, retrieved June 27, 2010

Infants taking all of their nutrition orally take up to 180 milliliters per kilogram per day. That volume would be comparable to an adult taking in about 14 liters of fluid per day (Poets, 2004). Additionally, after the infant completes his or her feeding, they are often positioned supine. These factors combined with inappropriate relaxation times of the lower esophageal sphincter put the infant at high risk for GER. In 2009 Craig reported that at the age of four months 67% of infants regurgitate at least one time per day.

GER occurs when the lower esophageal sphincter relaxes causing stomach contents to pass back into the esophagus. The contents, which also contain stomach acids, can cause the infant to “spit up” and appears to cause discomfort. The infant reacts to this by crying and at times by trying to move away from this pain, which is when arching is seen. A visual representation of the stomach during reflux is illustrated below:

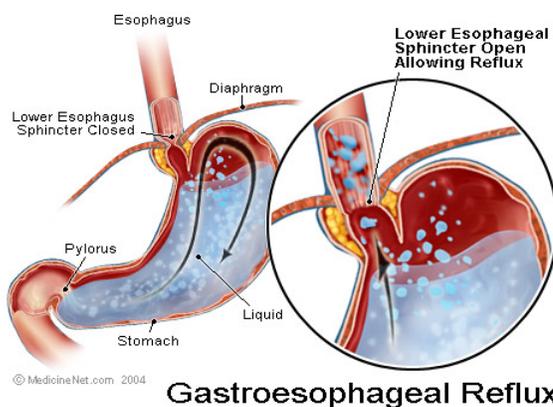


Figure 2. Gastroesophageal reflux. Stomach contents refluxing into the esophagus.
http://lifesharer.files.wordpress.com/2008/10/gastroesophageal_reflux.jpg retrieved June 5, 2010

Gastroesophageal reflux is described in Taber’s Medical Dictionary as “a common condition in which acid from the stomach flows back into the esophagus” (Venes, 2005, p. 859). In neonates with GER the symptoms are frequent regurgitation, irritability and crying. The infant may arch or have hiccups. Arguin & Swartz explain that GER is not the same as gastroesophageal reflux disease (GERD), a more severe form of the disease with symptoms of

poor weight gain, excessive crying, disturbed sleep, impaired feeding tolerances and respiratory complications that require more extensive diagnosis and treatment.

Preterm infants who experience symptoms from GER may also experience apneic episodes and may be diagnosed with apnea of prematurity. Clinicians and caregivers often see an association with the two conditions. Apnea is the “cessation of airflow that may be pathologic if absent airflow is prolonged – greater than 20 seconds.” “Most apneic spells are central (inspiratory efforts are absent) or mixed (airway obstruction with central apnea) and occur frequently in premature infants which increases with decreasing gestational age” (Stark, 2008, p. 369). Many caregivers believe that GER can exacerbate apneic episodes, but a random control trial published in 2005 with 119 infants could establish no relationship between these two conditions. The authors state that GER “does not induce apnea, does not prolong apnea duration, and does not exacerbate the apnea related decrease in heart rate and SaO₂” (Di Fiore et al, 2005, p. 1062). Caregivers who understand the physiology behind each condition are better equipped to utilize critical thinking skills and provide interventions for each condition which are independent from each other. A second study by Harris et al (2004) examined 102 infants and had the same findings. Apnea of prematurity usually resolves as the infant reaches 40 weeks corrected gestational age, whereas GER symptoms often are seen in infants up to age 10 to 12 months (Craig et al, 2009). It is important to avoid causal conclusions when data does not support a relationship.

When an infant displays symptoms of GER, professional caregivers and parents attempt a number of approaches to minimize the distress. Ewer et al (1999) state the elevation of the head of the bed came from an idea that infants lying flat may be more susceptible to GER symptoms. People have created devices such as wedges to elevate the head of the bed and cloth slings to

hold the infant in place once the head is elevated. Some crib companies now manufacture and sell cribs that allow the head of the bed to be elevated. There are multiple internet web sites offering advice to parents with recommendations for interventions for GER symptoms. Some of the interventions seem benign, but may increase the length of hospital stay, be costly to parents or lead to unsafe sleeping conditions for the infant. Parents may be encouraged to buy a special crib or to buy wedges and slings for an existing crib at home. Caregivers may improvise with head of bed elevation leading to unsafe sleeping conditions for the infant, for instance the use of pillows or blankets which may lead to increased risk for suffocation. Additionally, some may elevate the head of a normal crib which put the infant in a position where they are vulnerable to fall. These measures may be unsafe and are unfounded. It is wise to utilize the existing research to help establish best practice.

More invasive interventions for GER have been attempted by caregivers and professionals. These interventions have not been shown in studies to be effective, and may even be harmful. Caregivers have postulated that thickened breast milk or formula may alter the stomach contents from fluid based to more solid based and thereby decrease the occurrence of regurgitation into the esophagus. Corvaglia found that no reduction of GER has been noted from thickening breast milk or formula with a starch additive. While reviewing treatment options a possible relationship between necrotizing enterocolitis and starch thickened breast milk was noted. (Corvaglia et al, 2007). Necrotizing enterocolitis is an acute intestinal necrosis syndrome of unknown etiology. It is one of the most common surgical conditions in premature neonates and is a leading cause of premature neonatal death (Eichenwald, 2008). Anti-reflux medications are often ordered for infants with GER. An article from 2009 by Wheatley and Kennedy noted a lack of efficacy in clinical studies despite the widespread use of anti-reflux medications. They

went on to say, “even though metoclopramide and ranitidine are not approved by the Food and Drug Administration for use in neonates, they are ranked first and fourth, respectively, among the medications most frequently used in the NICU” (Wheatley & Kennedy, 2009, p. 519). As with most medication there may be adverse effects in preterm infants, most notably an increased risk of hospital acquired sepsis and a higher incidence of necrotizing enterocolitis. It is not consistent with evidenced based practice to order and administer these medications when their efficacy has not been proved and the potential side effects are as severe or more severe than the presenting condition being treated.

In review, clinical studies have been published that demonstrate no statistical benefit from medications or thickening of breast milk in the reduction of GER symptoms, yet these interventions continue to be prescribed in NICUs. Head of bed elevation has shown no reduction in incidence or severity of symptoms yet the practice has widespread prevalence. Given the prevalence and the potential severity of the consequences of the treatments, it is essential to develop and teach best practice guidelines through careful examination of the literature and research currently available.

Literature Review

An extensive literature search was done and studies that discussed gastric esophageal reflux and positioning were reviewed. The databases searched were Cumulative Index to Nursing and Allied Health Literature (CINHAL), the Cochrane library, Medline, PubMed and Google Scholar. As the articles were read, cited articles were noted and retrieved. Keywords were gastric esophageal reflux, gastric oesophageal reflex, head of bed elevation, positioning,

neonate, infant and baby. Eight articles, including one Cochrane review, were chosen to review and critique for this analysis. The articles were dated from 1983 to 2009.

In 2009 a Cochrane Review (Craig et al) analyzed five different studies regarding head of bed elevation. They discussed a study from 1999 by Bagucka et al which found the authors concluded that the head elevated position was not helpful in decreasing GER. This investigation is not available in common search engines of CINHALL, Medline, PubMed or Google Scholar, nor is it available at local university libraries. The other researches reviewed for the Cochrane were by Tobin and by Orenstein as described below.

The authors of the Cochrane Review classified the quality of the studies critiqued as good. Each study used pH probe monitoring as a determination of severity of symptoms. The probe was placed nasally down to the esophagus and continually recorded the pH level over a 24 hour period. Some of the research compared infants whose head of bed was elevated to those positioned in an elevated car seat (Orenstein, 1983); some compared infants placed prone to those placed supine; some compared left lateral to right lateral positioning. Of the five different investigations reviewed, none found any significant decrease in GER symptoms for infants with head of bed elevation. Elevated pH in the esophagus was the same for infants positioned flat and with the head of bed elevated (Bagucka, 1999; Orenstein, 1983; Orenstein & Whittington, 1983; Orenstein, 1990; Tobin, 1997). Prone and left lateral positioning was significantly superior to supine or right lateral positioning. In fact, research that analyzed positioning greater than 30 degrees, for instance in an infant car seat or utilizing positioning aids, found that prone and left lateral positioning were superior to elevation. Due to the risk of sudden infant death syndrome (SIDS), the prone position is not recommended for infants greater than 37 weeks corrected gestational age by the study authors or the review authors. The studies evaluated in the

Cochrane review were of small sample size and blind randomization was not achieved due to the nature of the studies.

Head of Bed Elevation

Due to anecdotal practices and unit history, head of bed elevation is the first treatment given to many infants when they display symptoms of GER. This treatment is suggested in many texts and articles, but not validated. Some nursing textbooks recommend the practice giving reference to a 2002 review of the literature compiled by Jadcherla. His article in *Clinics in Perinatology* discusses the problem of GER in neonates but he notes the information and recommendations for neonates are an extrapolation of research performed on older infants. The review names some factors that may contribute to GER: increased intra-abdominal pressure, excessive crying, delayed gastric emptying, and sluggish esophageal motility. The researcher notes that supine, right lateral and elevation in a car seat seem to exacerbate the symptoms of GER, whereas “prone with 30 degree elevation and left lateral positioning” (Jadcherla, 2002, p. 150) seem to lessen the symptoms, but points out that the prone position is associated with SIDS and is therefore not recommended. The articles referenced by Jadcherla are the same as those used for this critique and do not list any studies that support head of bed elevation.

Orenstein published two articles in 1983, both in *Journal of Pediatrics*. The research established that the 60 degree head elevated position, defined as placing the infant upright in a car seat, did not decrease symptoms of GER but in fact exacerbated the symptoms because the lower esophageal sphincter is more likely to be submerged in the 60 degree head elevated position (Orenstein & Whittington, 1983). The findings were based upon two prospective controlled comparisons. The first had 9 infants who had been referred to Orenstein’s group by primary pediatricians due to GER symptoms. The second study had 15 patients who were

analyzed. Each infant had a pH probe placed nasally and continuous pH monitoring was performed for 24 hours. The recordings were monitored for the percentage of time the esophageal pH was below 4, the number of episodes when the pH was less than 4, the number of such episodes lasting longer than 5 minutes and the duration of the longest episode. The infants were placed in either a car seat or in a prone position with the head of the bed elevated. Both investigations showed infants demonstrated longer exposure to GER while in the car seat, for a longer period of time and had more episodes (Orenstein, 1983). These studies did not examine either of the positions compared to any other sleeping positions of the infant.

In 1990 Orenstein published her third analysis on this subject. In this research there were 100 infants younger than six months, 90 of whom had suspected GER. Orenstein wanted to compare the efficacy of 30 degree head of bed elevation to the prone position. Infants had pH probes placed and continuous monitoring of esophageal pH was performed for 24 hours. The recordings were assessed for minutes with a pH less than 4, mean duration of each episode, number of episodes with pH less than 4 and number of episodes less than 5 minutes (Orenstein, 1990). Each infant was randomly placed in one position and then changed to the other position half way through the study. The results revealed “no measure of reflux that was significantly better in the head-elevated position than in the prone position” (Orenstein, 1990, p. 185). The author went on to conclude positioning infants in head elevated positions was not worth the effort to do so. Although she first demonstrated head of bed elevation of 30 degrees was superior to car seat sitting at 60 degrees, this 1990 study showed head of bed elevation of 30 degrees was, in fact, not superior to the prone position for the relief of GER symptoms. Upon reviewing Orenstein’s work, it is important to assess the research as a whole before reaching a consensus about the best intervention regarding positioning.

Left Lateral Position

In 1997 Tobin, McCloud and Cameron analyzed head of bed elevation as a position in their research in a pediatric hospital in England involving 24 infants. Infants with symptoms of GER were randomly assigned to one of four groups to be positioned prone, supine, right lateral or left lateral. The authors also compared infants placed horizontally to those with head of bed elevation at 30 degrees. After 24 hours the infants were then randomly assigned to another group. All infants had a pH probe inserted nasally into the esophagus to monitor acid levels. The clinicians used the reflux index which determines the percent of the time with a pH less than 4, number of episodes with a pH less than 4 during 24 hours, number of episodes lasting more than 5 minutes, the duration of the longest episode. The normal average index was previously established to be 10 for an infant under the age of 12 months. During the study, the results showed an index for supine positioning: 15.3, for right lateral: 12, for left lateral: 7.7 and for prone positioning: 6.7. For infants placed horizontally the index mean was 10.7 while those who were placed in a head of bed elevation had a mean index of 10.1, which is not a statistical difference. The investigation showed a significant difference between right lateral position and supine position compared to left lateral and prone position. The researchers were not able to demonstrate any significant difference between horizontal and head of bed elevation. Therefore, it was concluded that “in this study no benefit for head elevation was noted” (Tobin, McCloud & Cameron, 1997, p. 258). This is another inquiry in which the anecdotal remedy of head of bed elevation is not supported by research.

Another investigation in 1999 by Ewer, James and Tobin produced the same results when the reflux index was also utilized in a sample of 18 infants in a neonatal intensive care unit in a hospital in Britain. The analysts used a pH probe for a 24 hour period. The clinicians

investigated left lateral, right lateral and prone positions. The number of reflux episodes and the severity of the episodes for infants in the right lateral position documented by the pH probe exceeded those of the infants in the left lateral and prone position. The least frequent and least severe symptoms occurred in infants placed in the prone position or in the left lateral position. Ewer et al recommended left lateral position be implemented as a position for infants with symptoms of GER.

Although sampling size was still small, randomization was employed in the following analysis. In 2007 Corvaglia with his colleagues designed an inquiry to assess if left side lying position was effective not only with decreasing non-acid GER but also decreasing acid GER. The investigators recruited 22 premature infants with symptoms of GER. pH probes were placed and monitoring occurred for 24 hours assessing number of GER episodes and length of reflux occurrences. The investigation also differentiated between the liquid reflux and air reflux using modern impedance equipment. Each patient was randomly positioned in one of four positions, right lateral, left lateral, prone and supine. The findings were similar to previous inquiries showing the least occurrences of reflux in the prone position; the next fewest were in the left lateral position, then right lateral and the most occurrences in the supine position. This was the same for liquid reflux and air reflux. The authors concluded that there was no statistical difference between the prone and left lateral positions. They recorded only 1.9 episodes in the left lateral position and 1.1 episodes in the prone position. In conclusion, the “findings do not provide any information on clinical improvement” but rather a “simple way to limit GER” (Corvaglia et al, 2007, p. 596). After reviewing the literature it is clear that head of bed elevation is not supported by research and that the recommended positions for infants who are experiencing symptoms of GER is either prone or left lateral side lying.

Implications and Recommendations

In medicine it must be the highest priority to employ best practice interventions for patients. The purpose of this review was to critically appraise the literature regarding gastric esophageal reflux and the positioning treatments employed. Investigations reviewed showed that the acidity, frequency and duration of GER episodes were measured in four different positions: prone, supine, left lateral and right lateral, and noted that they were less severe and of a shorter duration in the prone and the left lateral position. Based on the research assessed, infants with symptoms of GER should be placed flat to sleep in a prone position or left lateral position until they are 37 weeks corrected gestational age and then the prone position should be avoided. Currently head of bed elevation has not been shown to be effective in decreasing the duration or severity of GER symptoms. Other treatment modalities utilized, including thickening of feedings and medications, in studies have not shown the ability to diminish symptoms in neonates.

For infants “with symptomatic GER, a stepwise approach, based mainly on conservative interventions is the best therapeutic choice” (Corvaglia et al, 2007, p. 594). When an infant presents with symptoms of GER, a thorough physical assessment and a review of the patient’s history should be done to eliminate other causes. While considering differential diagnoses, interventions to diminish symptoms of GER can be initiated. Holding the infant upright after feedings helps him or her eliminate some of the air from the stomach by burping. If the caregiver can hold the infant for up to 30 minutes, the usual time after feeding that an acid reflux episode occurs, the symptoms will be diminished and the caregiver can comfort the infant and help them transition back to a sleep state. When the infant is ready to sleep, he or she should be

placed in a left lateral position for at least 30 minutes and then repositioned onto the back for sleep. More research is required to give long-term recommendations.

Ideas for future research include a longitudinal or a qualitative study in which the previously listed interventions are employed and the results are evaluated again with pH probes and by telling the lived experience of caregivers who are utilizing the approaches. The sample sizes need to be much larger and the data needs to be assessed over a longer period of time. The benefit of a new study would demonstrate if any long term relief can be obtained from the proposed changes in sleeping positions for the infants who may experience GER and if short term cessation of symptoms is observed.

As more studies are performed, the information needs to be disseminated to healthcare providers in NICUs and to the parents of infants who experience GER. The current nursing textbooks and handbooks need to be updated and each unit's policy and standards of care need evidence based resources with current recommendations from current research.

Family Education

Having a new baby is a stress producing event in a person's life. Having a child hospitalized creates stress. Observing one's child experience irritability, prolonged crying and arching in an apparent response to pain also creates stress. To absorb more educational information while enduring these major stressors is difficult. In patient education, while undergoing stress, "the average number of facts retained was 3 out of 12 mentioned" (Godwin, 2000, p. 121). To provide adequate patient education, information needs to be repeated often, described in words that the family can understand, and be written out in a grade level that most non-medical people would be able to comprehend. Most of the current educational materials

provided to patients and families are far too complex. In fact, one study noted that the average citizen was only able to comprehend medical educational materials at a 6th grade level (Davis et al, 1990). Patient and family education needs to be started as soon as the condition is noted, explained fully and repeated often. Patients and family members want to be informed consumers of health care and require research based best practice interventions.

Education regarding GER should begin with a diagram of the stomach and esophagus and a discussion between the professional caregiver and the family as to why GER occurs.

Education would continue with demonstration and role-modeling of holding the infant upright and then placing him or her in a prone position if the infant is less than 37 weeks corrected gestational age. If the infant is older than 37 weeks, he or she should be placed in a left lateral position for the first 30 minutes of sleep. If the current interventions fail to provide relief, the potential next steps could be pursued collaboratively by professional caregivers and family members. After a full explanation and answering any questions, interventions would then be initiated. The caregiver would observe the intervention, have a verbal explanation of the intervention and provide a reading level appropriate handout to the parent. A handout prepared by this author is in appendix A.

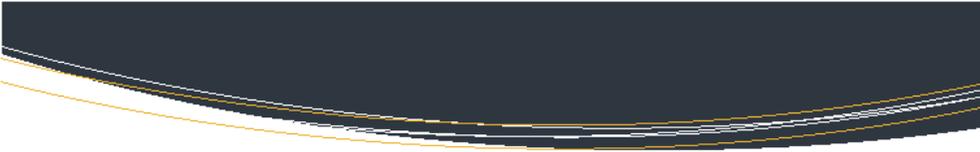
Conclusion

Health care professionals desire to keep themselves abreast of current best practice recommendations. This requires frequent examination of printed peer-review journals and on-line resources. If the data presented stands up to scrutiny, thoughtful interdisciplinary planning would be employed and the new interventions would be introduced into the practice of the health care professionals. In addition, patient and family educational materials would need to be

prepared. The patient and family are part of the health care team and to have the appropriate results from new interventions, all members of the health care team need to be fully invested in the intervention.

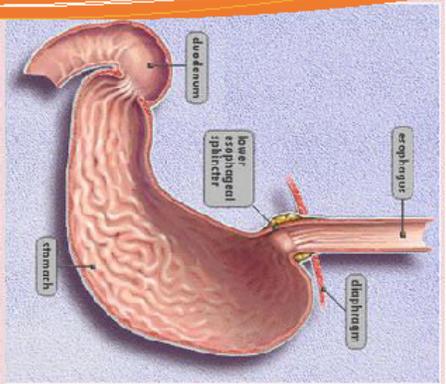
The condition of GER is troubling and appropriate interventions are elusive. An evaluation of the literature has shown that some of the most often applied positional interventions, head of bed elevation, slings and wedges, do not have evidence based origins and do not stand up to physiological testing. The most often recommended interventions, horizontal prone and horizontal left lateral positions, are not used as often in care settings and do not fit with preconceived ideas. This critical review of the literature shows the efficacy of the prone and left-lateral positions and reveals the need for evidence based practice changes.

Appendix A



Sueann Pflaster, RNC, 2011





What can we do?

WHILE IN THE HOSPITAL

- Make sure he or she burps well
- Holding him or her upright after eating
- Positioning him or her on the stomach or left side*

While your baby is still very small, under 37 weeks, we can help him or her lie on his or her stomach or left side for at least 30 minutes after eating. When your baby is 37 weeks, we will no longer place him or her on the stomach because the American Academy of Pediatrics has shown that sleeping on the stomach can cause Sudden Infant Death Syndrome (SIDS) in infants older than 37 weeks corrected gestational age. You and we will place him or her on the left side for about 30 minutes after eating and then onto his or her back to sleep.

WHEN YOUR BABY COMES HOME

- Make sure he or she burps well
- Hold him or her upright as long as possible after eating
- Position him or her on the left side for about 30 minutes when lying in the crib and then flat on his or her back to sleep.

Digestive System

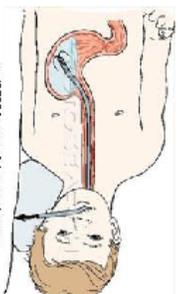
WHY BABIES EXPERIENCE GER

Food enters the stomach through the esophagus. The Lower Esophageal Sphincter, just below the diaphragm should prevent the food from coming back up into the esophagus, but in babies this sphincter doesn't work right yet.

This sphincter relaxes and food along with stomach acid goes back into the esophagus. This is called "reflux". The stomach makes acid to help break down the food.

When the food and stomach acid refluxes, your baby feels discomfort and becomes irritable, cries for a long time and may even curve him- or herself backwards to try to stop the discomfort.

WHY DOES THE LEFT SIDE POSITION HELP?



ped00014 www.fda.gov/cdr/cdrt/00014

The left side position helps keep liquid food pooled in the stomach away from the sphincter while stomach acid starts breaking down the food. When your baby is then placed on his or her back, normal digestion will then continue.

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