CASE STUDIES

A global collection of clinical case studies on the dietary management of functional gastrointestinal disorders with Nutricia's Comfort and Anti-Regurgitation (AR) formulas

Accurate at time of publication, April 2023.

NUTRICIA
LIFE-TRANSFORMING NUTRITION

INTRODUCTION

Functional gastrointestinal disorders (FGIDs) and related symptoms are very common in infancy[1]. While FGIDs are mostly harmless and accompany normal development, they may provoke abdominal pain and inconsolable crying in the infant. This may cause parental anxiety and stress, poor sleeping habits, shortened duration of full breastfeeding[2] as well as impacting long-term health outcomes[1]. Often it also results in numerous visits to paediatricians, impacting healthcare system costs[3].

International guidelines and experts recommend nutritional advice combined with parental reassurance and education as the first line management for FGIDs, offering a natural way to resolve symptoms[4,5].

That's why Nutricia was the first to introduce a formula for infants with colic and constipation: a comfort formula. This comfort formula is supported by an extensive clinical trial programme with over 20 years of research in >1000 infants with colic and constipation[6-11]. The comfort formula has been shown to reduce crying episodes[6] and improve gastrointestinal (GI) symptoms[9], stool consistency[10] and stool frequency[7].

More than 20 years ago, Nutricia has developed its first Anti-Regurgitation (AR) formula with Carob Bean Gum (CBG) for the dietary management of regurgitation. This AR formula is thickened with the fibre CBG* and contains prebiotics scGOS/lcFOS (9:1) and postbiotics. The formula is studied in >3000 infants, and clinically proven to reduce regurgitation episodes[12,13] and new data shows improvement of overall GI burden over time[13].

The aim of this case study booklet is to provide you with clinical insights from daily practice into the diagnosis and dietary management of colic, constipation and regurgitation in infancy. The cases illustrate the use of Nutricia's comfort and AR formulas in real-life practice, to complement the extensive evidence available on our comfort and AR formulas from clinical studies.**

This case study booklet contains 11 different case studies written by healthcare professionals (HCPs) from around the world. The case studies aim to share best practices between HCPs, allowing us to learn from each other's experiences and expertise, and optimise the management of FGIDs.

Each case illustrates different challenges and describes the impact of these FGIDs on infants and their families. Such challenges include excessive and inconsolable crying, infrequent passage of stools, faltering growth, parental sleep deprivation and use of medication.

Nutricia would like to thank all the HCPs for sharing their case studies and for their contributions to this booklet.

This case study booklet is intended for healthcare professionals only, not for distribution to the general public.

**Also known as Locust Bean Gum.*

***Comfort and AR formulas are Food for Special Medical Purposes (FSMPs) for use under medical supervision, after full consideration of all suitable options for feeding including breast feeding.*

1. Vandenplas Y et al. J Pediatr Gastroenterol Nutr, 2015. 61(5): p. 531-7.
2. Howard CR et al. Breastfeed Med, 2006. 1(3): p. 146-55.
3. Vandenplas Y et al. Nutrition, 2013. 29(1): p. 184-94.
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CASE STUDIES OVERVIEW

COMFORT FORMULA

Case study	Short case description	Healthcare professional, profession	Country
Baby A	Infant with constipation on mixed feeding with standard infant formula	**Dr Ivo Roberto Dorneles Prola** Paediatric Gastroenterologist	Brazil
Baby B	Exclusively formula fed infant with colic and severe constipation	**Dr Ilaria Cavecchia** Paediatric General Practitioner	Italy
Baby C	Infant with multiple gastrointestinal symptoms	**Dr Konstantelos Dimitrios** Paediatrician, Neonatologist	Greece
Baby D	Infant with colic and constipation on standard infant formula	**Health Visitor***	UK
Baby E	Distressed infant with frequent crying and multiple gastrointestinal symptoms	**Dr Alicia Bressan** Paediatrician	Argentina
Baby F	Mixed fed infant with inconsolable crying, cramps and constipation	**Dr Anna Fàbrega Riera** Paediatrician	Spain
Baby G	Exclusively formula fed infant with colic and constipation	**Dr Nevine El Kabbany** Paediatric Specialist	United Arab Emirates
Baby H	Infant with multiple gastrointestinal symptoms on standard infant formula	**Prof Mostafa Alhodhod** Paediatrician	Egypt

ANTI-REGURGITATION (AR) FORMULA

Case study	Short case description	Healthcare professional, profession	Country
Baby I	Exclusively formula fed infant with gastroesophageal reflux	**Health Visitor***	UK
Baby J	Infant with primary gastroesophageal reflux**, crying and faltering growth	**Dr Omar Tabacco** Paediatric gastroenterologist	Argentina
Baby K	Infant with reflux**, crying and irritability on standard infant formula	**Dr Valentina Zattoni** Paediatrician	Italy

* This case has been anonymised for confidentiality purposes

**"Reflux" and "Regurgitation" are terms that are often used interchangeably by healthcare professionals, authorities and consumers. Gastroesophageal reflux (GER) or reflux refers to the bringing up of stomach contents into the oesophagus. Regurgitation is when the stomach contents are actually expelled from the mouth and is also known as 'spitting up' or 'posseting'[1-3].

1. Lightdale JR and Gremse DA. Pediatrics, 2013. 131: p. e1684–95.
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COMFORT FORMULA CASE STUDIES

BABY A

INFANT WITH CONSTIPATION ON MIXED FEEDING WITH STANDARD INFANT FORMULA

Ivo Roberto Dorneles Prola
Paediatric Gastroenterologist
University Hospital of Santa Maria, Santa Maria

PATIENT PROFILE

Full term infant saw a fast resolution of his constipation, and relief from the associated pain and crying, following a switch from mixed feeding with standard infant formula to mixed feeding with comfort formula*.

BACKGROUND

Baby A was born at full term, weighing 3.5kg, and had no family history of atopy. He was exclusively breastfed from birth until nine weeks old when his mother returned to work. At nine weeks old, baby A was switched onto mixed feeding; he was breastfed six times per day and had two standard infant formula bottles (130ml per bottle) each day. Whilst being exclusively breastfed, baby A was passing loose stools (type six on the Bristol Stool Chart[1]) five times a day. However, soon after commencing the standard infant formula his stools changed. Baby A began passing hard stools (type one on the Bristol Stool Chart[1]) once a day with pain and exertion.

DIAGNOSIS AND MANAGEMENT

Baby A's mother was worried about the appearance of his stools and anxious about the resulting discomfort and pain he was in. To soften his stools, his mother tried feeding him plum black tea once a day for three to four days, but this method wasn't successful. Plum black tea given to infants is a common practice for mothers in the area whose children present with hard stools, as it is rich in sorbitol and fibres (soluble and insoluble). However, it's not in the guidelines for constipation treatment and can increase gas production and cause colic pain, bloating and abdominal distension.

Baby A was first seen by the paediatric gastroenterologist at 12 weeks old after presenting with hard stools which were causing pain and lots of crying. After a history was taken and a physical exam was conducted, he was diagnosed with functional constipation. A flowchart for assessment of constipation in infants and the Rome IV criteria for constipation aided the diagnosis. Cow's milk allergy (CMA) was considered but ruled out given that no other symptoms of CMA were present and baby A had no family history of atopy. He was growing well, and nothing was noted during his physical exam.

At this first appointment, at 12 weeks old, baby A's mother was advised to stop the plum tea and switch his regular infant formula (150ml twice a day) to the **comfort formula*** (150ml twice a day). Breastmilk was continued alongside the **comfort formula** six times a day. This formula was chosen in view of baby A's constipation, as this **comfort formula** has a high content of beta-palmitate fatty acid. The **comfort formula** was well accepted by baby A, and three days after commencing it, his stools softened. He began passing two soft stools (type four and five on the Bristol Stool Chart[1]) per day, and experienced relief from the pain and crying previously associated with passing stools.

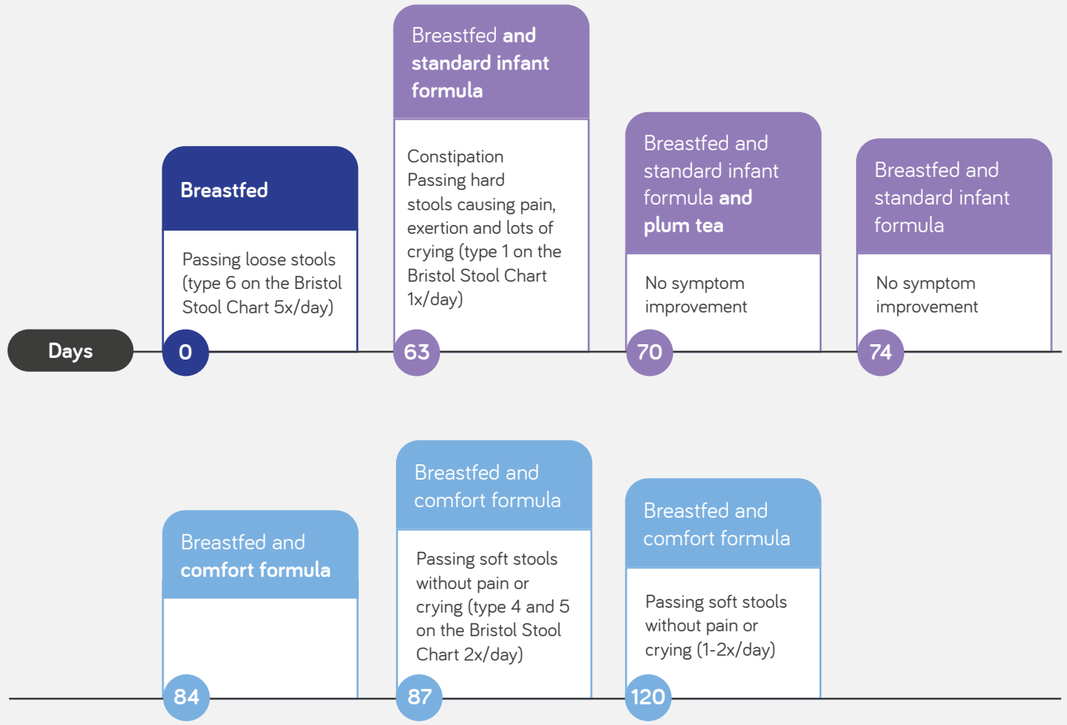
*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

DIAGNOSIS AND MANAGEMENT *continued*

Two weeks after the initial appointment, the parents of baby A had a telephone appointment. He was passing softer stools twice a day with no pain or crying. It was recommended that he continued with the same diet and be reviewed in two weeks. At around 17 weeks old, 20 days after the telephone appointment, baby A was having breastmilk five times a day and 150ml of **comfort formula** three times a day. He continued to pass soft stools (once or twice a day) without pain or crying. Baby A was advised to continue with the current diet until he started on solids, probably at around six months old. Baby A was discharged at this appointment, aged 120 days, as his constipation was resolved. He will be followed up by his private paediatrician.

No drugs were used in the management of baby A's constipation.

TIMELINE



Case study continues on the next page.

DISCUSSION[2,3,4]

The dramatic change in baby A's stool characteristics soon after switching onto formula from exclusive breastfeeding calls into question the possibility of CMA. However, this was ruled out as the challenge with a beta-palmitate fatty acid containing formula (comfort formula) showed a fast improvement in his stools and symptoms.

Constipation in bottle fed babies is a very prevalent complaint during the first year of life and most cases are diagnosed as functional constipation[3]. The main treatment for functional constipation is nutritional management, so choosing the right formula is often important. The paediatric gastroenterologist considers that for infants with constipation, formulas with a fatty acid profile similar to that of breast milk are the best option i.e., formulas enriched with beta-palmitate fatty acid. Beta-palmitate fatty acid has been shown to prevent the formation of calcium soaps, which are closely related to the occurrence of hard stools in bottle fed infants[4].

The comfort the formula exceeded expectations, and left the paediatric gastroenterologist completely satisfied with the prompt response that baby A's symptoms had following the switch. The change to the comfort formula also had a positive impact on baby A's families' quality of life, namely the reduction of baby A's mother's anxiety. Following the formula switch, baby A's mother commented, "My gosh, I lost precious time trying that old recipe made of black plum tea; why hadn't his [previous] paediatrician switched to a comfort formula when I told him about the hard stools?"

Based on the positive response observed, it's logical to consider that every bottle fed (with standard infant formula) infant who presents with constipation should have a short trial on a formula with beta-palmitate fatty acid before undergoing any further investigation.

> *"My gosh, I lost precious time trying that old recipe made of black plum tea [a common practice for mothers in this area when children present with hard stools]; why hadn't his paediatrician switched to a comfort formula when I told him about the hard stools?"*

CONCLUSION

In this mixed fed infant, the switch from a standard infant formula to comfort formula brought quick relief from his hard and painful bowel movements, without the use of any medication. The formula was well accepted by the infant and the switch positively impacted his family's quality of life, namely reducing his mother's anxiety.

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4. Havlicekova Z, Jesenak M, Banovcin P, Kuchta M. Beta-palmitate – a natural component of human milk in supplemental milk formulas. Nutrition Journal. 2016 Mar;15:28.

Please find the Bristol Stool Chart scale on the last page of the booklet.

BABY B

EXCLUSIVELY FORMULA FED INFANT WITH COLIC AND SEVERE CONSTIPATION

Dr Ilaria Cavecchia
Paediatric General Practitioner
Private practice, Torino

PATIENT PROFILE

Exclusively formula fed infant, born to a surrogate mother by caesarean section, saw a fast resolution of his symptoms of severe constipation and colic following a switch to comfort formula*.

BACKGROUND

Baby B was delivered by caesarean section at full term. He was born to a surrogate mother in Ukraine, before moving to Italy at around four weeks old to live with his biological parents. Baby B was fed with a standard infant formula from birth. At three days old he was advised by a Ukrainian pediatrician to switch onto another standard infant formula (Ukraine)**, due to presenting with full body dermatitis. Following the switch, baby B's dermatitis improved. However, he began to experience colic and severe constipation, worsening his already limited stool transit which had been present since birth.

DIAGNOSIS AND MANAGEMENT

From the start of Baby B's biological parents' caregiving, in an effort to relieve Baby B's constipation symptoms, they trialled enemas, mechanical stimulation and massages; his mother had to stimulate him or perform an enema every day for baby B to pass his hard stools. Baby B's parents took initiative and began enemas without recommendation from a healthcare professional. They also trialled mineral oil (more than suggested), following their friends' advice, without success.

At 40 days old, baby B was switched onto another standard infant formula (Russia)** as his original Ukrainian standard infant formula was not available. He continued to experience 30 minutes of colic each evening and severe constipation.

Following the worsening of baby B's constipation, he was seen at 13 weeks old by the paediatric general practitioner in Italy; his parents were very worried that he couldn't pass stools independently. At this appointment he was switched onto exclusive feeding with the **comfort formula***, with the aim of more easily passing softer stools. It was also recommended that baby B was fed using an anti-colic bottle and was given tummy massage. There were no issues with baby B's parents accepting the formula change, as they were exhausted by his symptoms. Baby B also had no issues switching to the **comfort formula.** Two days after starting the new formula, baby B was spontaneously passing regular softer stools daily and his enemas were stopped. His evening crying decreased following the switch and after seven days on the **comfort formula** his colic ceased.

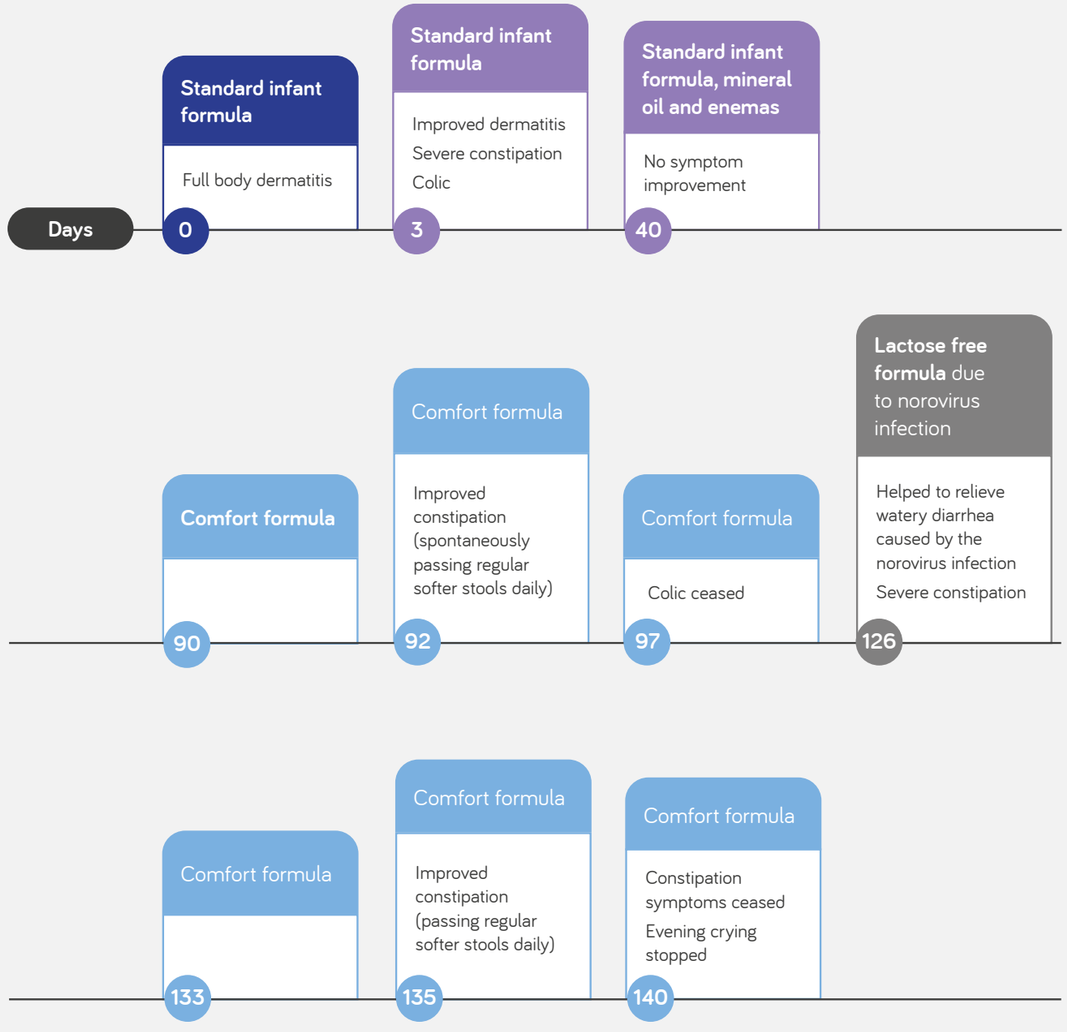
The **comfort formula** was trialled so that the clinical effect of a different type of milk could be seen, before starting more invasive diagnostic screening tests (like imaging tests). Other pathologies were excluded in light of baby B's symptom resolution following the formula switch.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.
**Origin of standard infant formula

DIAGNOSIS AND MANAGEMENT *continued*

At 18 weeks old baby B had an episode of watery diarrhoea due to a norovirus infection. After presenting at the hospital, he was switched onto a lactose free formula by an emergency room doctor. This switch helped to relieve his watery diarrhoea but caused his symptoms of severe constipation to return. At 19 weeks old, baby B was seen in person for the second time by the paediatric general practitioner and was re-started on **comfort formula**; after two days his bowel habits returned to passing regular softer stools daily. Baby B is planned to continue on **comfort formula** until weaning.

TIMELINE



Case study continues on the next page.

DISCUSSION

In this case, using maternal milk wasn't an option, so formula feeding was necessary. Following baby B's colic and constipation, this comfort formula was chosen because of its properties, which are well known for helping to relieve gastrointestinal symptoms. It's likely that the quick symptom resolution seen after switching formula was due to a combination of the beta-palmitate and prebiotics galacto-oligosaccharides (GOS) and fructo-oligosaccharides (FOS) found in this comfort formula. The beta-palmitate limits fat saponification in stools, and the GOS/FOS may improve some components of the infants' gut microbiota, such as Bifidobacteria, which are usually less abundant in formula fed infants.

The comfort formula was a success, more so than expected, leaving the parents relieved and the healthcare professional satisfied. Baby B's parents' quality of life was improved as they were able to sleep again after baby B's evening crying stopped. His parents' anxiety also fell following the formula switch.

The comfort formula was a success, leaving the parents relieved and the healthcare professional satisfied. Baby B's parents' quality of life was improved and his parents' anxiety also fell following the formula switch

CONCLUSION

This exclusively formula fed infant saw a fast resolution of his constipation and colic after commencing the comfort formula; enemas were no longer needed due to the infant passing spontaneous stools. Baby B's symptom relief, as a result of the formula switch, also reduced his parents' anxiety and improved their quality of life.

BABY C

INFANT WITH MULTIPLE GASTROINTESTINAL SYMPTOMS

Konstantelos Dimitrios
Paediatrician, Neonatologist
Private practice, Athens

PATIENT PROFILE

Mixed fed infant saw a fast resolution of her colic, gastrointestinal cramps, inconsolable crying, constipation, and flatulence following a switch to exclusive feeding with comfort formula*.

BACKGROUND

Baby C's mother didn't experience any complications during pregnancy and baby C was born at 41 weeks by vaginal delivery after an uncomplicated labour. Baby C was mixed fed with a standard infant formula from birth due to her mother's limited breastmilk supply.

From around ten days old baby C was passing hard stools once a day. At four weeks old (~25 days), baby C presented with clinical symptoms of '1st trimester colic' (colic which only occurs in the first three months of life). Baby C experienced colic and gastrointestinal cramps three to four times a day for around two hours at a time (especially in the afternoon, evening and night time). Baby C had intense and inconsolable crying episodes every time she had colic and gastrointestinal cramps; her crying lasted as long as the episodes of colic. After the onset of colic, baby C had difficulty sleeping and was waking up five to six times a night because of her crying. She also presented with increased abdominal gas and sustained flatulence.

DIAGNOSIS AND MANAGEMENT

Baby C was seen by the paediatrician/neonatologist at 28 days old for a general check-up appointment. Her colic and gastrointestinal cramps had begun two to three days prior. Baby C's parents were concerned about their infant's pain and were keen to find a solution. They were also exhausted after sleeping poorly due to their anxiety and baby C's crying. Infacolic drops (containing simeticone) were recommended before each meal to improve baby C's abdominal flatulence and facilitate the elimination of faeces and gas. Baby C was started on 0.5ml and after no symptom improvement, two days later, the dose was increased to 1ml before each meal. The increased dose resulted in minimal symptom improvement. Other strategies recommended to relieve baby C's symptoms were lightly massaging her abdomen, using a baby carrier, soft lighting, frequent physical contact with her mother and changing her feeding position. However, no reduction of symptoms was seen following these strategies.

At six weeks old, breastfeeding was stopped due to a lack of milk supply and baby C was seen by the paediatrician/neonatologist. Baby C's parents were advised to discontinue the infacolic drops and to switch the formula to the **comfort formula***, with the aim of relieving baby C's symptoms and improving her quality of life. The infant's parents were instructed to leave 10ml of feed in the bottle after each feed to prevent baby C from swallowing air. Baby C accepted the change in feed without difficulty.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

DIAGNOSIS AND MANAGEMENT *continued*

Following the switch to the **comfort formula**, baby C's symptoms improved. After one day of being exclusively fed by **comfort formula** her inconsolable crying reduced to less than one hour a day, and it completely stopped after three days. Two days following the switch, she was passing softer, more frequent stools (around three to four times per day) and sleeping better and for longer; waking up only one to two times per night, compared to the previous five to six times a night. Baby C's colic and gastrointestinal cramps improved after three days and fully resolved after four to five days. The infant also saw a reduction in her flatulence and gas three days after the switch to the **comfort formula** and after five days she had only minimal gas and no flatulence.

Baby C's parents were completely satisfied with the new formula. Following the switch, baby C's family's stress decreased and both baby C and her parents' sleep quality improved. At seven weeks old, baby C was seen again by the paediatrician who was satisfied with the **comfort formula**. Baby C is planned to carry on with **comfort formula** until four months old and she will continue to be monitored.

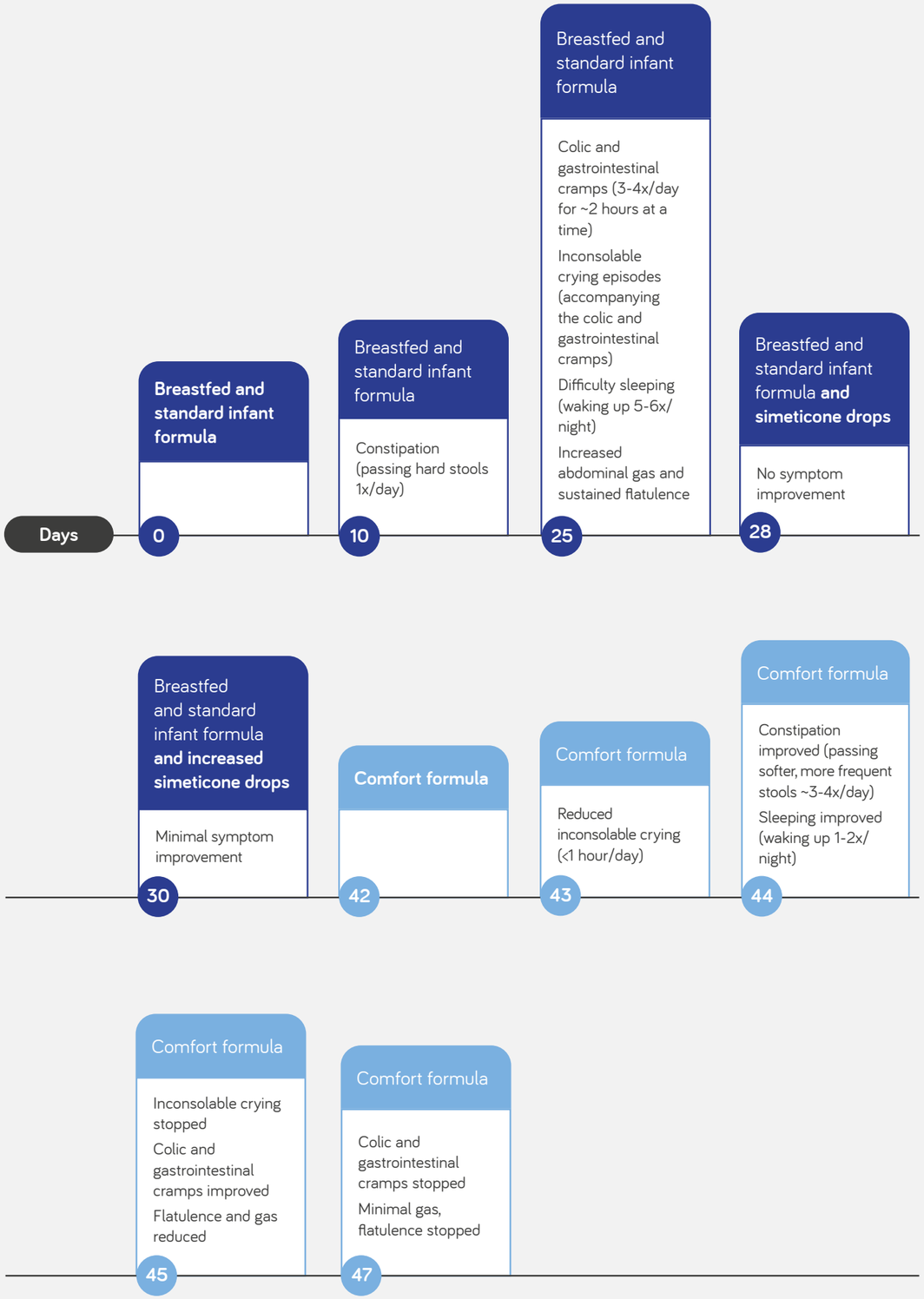
DISCUSSION

The comfort formula was chosen due to the colic symptoms that baby C was displaying. The quick impact that the formula had on her symptoms, leading to full symptom resolution, highlighted that it was a good choice of formula. In the future, if other babies are suffering from colic, this paediatrician would suggest this comfort formula to their parents.

Two days following the switch [to comfort formula] she was passing softer, more frequent stools and sleeping better and for longer. Baby C's colic and gastrointestinal cramps fully resolved after four to five days

Case study continues on the next page.

TIMELINE



CONCLUSION

This mixed fed infant had success with the comfort formula. She experienced complete resolution of her colic, gastrointestinal cramps, inconsolable crying, constipation, and flatulence after switching to comfort formula. Her gas and sleep deprivation were also improved following the feed change. The switch positively impacted baby C's family's quality of life, with her parents' stress being reduced and their sleep quality improved. The intervention left both the family and healthcare professional satisfied.

BABY D

INFANT WITH COLIC AND CONSTIPATION ON STANDARD INFANT FORMULA

Health Visitor*
Independent Practitioner, United Kingdom (UK)

*This case has been anonymised for confidentiality purposes

PATIENT PROFILE

Following a switch in formula to the comfort formula*, an infant with colic and constipation saw a fast improvement in his symptoms and subsequent symptom resolution.

BACKGROUND

Baby D was born by normal vaginal delivery at 42 weeks weighing 4.6kg (above the 91st centile); he was healthy, with no congenital abnormalities. Baby D was discharged from hospital after one day (as is standard practice in the UK) with no follow-up. He was his parent's first child. For the first 24 hours of life baby D was breastfed, before being switched onto a standard infant formula as his mother didn't feel she was producing enough breastmilk for him.

At baby D's first consultation at 10 days old, as per the Healthy Child Programme protocol, no concerns were reported. He was growing well and tolerating his formula, taking ~90ml at each feed every three to four hours.

However, at 17 days old baby D's mother contacted the health visitor with concerns. Baby D was sleep deprived and fatigued between feeds. Following feeds, he was presenting with symptoms of gastrointestinal cramps (three times/day for around two minutes) and inconsolable crying (high pitched scream for two minutes and going red in the face three times/day). He also had abdominal rumbling (twice daily), back arching (twice a day for 30 seconds each), fist clenching (twice daily) and was bringing his knees up (twice daily) after feeding. Baby D also had a change in stools from soft to hard pellet-like stools and was only passing stools every other day (type one in accordance with the Bristol Stool Chart[1]). He was also passing foul-smelling wind twice a day.

DIAGNOSIS AND MANAGEMENT

At 17 days old, ahead of his next appointment, the health visitor provided advice to alleviate his colic symptoms including: baby massage (specific instructions provided), ensuring correct positioning when feeding (hold him upright to prevent swallowing of air), hold baby D during his crying episodes, using different teats, giving smaller feeds, winding during and between feeding, considering a change of bottles and teats to anti-colic varieties and considering the addition of white noise and motion.

Baby D was seen at 19 days old due to his parent's concerns about his colic. He continued to grow well and was still being fed responsively with the standard infant formula, drinking ~90-120ml each feed. However, the techniques advised by the health visitor had only provided transient symptom relief and his parents were concerned, anxious, stressed and not sleeping well. They felt helpless as they were unable to settle him, despite advice given from the health visitor.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

DIAGNOSIS AND MANAGEMENT *continued*

Baby D's parents described the colic as a high-pitched scream following feeds. The colic symptoms were occurring for three hours per day, but more frequently occurred in the evenings. The excessive crying occurred for five to ten minutes, six times per day. Baby D was arching his back five times per day for one minute each time and clenching his fists and bringing his knees up twice daily. His parents reported abdominal rumbling five times per day, which coincided with the back arching and lasted for 30 seconds. Baby D also appeared sleep deprived and fatigued between feeds, occurring five times per day.

A colic diagnosis was made by the healthcare professional as per the National Institute for Health and Care Excellence (NICE) Guidelines[2,3].

A joint plan, with the parents and healthcare professional, was made to switch baby D onto a partially hydrolysed whey protein formula, **comfort formula***. Baby D's parents had already researched this **comfort formula** prior to the consultation. The **comfort formula** was recommended by the healthcare professional as it is indicated for the dietary management of colic and constipation. The desired outcomes were to stop baby D's excessive crying and high-pitched screaming, to ensure that he passed soft stools at least once daily and to alleviate his abdominal rumbling, back arching and fist clenching. Another desired outcome was to alleviate baby D's parent's anxiety and stress.

Alongside the recommendation to switch to the **comfort formula**, the healthcare professional advised baby D's parents to continue with the advice previously given. Baby D's mother was also advised to use variable flow teats as the consistency of the **comfort formula** is thicker than the standard infant formula.

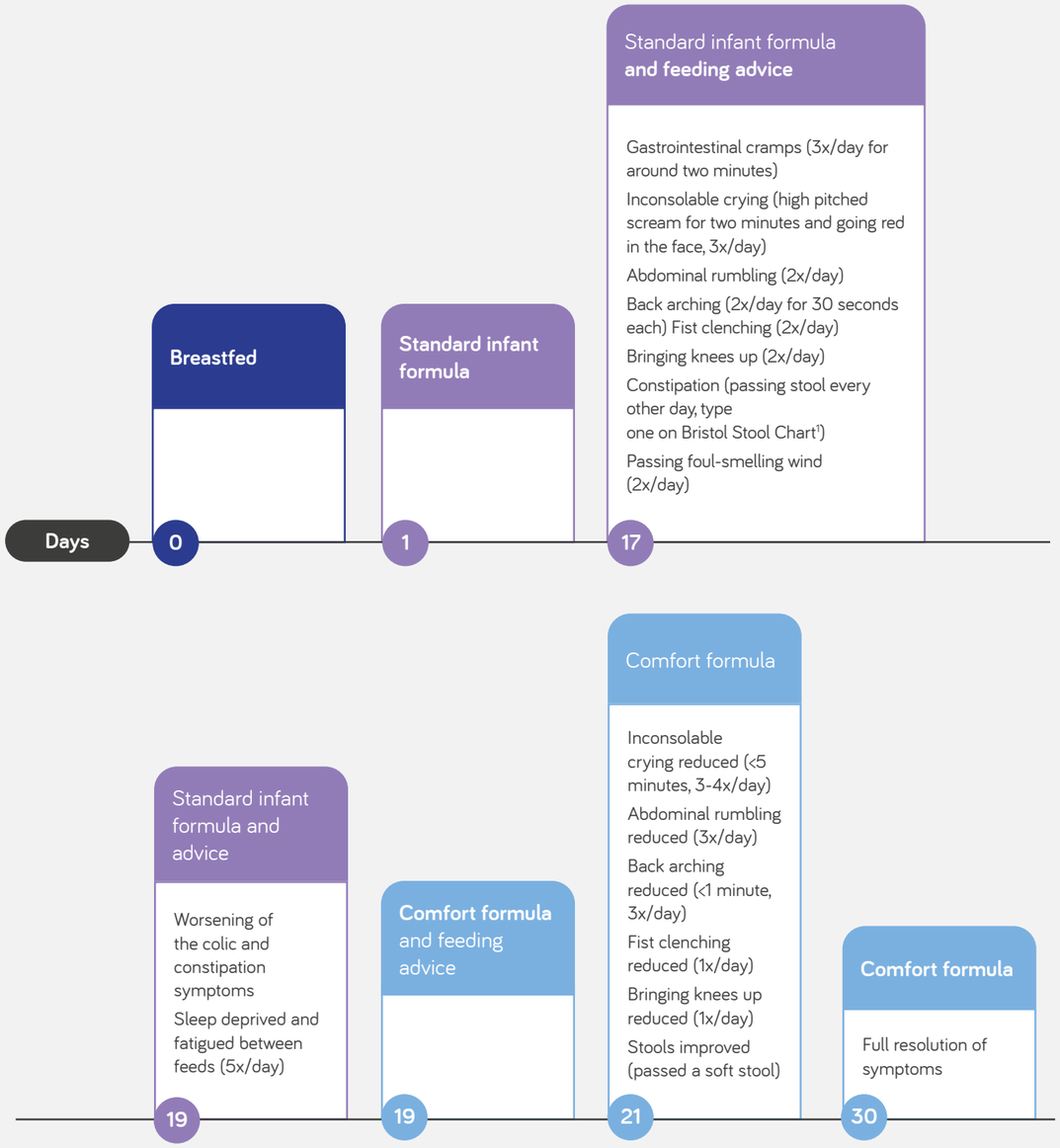
Baby D tolerated the **comfort formula** well and there were no concerns regarding palatability or acceptance. After two days, at 21 days old, Baby D's symptoms had reduced including his inconsolable crying (less than five minutes three to four times per day), abdominal rumbling (three times per day), back arching (three times per day for less than one minute), clenching of fists and bring his knees up (once per day). He also passed a soft stool.

Baby D was followed up at 30 days old; his symptoms had fully resolved by day 30. The **comfort formula** met the healthcare professional's expectation and baby D's parents were very pleased that they used this formula; their anxiety, stress and sleep quality had all improved by the time baby D was 30 days old. Baby D's father was able to interact with his son with more emotional warmth as he was feeling less concerned. At around 40 days old, both parents reported increased confidence.

Baby D will remain on **comfort formula** until 12 weeks old when he'll be reviewed to determine whether this formula is continued. Baby D will also be followed up at six months old.

Case study continues on the next page.

TIMELINE



DISCUSSION

Infantile colic and excessive crying in healthy thriving infants is a common problem during the first months of childhood and causes one in six families to consult a healthcare professional; it usually starts in the first few weeks of life and subsides at 12 -16 weeks[4].

No medical intervention was necessary for baby D's colic; a combination of feeding with comfort formula and advice, including baby massages and ensuring correct positioning, resolved baby D's colic symptoms. In this case, the comfort formula was recommended as it is indicated for the dietary management of colic and constipation. This comfort formula is a partially hydrolysed whey protein formula and contains beta-palmitate, which helps to promote softer stools.

> *My bond with Baby D has been enhanced as I am no longer worried that he is in pain when I am feeding him" - Father*
>
> *I am less anxious and no longer stressed as he is no longer crying a lot following feeds" - Mother*

CONCLUSION

In this infant with symptoms of colic and constipation, a switch from infant first formula milk to comfort formula resulted in initial improvements to baby D's symptoms within two days, before being fully resolved by four weeks old. The switch also led to improvement in his parents' anxiety, stress and sleep quality.

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2. National Institute for Health and Care Excellence (NICE). Clinical Knowledge Summary: Colic - infantile. Last revised 2022 Dec. https://cks.nice.org.uk/topics/colic-infantile/ [Accessed February 2023].

3. National Health Service (NHS). Colic. https://www.nhs.uk/conditions/colic/ [Accessed February 2023].

4. Lucassen P. Infantile colic. BMJ Clin Evid. 2007 Jul 1;2007:0309

Please find the Bristol Stool Chart scale on the last page of the booklet.

BABY E

DISTRESSED INFANT WITH FREQUENT CRYING AND MULTIPLE GASTROINTESTINAL SYMPTOMS

Alicia Maria Bressan
Paediatrician
Consulting Room Vitus,
Córdoba, Argentina

PATIENT PROFILE

Infant with colic and gastrointestinal (GI) symptoms saw improvements in her colic within 48 hours of switching formula to the comfort formula*, and improvement in all her symptoms within two weeks.

BACKGROUND

Baby E was born by planned caesarean section at 37 weeks old due the mother's medical history (systemic lupus erythematosus with kidney failure). She weighed 2850g at birth. Baby E's mother was unable to breastfeed due to contraindicated medication for breastfeeding. Baby E's mother felt very guilty that she was unable to breastfeed her daughter. Standard infant formula was indicated.

The day after standard infant formula feeding commenced, baby E began presenting with regurgitation. Three days after starting the standard infant formula, baby E experienced colic and was crying frequently, mostly at night-time and thereafter all day, becoming more intense (approximately five hours per day) causing difficulty to sleep from day seven. Baby E's expulsion of gas was foul-smelling and she started to pass hard stools from day ten. From day 15, baby E's parents also noticed arms, legs, and trunk extension and contraction movements, including arching of the back. This continued to become more frequent, with inconsolable crying episodes after four weeks, becoming unsustainable for the parents. Baby E's parents were very distressed and worried.

DIAGNOSIS AND MANAGEMENT

At seven days old, baby E had her first consultation with the paediatrician. Her parents were thrilled about the birth of their baby girl but were distressed by the mother's medical conditions. Baby E's mother was visibly upset due to not being able to breastfeed and witnessing her baby in permanent discomfort. Reassurance was given to the family that baby E would grow and develop well without breastmilk, and information was provided as to a feeding schedule.

Five days after Baby E's first consultation, her mother called the on-call service due to baby E's continuous crying and hard stools. The family were advised to administer proton pump inhibitors (PPI's; omeprazole) and laxatives (petroleum jelly and lactulose) for 15 days however the medication was discontinued after four to five days after discussion with the paediatrician, as there was no improvement notable.

Baby E was reviewed at four weeks old. Although normal growth and development was observed, baby E was still frequently crying (particularly at night), showed delayed bowel movement, was very irritable and had continuous regurgitation after every feed, with some vomiting. Baby E's mother was feeding her high volumes (80-90ml) of formula every two to three hours as a minimum during the day and smaller volumes (20-50ml) every hour at night. Also baby E's stools changed to creamy green coloured stools one to three times per day (type five to six on the Bristol Stool Chart[1]). Clear and detailed guidance as to an appropriate feeding schedule (including volumes and timing) was provided by the paediatrician, including advice to avoid excessive volumes of feed, avoid sudden changes in the position, encourage calming measures such as bending of the legs to the abdomen, massage the abdomen, warm baths. Baby E's mother was asked to return for a review consultation after two weeks.

Baby E was next reviewed at six weeks old. Her mother was following the new feeding schedule and normal growth and development were observed, however, the frequent crying continued. The crying became increasingly intense and at times baby E was inconsolable. The crying transitioned to particularly at night to all day. Baby E also appeared more irritable which was accompanied by continued arms, legs, and trunk extension and contraction movements, with clear gestures of pain. Baby E was regurgitating after almost every feed. Baby E was passing infrequent stools every three to five days, and expulsion of gas was foul-smelling and very frequent. Baby E was diagnosed as having suspected colic.

DIAGNOSIS AND MANAGEMENT *continued*

The physical examination found baby E to have a distended abdomen. Further investigations (including an abdominal ultrasound) ruled out underlying infections including the urinary tract and ear. Based on the results of the physical examination and investigations, the paediatrician concluded that the issue with baby E was localised to the gastrointestinal tract. A change of formula was indicated, and baby E's standard infant formula was switched to the **comfort formula*.** The **comfort formula** was chosen to manage colic, decrease regurgitations and normalise bowel movements.

The **comfort formula** was well accepted by baby E and 48 hours after commencing it, baby E's colic was reduced to less than one hour per day. After three days her back arching had ceased and after four days, her inconsolable crying had resolved. A week after the switch, baby E was passing softer and more frequent stools, and her regurgitation and gas were improved, with her foul-smelling wind resolving in ten days. Normal growth and development continued, baby E became calmer, and her parents were very satisfied.

DISCUSSION

There are situations where, for a number of reasons, exclusive feeding with breastmilk cannot occur, such as in this case. It is difficult to make the decision to initiate formula feeding from birth, but if it helps the infant's growth, healthcare professionals can provide additional support when this would be the case. Often, the initial standard infant formulas are not well tolerated, and symptoms (e.g., colic, vomiting, diarrhea or constipation) appear that make the baby uncomfortable and scare the family. In these cases, we need to use special formulas to address the symptoms. The comfort formula, due to its composition with partially hydrolyzed protein, reduced lactose and beta-palmitate, significantly improves colic, prevents regurgitations and regularises the intestinal rhythm.

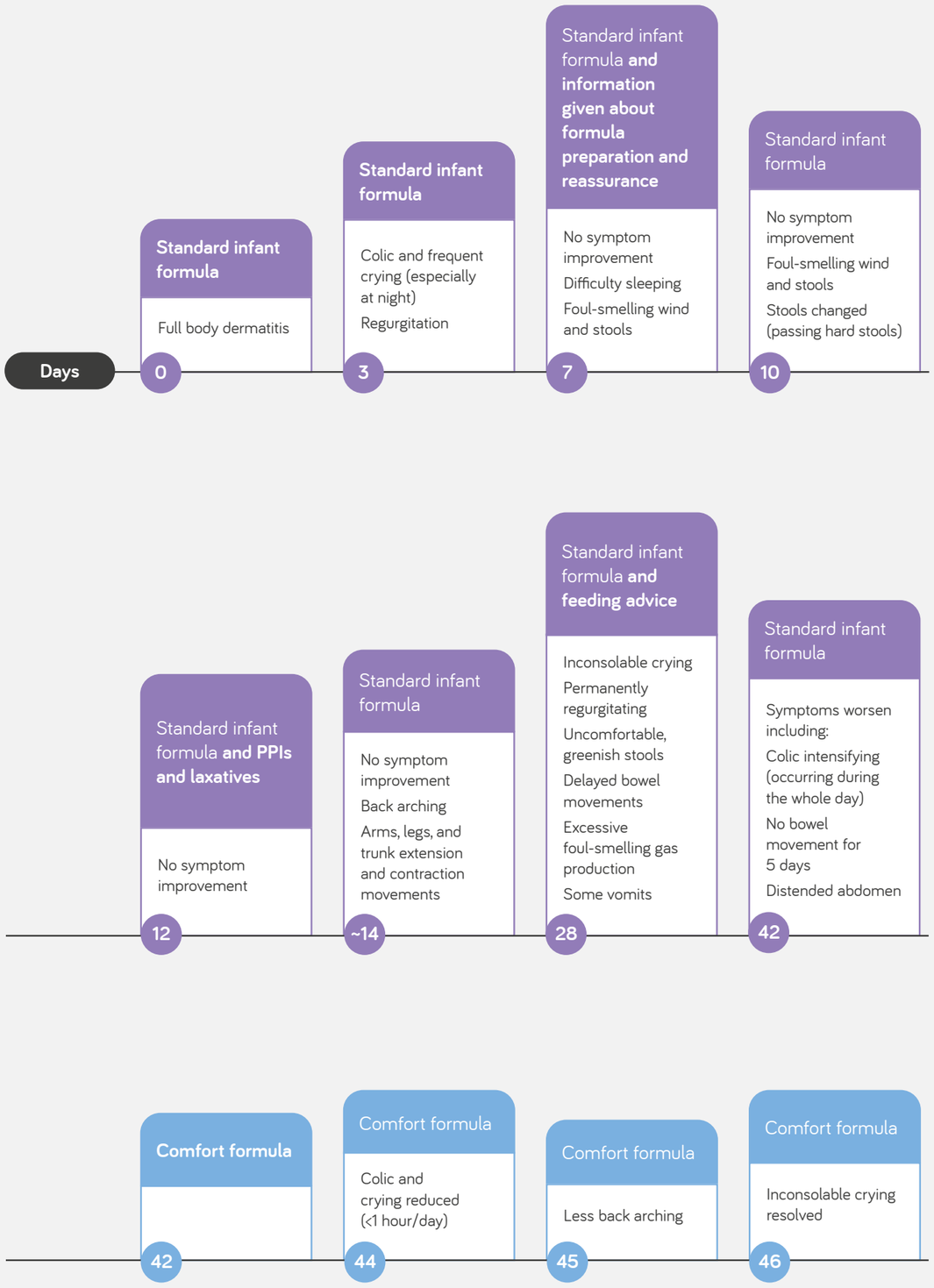
When infants stop crying and are able to rest well, it's a relief for families. In my experience as a paediatrician, having comfort formula has been very useful for both the child and the families. With the correct choice of formula, the child will grow up healthy and comfortable.

> *"I never thought I was going to get my baby to sleep, not to cry and grow so well without breastfeeding her"*

Case study continues on the next page.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

TIMELINE



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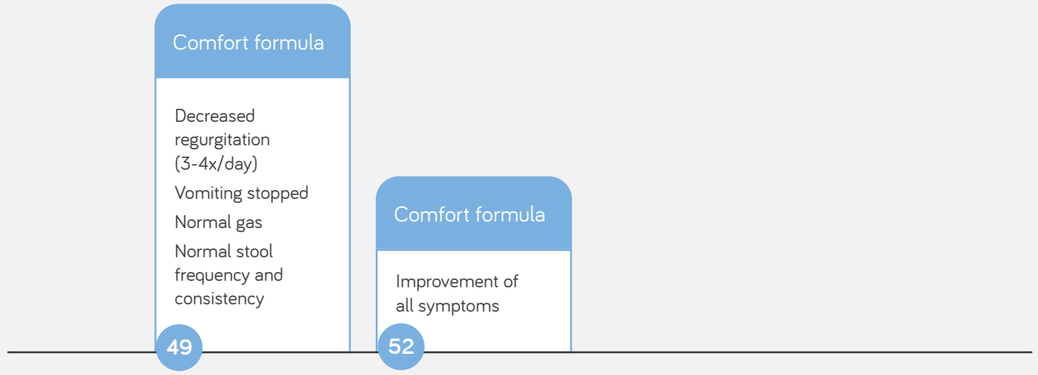


CONCLUSION

Baby E's symptoms presented from day one on the standard infant formula. Baby E's main symptoms were inconsolable colic and crying, with other GI symptoms including regurgitation and infrequent bowel movements. The introduction of comfort formula was well accepted and resulted in a quick noticeable improvement in her symptoms. Baby E is able to rest, her parents are very calm and very satisfied with the formula switch.

1. Lewis S, Heaton K. Stool Form Scale as a Useful Guide to Intestinal Transit Time. Scandinavian Journal of Gastroenterology. 1997;32(9):920-924.

Please find the Bristol Stool Chart scale on the last page of the booklet.

BABY F

MIXED FED INFANT WITH INCONSOLABLE CRYING, CRAMPS AND CONSTIPATION

Dr. Anna Fàbrega Riera
Paediatrician
Clínica Bofill Figueres, Figueres

PATIENT PROFILE

Infant with colic and constipation saw a significant improvement in her colic and a complete resolution of constipation in less than seven days following a switch to mixed feeding with a comfort formula*.

BACKGROUND

Baby F was born at full term by vaginal delivery at an adequate weight for her gestational age. Baby F was her parents' first child, and she had a stable home environment, both emotionally and financially. She was exclusively breastfed for the first three days of life and passed meconium within the first 24 hours. From day four, breastmilk was supplemented sporadically with standard infant formula (~60-90ml once a day or less) as baby F's mother suspected that breastmilk alone was not sufficient; she believed that baby F was crying as a result of hunger.

Baby F was first seen by the paediatrician at ten days old and no concerns were reported. However, at four weeks old, baby F started to present with symptoms. Baby F displayed abdominal cramps (several times a day, in the morning and afternoon), had daily episodes of intense inconsolable crying (over one hour per day) and associated facial flushing. This caused parental anxiety and concern, particularly about baby F's excessive crying.

DIAGNOSIS AND MANAGEMENT

Baby F was seen by the paediatrician at four weeks old where she was prescribed five drops of probiotic supplements *(L. reuteri)* per day, with aim of improving her colic symptoms. The paediatrician advised that breastfeeding should be prioritised, and feeding advice such as ensuring an adequate postural position during feeding and trialling abdominal massage was recommended. A mild improvement in symptoms was reported following these measures.

At 37 days old, baby F's parents believed her intense crying was due to hunger and started to offer her higher volumes of standard infant formula, alongside breast milk (60-90ml after each breastfeed). Following this change, baby F's cramps and irritability worsened, and she developed constipation (taking two to four days to pass soft stool, type 6 on the Bristol Stool Chart[1]).

At six weeks old, a diagnosis of a functional gastrointestinal disorder (FGID) was made based on baby F's medical history and a physical examination. No diagnostic tests were performed. Severe organic pathology was ruled out as baby F had a good appearance, a normal abdominal examination, and adequate weight gain. Following this diagnosis, baby F's parents were advised to supplement breastmilk with the **comfort formula*** instead of standard infant formula, which they agreed with. The short-term aim of this switch was to improve baby F's colic and constipation symptoms, and long-term was to ensure Baby F maintained optimal nutritional intake and weight gain.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

DIAGNOSIS AND MANAGEMENT *continued*

The switch to **comfort formula** was easy and the formula was well accepted by baby F. Three days following the switch, baby F's parents stopped the probiotic supplements due to the significant symptom improvement. Baby F's cramp resolved within two days of the switch to the **comfort formula** and her crying began improving. Her crying episodes reduced in length and no longer occurred daily; she was a significantly calmer baby. The associated facial flushing also improved. After three days, Baby F's constipation improved and she was passing soft stool without straining, a maximum of one every two days. In less than seven days after the switch to the **comfort formula** her colic and constipation symptoms had fully resolved.

The switch to **comfort formula** also had a positive effect on baby F's parents' quality of life. They reported a drastic reduction in anxiety levels and increased confidence in their parental capacity, especially baby F's mother. The switch also left the paediatrician satisfied.

Baby F will continue to be mixed fed, with breastmilk and this **comfort formula**, until at least six months old, or until baby F's mother wishes to stop breastfeeding. Baby F will continue to be reviewed monthly by the paediatrician.

DISCUSSION

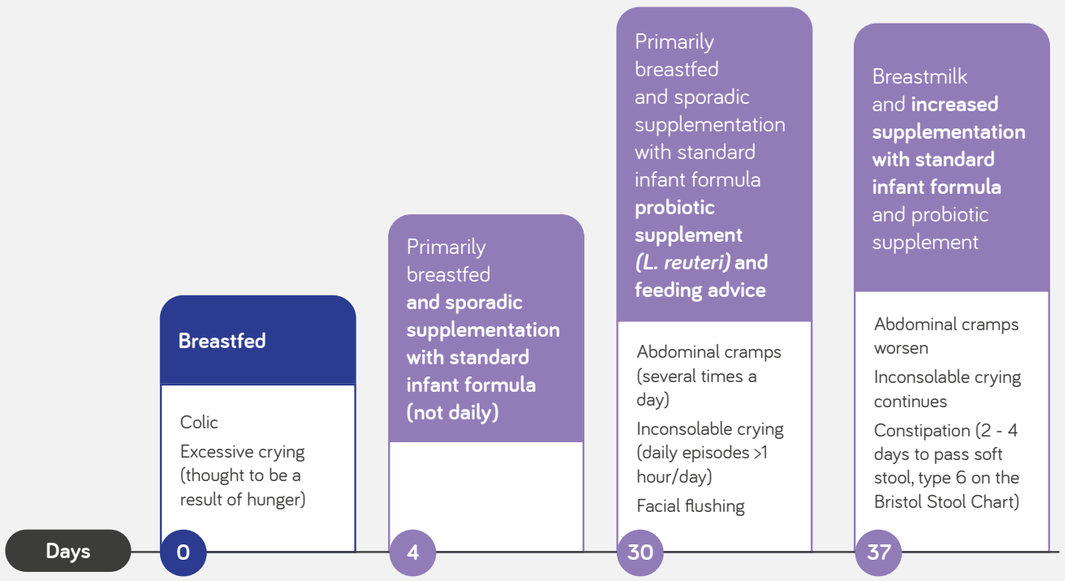
FGIDs should always be considered in an infant with symptoms of excessive crying or irritability where it's accompanied by mild or moderate digestive symptoms, especially in those who are fed with infant formula. There are gastrointestinal (GI) and behavioural hypotheses for the causes of FGIDs development. The GI hypothesis involves the immaturity of the gut function, dysmotility, imbalance of the intestinal microbiota, changes in gut hormones and food hypersensitivities or allergies. The first-line management of common FGIDs should focus on parental education, reassurance, and nutritional advice, while special infant formulas may be considered for non-breastfed infants with common FGIDs[2]. A special formula with a partial hydrolysis of cow's milk proteins and a low lactose content (e.g. comfort formula) can provide a clinical benefit to the GI symptoms.

The main lesson from this case is that the excessive crying of a healthy infant should not be underestimated, as it can sometimes be the sign of a GI disorder. Although the GI disorder may not be serious, it can cause great concern for parents and discomfort for infants, and there are effective, accessible, and safe therapeutic measures to treat it.

> *"My daughter's constipation and colic have resolved with the comfort formula change. She is now calm during the day and has no trouble passing stools"*

Case study continues on the next page.

TIMELINE



CONCLUSION

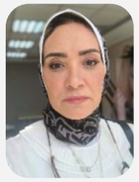
In this mixed fed infant, the switch from a standard infant formula to the comfort formula resulted in a significant improvement of her colic and a full resolution of her constipation and cramp in less than seven days. The comfort formula was well accepted by baby F and the switch positively impacted the family's quality of life, namely reducing her mother's anxiety.

1. Lewis S, Heaton K. Stool Form Scale as a Useful Guide to Intestinal Transit Time. Scandinavian Journal of Gastroenterology. 1997;32(9):920-924.
2. Salvatore, S., Abkari, A., Cai, W., Catto-Smith, A., Cruchet, S., Gottrand, F., Hegar, B., Lifschitz, C., Ludwig, T., Shah, N., Staiano, A., Szajewska, H., Treepongkaruna, S. and Vandenplas, Y. (2018). Review shows that parental reassurance and nutritional advice help to optimise the management of functional gastrointestinal disorders in infants. Acta Paediatr, 107: 1512-1520. https://doi.org/10.1111/apa.14378

Please find the Bristol Stool Chart scale on the last page of the booklet.

BABY G

EXCLUSIVELY FORMULA FED INFANT WITH COLIC AND CONSTIPATION



Dr Nevine Ahmed El Kabbany
Paediatrician
Medicine-WellCare Hospital, Dubai

PATIENT PROFILE

Infant on an amino acid infant formula saw a full and fast resolution in colic and constipation symptoms following a switch to a comfort formula*. The switch also resulted in an improved quality of life for the whole family.

BACKGROUND

Baby G was born at full term (38 weeks) via spontaneous vaginal delivery to a mother with hypothyroidism. Baby G was his parents' third baby, and he was born into a well-educated and financially stable upper middle-class family. Baby G was mixed fed from birth with a standard infant formula. At ten days old, breastfeeding was stopped due baby G's mother's poor milk supply; her medication for hypothyroidism may have had an impact on her milk supply. Therefore, his mother switched to feeding baby G exclusively with a goat milk infant formula. Following this switch, at two weeks old, baby G developed colic like symptoms, he was crying as if in pain and was generally unsettled (mainly in the evenings). Baby G also developed regurgitation, experiencing two to three episodes per day (~5ml of milk), and he was passing hard and bloody stools. After around three days on the goat milk infant formula, his parents switched to a hypoallergenic, amino acid infant formula as cow's milk allergy (CMA) was suspected. Baby G struggled to take the amino acid infant formula but was growing normally. At this stage, his parents also commenced a daily probiotic supplement (BioGaia drops) in an attempt to alleviate the colic symptoms, and simethicone (Pediacol).

Around four weeks old, baby G's colic was at its worst, lasting for approximately three hours per day (30-50 minutes per episode). Baby G was passing hard stool (type one on the Bristol Stool Chart[1]), accompanied by straining. Baby G's mother also reported two episodes of small, hard, bloody stools. Baby G was unsettled at night and was only sleeping one hour at a time during the day. He was also experiencing bloating at least twice a day with an associated flushed face and had foul-smelling wind.

DIAGNOSIS AND MANAGEMENT

Baby G was first seen by the paediatrician at four weeks old, presenting with a history of generalised discomfort. At this appointment, baby G's parents appeared anxious and worried about their child's symptoms; his mother was concerned that the infant formula was causing his symptoms and felt the milk was not suitable for him. His mother also felt guilty for not breastfeeding him. At this initial appointment, reassurance was provided along with first line advice for strategies to manage baby G's symptoms. These strategies included the use of white noise, battery operated swings for soothing, and warm massage. The paediatrician also advised baby G's parents to feed on demand, hold baby G in an upright position and maintain eye contact with him during feeds. They discussed methods to stimulate the rooting reflex, to pace feeding and to read the baby's cues to stop feeding (i.e. when he indicates he's had enough). Advice was also given to change the type of teat on the bottle to regulate the flow of milk from the bottle. At this stage, the paediatrician requested a stool test (faecal calprotectin and a faecal occult blood test). The results indicated some malabsorption of lactose and therefore a possible transient lactase enzyme deficiency. Regurgitation ceased; the regurgitation was due to overfeeding therefore once this was corrected, it fully resolved.

Baby G was seen again by the paediatrician at five weeks old. Given that the amino acid infant formula failed to resolve his symptoms after two weeks elimination, CMA was ruled out. Given that baby G's symptoms were persisting, the paediatrician discussed alternative formulas with baby G's parents. Together the decision was made to switch onto the **comfort formula***. The short-term aim was to relieve baby G's symptoms of colic and constipation, and long term to provide baby G was a nutritionally complete formula to aid optimal growth and development.

Baby G was gradually transitioned over three days from the amino acid infant formula to the **comfort formula**. The **comfort formula** was well tolerated, and baby G took to the formula quickly and easily. The probiotic drops were stopped at this stage and the simethicone was continued. Two to three days following the switch to the **comfort formula** his stools became softer and after ten days, baby G was passing stools every other day. Baby G was seen again at six weeks and was tolerating his full **comfort formula** feeds and the simethicone was stopped. After ten days, baby G's colic symptoms improved, becoming much milder and occurring only in the day. His crying episodes and duration also gradually decreased (from three hours per day to 20 minutes occasionally), with a significant improvement seen after two weeks. His sleep was improved after three weeks and after four weeks, his episodes of excessive, foul-smelling wind ceased.

A repeat stool test was requested at eight weeks old, and the results showed a marked improvement. Baby G was seen again at ten weeks old and advised to continue with the **comfort formula**.

DISCUSSION

It is important to consider all differential diagnoses prior to deciding on management strategies. In this case, the initial management at ten days old was based on excluding cow's milk protein, due to suspected CMA, however, it was important to rechallenge dairy before confirming this diagnosis. In this case, baby G wasn't diagnosed with CMA.

For baby G, the comfort formula was deemed to be the most appropriate formula given its properties including prebiotics, optimal galacto-oligosaccharides:fructo-oligosaccharides ratio, reduced lactose, and the evidence of its benefit in functional gastrointestinal disorders.

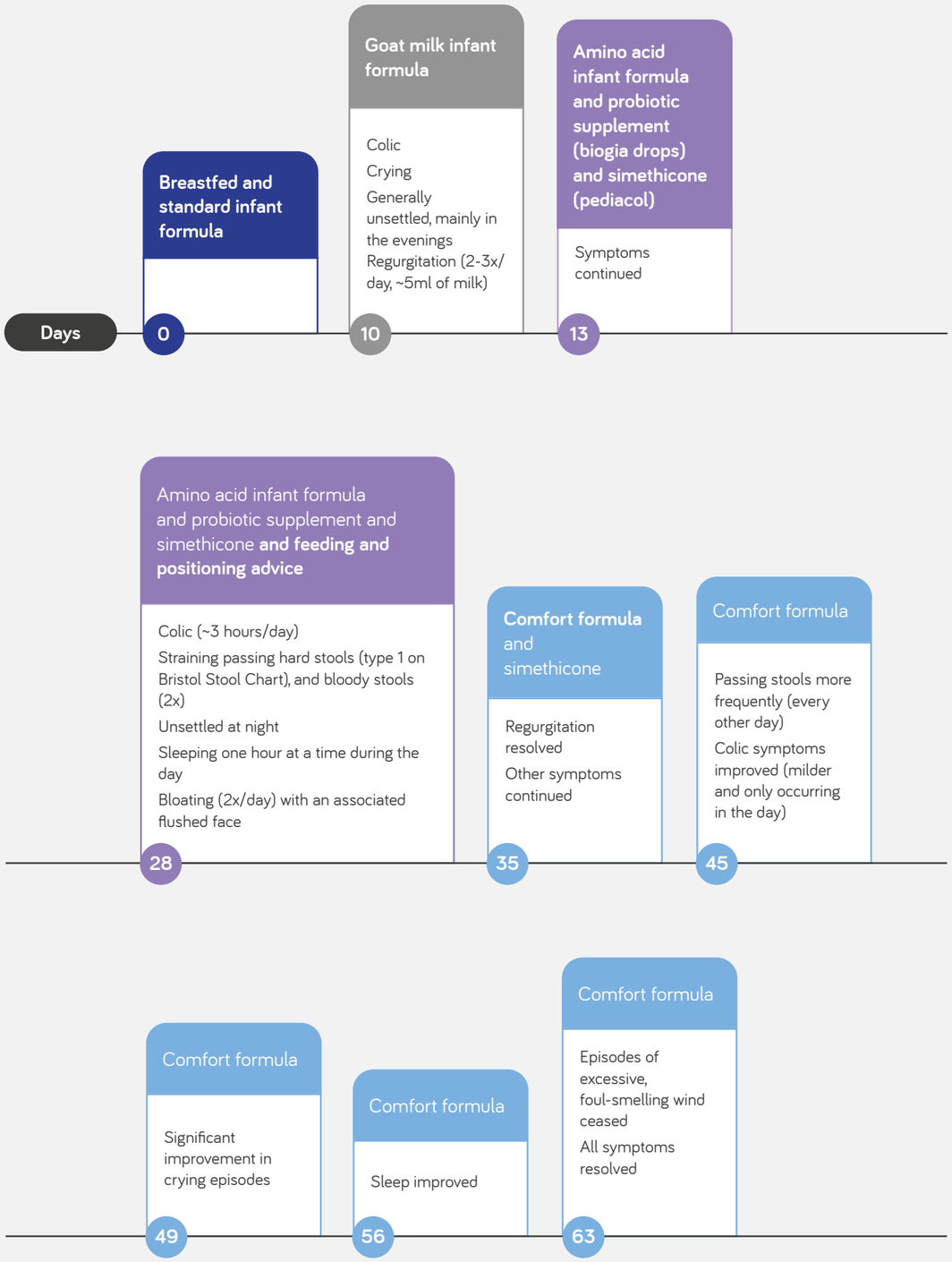
The paediatrician felt the use of the comfort formula was highly effective and in line with their expectations. Baby G's parents were also very satisfied and relieved following the switch to the comfort formula.

The comfort formula was highly effective and in line with the paediatricians' expectations. It also left the parents feeling relieved.

Case study continues on the next page.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

TIMELINE



CONCLUSION

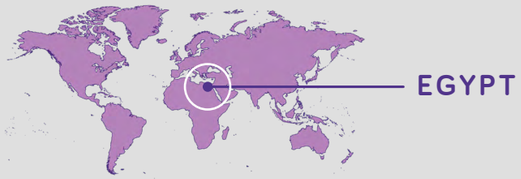
The introduction of comfort formula was shown to be highly effective in managing baby G's symptoms, with full symptom resolution four weeks after starting the formula. Baby G's parents were very happy and relieved with the results, and the whole family's quality of life was improved as a result of the switch.

1. Lewis S, Heaton K. Stool Form Scale as a Useful Guide to Intestinal Transit Time. Scandinavian Journal of Gastroenterology. 1997;32(9):920-924

Please find the Bristol Stool Chart scale on the last page of the booklet.

BABY H

INFANT WITH MULTIPLE GASTROINTESTINAL SYMPTOMS ON STANDARD INFANT FORMULA



Moustafa Abdel-Aziz El-Hodhod
Paediatrician, Professor of Paediatrics
Ain Shams University, Cairo

PATIENT PROFILE

Infant with colic, constipation, bloating, and regurgitation experienced a significant improvement in her symptoms after two weeks, following a switch from lactose free formula to the comfort formula*.

BACKGROUND

Baby H was born at full term by elective caesarean section, weighing 3.1kg. She was breastfed from birth. At 15 days old, mixed feeding was commenced with a standard infant formula following the primary care doctor's recommendation, due to concerns about inadequate weight gain (see growth chart). Following this switch, baby H developed mild colic and associated mild regurgitation and significant sleep deprivation.

At 30 days old, baby H was switched exclusively to formula feeding with a standard infant formula as her mother was no longer able to produce breastmilk. In addition, herbal-based remedies were introduced. However, following the switch, baby H's symptoms worsened to severe colic occurring in one-hour bouts seven to ten times daily, mainly between 9pm-5am, and during her colic bouts baby H refused feeding. At this stage, baby H also started experiencing bloating and constipation (passing hard stool with difficulty every four days) and refusing her food. Baby H was followed up in primary care every two weeks, with the aim of improving her symptoms. At 36 days old and three weeks after the onset of colic, baby H begun passing foul smelling wind and developed perianal dermatitis.

At 45 days old, baby H was started on an anti-reflux formula and prescribed Gaviscon (alginates) as her regurgitation had increased to seven times a day. This change improved baby H's regurgitation but her colic and constipation worsened.

At 60 days old, the herbal remedies were discontinued as they were considered ineffective by the primary care doctor. At this point, laxatives (lactulose) were introduced to treat her constipation. Over the next seven days, baby H's stools softened. However, she was passing stools infrequently (every three days) and with significant straining. She also had an increase in flatulence. For this reason, her mother discontinued the lactulose after one week. This resulted in baby H passing harder stools once again.

At 75 days old, baby H was switched onto a lactose free formula along with lactase drops with the aim of combatting her excess flatulence and distension; baby H's flatulence decreased following the switch but her colic and constipation worsened.

*Comfort formula with Beta-palmitate, partially hydrolysed protein, prebiotic oligosaccharides scGOS/lcFOS 9:1 and reduced lactose.

DIAGNOSIS AND MANAGEMENT

At 90 days old, baby H was first seen by the paediatrician and was diagnosed with multiple functional gastrointestinal disorders (FGIDs) (infant colic, constipation, and regurgitation) as per the Rome IV criteria[1]. She was thought to be mildly underweight largely due to her feeding refusal. Baby H's parents were concerned that she may have a serious underlying condition and were both evidently low in mood and severely sleep deprived. Baby H's mother was also feeling guilty for not being able to breastfeed.

Given that multiple gastrointestinal disorders were present, it was thought that isolated solutions wouldn't be sufficient, and the **comfort formula*** was commenced on the first visit to the paediatrician. The alginates were also stopped at this appointment and routine advice regarding the preparation of feeds and bottle care was given. The **comfort formula** was well accepted by Baby H.

After seven days on the **comfort formula**, there was a noticeable improvement in Baby H's colic, constipation, bloating and flatulence, with almost full resolution after two weeks. Baby H's regurgitation also became infrequent. She was reviewed again at 120 days old and was advised to continue with the **comfort formula**, no medications were required. At this stage, her colic and crying were minimal, her perianal dermatitis had resolved, and she was passing soft stool daily. Her growth had also improved (see growth chart).

Baby H was followed up at 135 days old. Advice was given to continue with the **comfort formula** for a year.
At this appointment, Baby H was reported to be sleeping well and her parents' low mood was improved. Routine follow ups were offered by the paediatrician every two months, following her symptom resolution, as is standard practice.

The use of the **comfort formula** resulted in the full resolution of baby H's gastrointestinal symptoms. Baby H's parents were satisfied with the intervention and the paediatrician was very pleased to see her mothers' mood improve.

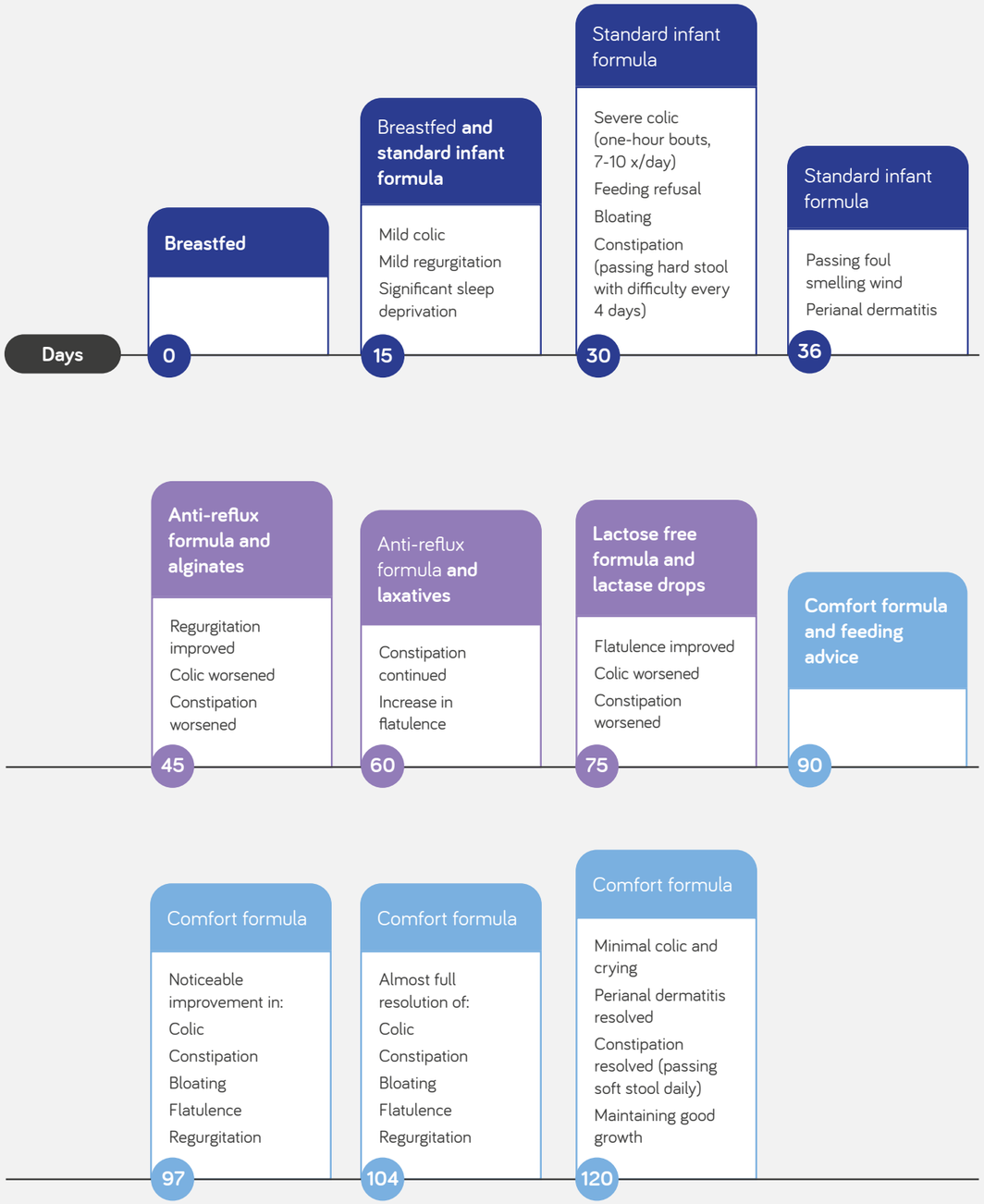
> *"Baby H's parents were satisfied with the comfort formula and the paediatrician was very pleased to see her mothers' mood improve. "I am a happy mother"*

DISCUSSION

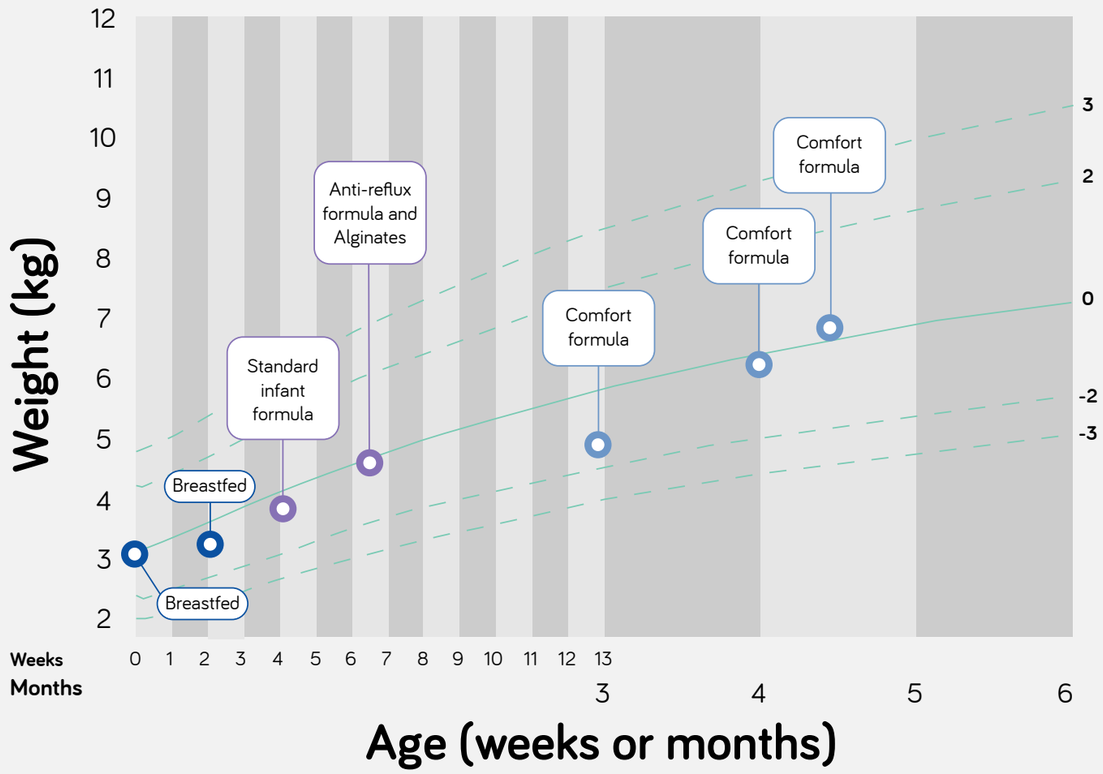
Complex FGIDs are not uncommon in paediatric practice. It has been proposed that nutritional management is the cornerstone in the management of FGIDs in infants[1,2]. The isolated management of each separate symptom is impossible in complex states. So, the comfort formula was chosen in this case to reverse this complexity. This comfort formula contains partially hydrolysed protein (to enhance digestion[3]), beta palmitate (reducing saponification, constipation, and calorie loss[4]), low lactose levels (reducing flatulence and abdominal discomfort[5]) and has a laxative effect. Importantly, it also contains prebiotic galacto- and fructo- oligosaccharides. Prebiotic health effects include gut microbiome modulation and immune stimulation[6].

Case study continues on the next page.

TIMELINE



GROWTH CHART



Based on WHO Growth Chart Weight-for-age girls, birth to six months (z-scores)[7]

CONCLUSION

The switch to the comfort formula significantly improved baby H's multiple functional gastrointestinal symptoms and consequently improved the whole family's quality of life. The switch also improved Baby H's sleep and her growth, and left her parents satisfied.

1. Zeevenhooven J, Koppen IJN, Benninga MA. The New Rome IV Criteria for Functional Gastrointestinal Disorders in Infants and Toddlers. Pediatr Gastroenterol Hepatol Nutr 2017 March;20(1):1-13.
2. Vandenplas Y, Hauser B, Salvatore S. Functional Gastrointestinal Disorders in Infancy: Impact on the Health of the Infant and Family. Pediatr Gastroenterol Hepatol Nutr. 2019 May;22(3):207-216. doi: 10.5223/pghn.2019.22.3.207.
3. Tolia V et al. J Pediatr Gastroenterol Nutr. 1992;15(3):297–301.
4. Havlicekova Z et al. Nutr J. 2016;15:28.
5. Kanabar D, Randhawa M, Clayton P. Improvement of symptoms in infant colic following reduction of lactose load with lactase. J Hum Nutr Diet. 2001 Oct;14(5):359-63. doi: 10.1046/j.1365-277x.2001.00304.x. Erratum in: J Hum Nutr Diet. 2007 Oct;20(5):509.
6. Gibson GR, Hutkins R, Sanders ME, Prescott SL, Reimer RA, Salminen SJ, et al. Expert consensus document: The International Scientific Association for Probiotics and Prebiotics (ISAPP) consensus statement on the definition and scope of prebiotics. Nat Rev Gastroenterol Hepatol. 2017 June; 14:491-502.
7. WHO. WHO Growth Standards: https://cdn.who.int/media/docs/default-source/child-growth/child-growth-standards/indicators/weight-for-age/cht-wfa-girls-z-0-6.pdf?sfvrsn=261b5150_12 (Accessed date: 27/2/2023)

ANTI-REGURGITATION (AR) FORMULA CASE STUDIES

BABY I

EXCLUSIVELY FORMULA FED INFANT WITH GASTROESOPHAGEAL REFLUX

Health Visitor*
Independent Practitioner, United Kingdom (UK)

*This case has been anonymised for confidentiality purposes

PATIENT PROFILE

Infant with reflux who had unsuccessful treatment with medication and feeding advice, saw progressive improvements in his reflux symptoms after two weeks following a switch to the anti-regurgitation (AR) formula with Carob Bean Gum (CBG)*, resulting in full symptom resolution after six weeks.

BACKGROUND

Baby I was born at 40 weeks and five days by emergency caesarean section due to poor progression in labour. His birth weight was 4.4kg (91st centile) and he was discharged from hospital at one day old with no concerns. Baby I was breastfed for the first two days of life before switching to standard infant formula due to his mother's concerns about producing enough breastmilk.

At 12 days old, the health visitor visited baby I, as per the Healthy Child Programme protocol. Baby I presented as a large, well-nourished and hydrated baby, and his parents had no concerns regarding his health.

Baby I continued with standard infant formula (120-175ml responsively at each feed) with no symptoms until four weeks old. However, at four weeks old, baby I developed reflux symptoms, regurgitating small volumes around 30 minutes after every feed (eight times per day, Adapted Vandenplas Score 4[1]). Baby I was also making gulping sounds, had frequent hiccups and was arching his back and crying during and in between feeds (12 times per day). His parents were sleep deprived and felt stressed and anxious. Baby I was also very distressed and had unsettled sleep. Given baby I's symptoms, his mother switched into a hungry infant formula (casein dominant formula), without advice from a healthcare professional.

DIAGNOSIS AND MANAGEMENT

Around five weeks old, baby I's mother took him to see the general practitioner (GP) due to his reflux symptoms. The GP undertook a physical examination which didn't highlight any abnormalities. Based on his symptom history, baby I was diagnosed with moderately severe gastroesophageal reflux. The GP prescribed antacids (one sachet of Gaviscon) following every feed, totalling a maximum of eight sachets in 24 hours (therefore, four feeds without antacids as baby I was fed 12 times per day). Following the introduction of antacids, baby I's stool habits changed from soft and mustard yellow colour stools passed at least once per day to more formed 'rabbit pellets' (type one on the Bristol Stool Form Scale[2]) every other day.

Following the GP consultation, baby I's parents telephoned the health visitor as baby I's symptoms continued to persist. The health visitor discussed NICE guidelines[3] for reflux and advised trialling smaller and more frequent meals, feeding baby I in an upright position, winding regularly during feeding, and keeping baby I upright for 30 minutes following feeds, before laying him flat on his back. It was also advised to consider a change of teats.

*AR formula with carob bean gum, prebiotics scGOS/lcFOS (9:1) and postbiotics derived from the Lactofidus™ fermentation

DIAGNOSIS AND MANAGEMENT *continued*

At six weeks old, baby I had a review consultation with the health visitor. There were no concerns with his weight or growth; his development was age-appropriate and his measurements were in proportion. Overfeeding was ruled out. However, baby I's symptoms had not improved, despite implementing the health visitor's advice. Baby I was advised to trial an **AR formula with CBG***, in accordance with the NICE guidelines for reflux; his parents had already researched this formula. They were also advised to feed responsively, use a fast flow single hole teat, and to discontinue the antacids. The aim of trialling the **AR formula** was to prevent baby I's regurgitation, back arching and crying during and in between feeds, as well as alleviating parental anxiety and stress. Baby I tolerated the **AR formula** well and there were no concerns regarding palatability or acceptance.

At eight weeks old, baby I was followed-up by the health visitor. Baby I's reflux symptoms had greatly improved since the switch to the **AR Formula**; his regurgitating episodes reduced to approximately five times per day (Adapted Vandenplas score 2[1]). His back arching and crying had also reduced to five times per day, he was no longer gulping or having hiccups and he had more settled sleep. At eight weeks old baby I passed a normal daily stool of soft consistency.

At ten weeks old, baby I's parents had a telephone consultation with the health visitor. They reported further improvements in his symptoms. Baby I was only having three to five episodes of regurgitation (small volumes) per day, three to five episodes of crying and was no longer arching his back (Adapted Vandenplas Score 1[1]). By 12 weeks old his symptoms had resolved and crying episodes had reduced further to zero to two episodes per day (Adapted Vandenplas score 0[1]). Baby I is planned to continue with the **AR Formula** until his next review at 16 weeks old.

DISCUSSION

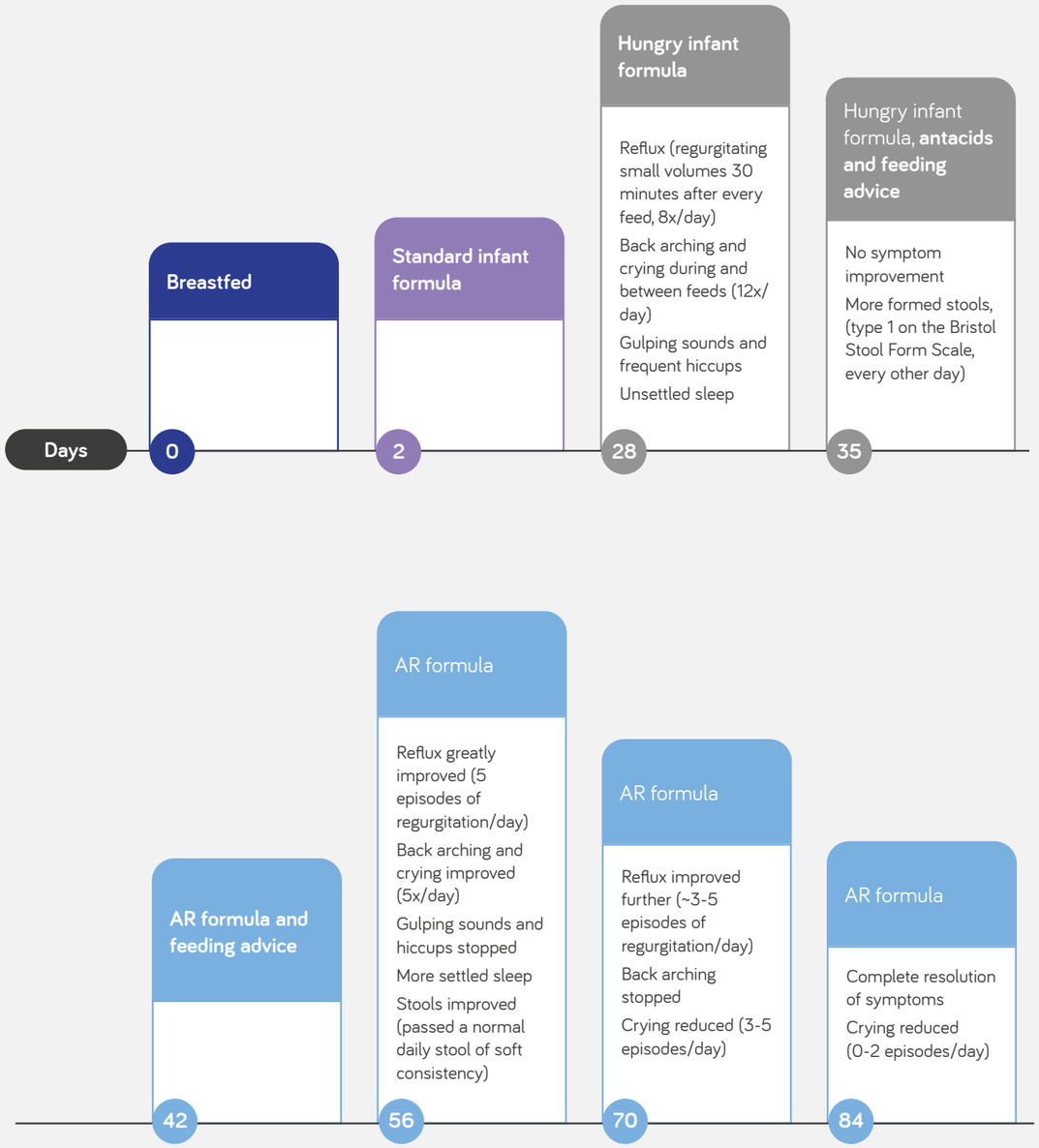
Reflux is a normal physiological event, whereas reflux disease (i.e. gastro oesophageal reflux disease; GORD) occurs when symptoms are severe enough to warrant medical intervention or when there are associated health complications. In infants, it is particularly difficult to differentiate between the two scenarios due to wide variations in reported symptoms and the lack of a simple and reliable diagnostic test. The true burden of the problem is therefore difficult to quantify, and it is accepted that clinical practice varies greatly[3].

In this case, the AR formula was recommended because it's indicated for the dietary management of reflux. It contains CBG which resists digestion and acts as a thickener resulting in a high viscosity gel-like substance when it reaches the gut (compared to starch-based formulae) and promotes a balanced oesophageal pH[4] and therefore expected to be a more effective thickener. In addition, the AR formula contains prebiotics (galactooligosaccharides and fructooligosaccharides) and postbiotics (derived from the Lactofidus™ fermentation process). Baby I's symptoms of reflux were improved by a combination of the AR formula and feeding strategies.

> *I am happy that baby I is settled now and I am sleeping more"*
> *- Father*
>
> *I am less anxious and glad that we persevered with the feeding regime"*
> *- Mother*

Case study continues on the next page.

TIMELINE



CONCLUSION

In this infant with moderately severe reflux, a switch to AR formula resulted into an improvement of symptoms after two weeks and effectively resolved his symptoms after six weeks. Baby I appeared more content. His parents reported less anxiety and stress, and felt more confident in caring for baby I. The intervention was considered effective by the health visitor.

1. Dupont C, Vandenplas Y. Pediatr Gastroenterol Hepatol Nutr. 2016;19:104–9.
2. Lewis S, Heaton K. Stool Form Scale as a Useful Guide to Intestinal Transit Time. Scandinavian Journal of Gastroenterology. 1997;32(9):920-924.
3. Davies et al. Gastro-oesophageal reflux disease in children: NICE guidelines. BMJ. 2015;350:g7703.
4. Salvatore S, Savino F, Singendonk M, et al. Thickened infant formula: What to know. Nutrition. 2018;49:51-56.

Please find Bristol Stool Chart and Adapted Vandenplas Score scales on the last page of the booklet.

BABY J

INFANT WITH PRIMARY GASTROESOPHAGEAL REFLUX, CRYING AND FALTERING GROWTH

Omar Tabacco
Paediatric Gastroenterologist
Sanatorio de Niños, Rosario, Argentina

PATIENT PROFILE

Infant with gastroesophageal reflux (GER) and faltering growth saw improvement of all symptoms after ten days and a full symptom resolution in 30 days following a switch in formula to the anti-regurgitation (AR) formula with Carob Bean Gum (CBG)*.

BACKGROUND

Baby J was delivered by caesarean section and breastfed until he was seven days old. At seven days old, the paediatrician advised baby J switch from breastfeeding to a standard infant formula due to concerns around his growth (failure to thrive) and low quantity of breastmilk. Following this switch to the standard infant formula, in his second week of life, baby J presented with symptoms including vomiting (regurgitation), continuous crying, irritability, abdominal pain, failure to thrive and disturbed sleep. His family were very concerned and distressed.

Baby J's main symptom was continuous regurgitation/vomiting (small volumes, less than 30 minutes after each feed, no bilious vomiting). Baby J was also irritable, which appeared to somewhat improve after regurgitation, and would sometimes refuse food, only eating very small amounts. His parents reported continuous crying (colic) for five to six hours per day which appeared to be unrelated to the time of day or feeding. Baby J also had faltering growth; his weight gain was lower than expected for his height.

DIAGNOSIS AND MANAGEMENT

At 30 days old, baby J's symptoms of regurgitation and continuous crying continued to persist. Baby J was switched to an extensively hydrolysed formula with probiotics and prescribed proton pump inhibitors (PPIs) (omeprazole) as cow's milk allergy (CMA) was suspected. These methods were both unsuccessful in resolving baby J's symptoms.

Around 40 days old, baby J had his first consultation with the paediatric gastroenterologist. Baby J had faltering growth; he'd only gained 550g and according to the 50th height percentile, he should have gained 1200g. The suspected primary cause of his symptoms was gastroesophageal reflux (GER) after unsuccessful management with an extensively hydrolysed and vomiting being the main symptom. Baby J was prescribed **AR formula with CBG*** by the paediatric gastroenterologist and his PPIs were stopped as no improvement in symptoms was observed.

This **AR formula** was recommended because of its texture and pre- and postbiotic content. The aim was to alleviate his symptoms by improving formula feeding tolerance, reducing regurgitation and discomfort, and allowing baby J to reach his nutritional requirements. The **AR formula with CBG,** pre- and postbiotic was also recommended to improve baby J's gut microbiome composition.

*AR formula with carob bean gum, prebiotics scGOS/lcFOS (9:1) and postbiotics derived from the Lactofidus™ fermentation

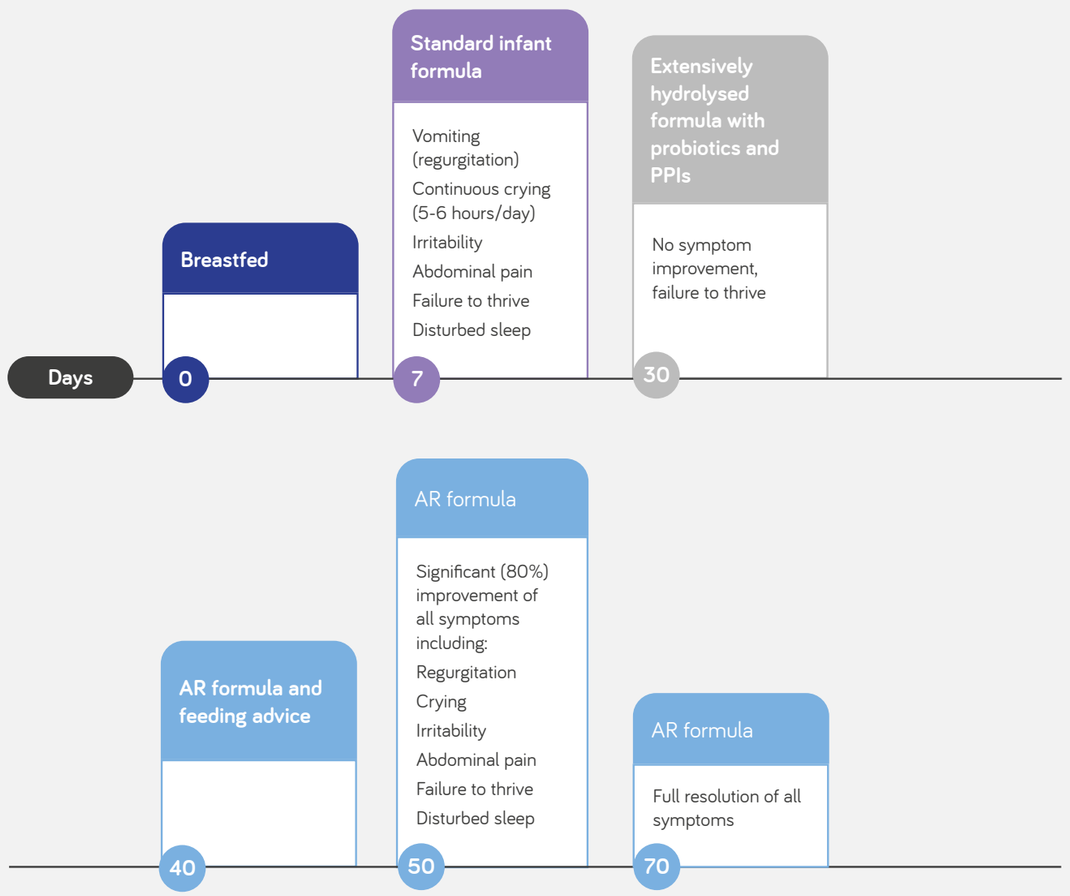
DIAGNOSIS AND MANAGEMENT *continued*

The introduction of the **AR formula** was reported to be very easy and was readily accepted by baby J. Baby J's parents were advised to feed him seven times per day (25mls per kg/feed), and baby J managed the full volume. His parents were also given advice and guidance on the feeding positioning, frequency of feeding, burping and sleeping position.

In the first 10 days after the introduction of the **AR formula**, baby J's regurgitation improved 80% based on the adapted Vandenplas score[1]. All his other symptoms, including the crying and unsettled sleep, also significantly improved to the same level, and 30 days after the introduction of the **AR formula**, his symptoms had fully resolved.

At 90 days old, the number of feeds reduced to six times per day (30mls per kg/feed) and baby J continued to achieve his target volume. At six months old, complementary feeding commenced and no change in symptoms was observed. Baby J was switched to standard infant formula at nine months old and the paediatric gastroenterologist continued to see him once a month for the first year of life.

TIMELINE



Case study continues on the next page.

DISCUSSION

The AR formula enabled the rapid and full resolution of all of baby J's symptoms. Baby J's family were fully satisfied with the formula and very happy as their child was growing up feeling well and calm.

Non-specific symptoms (such as regurgitation, continuous crying, food refusal and colic) present a clinical challenge in the patients' first months of life. After unsuccessful treatment with an extensively hydrolysed formula, approaching GER with a thickened formula should be considered the most appropriate initial treatment. Close monitoring will prevent the use of unnecessary pharmacological therapy[2].

Baby J's symptoms fully resolved after commencing the AR formula. Baby J's symptom relief also improved his parents' sleep and reduced their distress

CONCLUSION

In this exclusively formula fed infant, the switch from a hydrolysed formula to the AR formula was successful. Baby J's symptoms such as reflux and crying fully resolved after commencing the AR formula. Baby J's symptom relief, as a result of the formula switch, also improved his parents' sleep and reduced their distress. No further investigations or pharmacological therapy were required. The family and healthcare professional were fully satisfied with the clinical outcome.

1. Dupont C, Vandenplas Y, SONAR Study Group. Efficacy and Tolerance of a New Anti-Regurgitation Formula. Pediatric Gastroenterology, Hepatology & Nutrition. 2016 Jun;19:104-9.
2. Rosen R, Vandenplas Y, Singendonk M, Cabana M, DiLorenzo C, Gottrand F, Gupta S, Langendam M, Staiano A, Thapar N, Tipnis N, Tabbers M. Pediatric Gastroesophageal Reflux Clinical Practice: Joint Recommendations of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition and the European Society for Pediatric Gastroenterology, Hepatology and Nutrition. Journal of Pediatric Gastroenterology and Nutrition. 2018 Mar; 66:516-554.

Please find the Adapted Vandenplas Score scale on the last page of the booklet.

BABY K

INFANT WITH REFLUX, CRYING AND IRRITABILITY ON STANDARD INFANT FORMULA

Dr Valentina Zattoni
Paediatrician, Private clinic, Trenzano

PATIENT PROFILE

Infant with reflux, crying and irritability saw an improvement in all her symptoms after three weeks following a switch from standard infant formula to anti-regurgitation (AR) formula with Carob Bean Gum (CBG)*.

BACKGROUND

Baby K was born via normal delivery at 39 weeks and three days, weighing 2.8kg. Baby K's mother had an uncomplicated pregnancy. Baby K was breastfed until seven days old before being exclusively fed with standard infant formula as her mother was anxious and fearful that baby K would be underfed.

At ten days old, baby K began to show signs of irritability, particularly after feeding. Baby K would arch her back (one to two times per day) and often cry after each feed, as well as presenting with colic in the evening after feeding (one episode daily, for 30-60 minutes). Due to her crying, baby K had difficulty sleeping. Despite her symptoms, her growth was regular.

DIAGNOSIS AND MANAGEMENT

At 14 days old baby K's mother had a telephone call with the paediatrician. In an attempt to reduce baby K's irritability and crying after feeding, an anti-reflux syrup was recommended (Magnesium Alginate, three ml, four times per day) as per the National Institute for Health and Care Excellence (NICE) guidelines[1]. No significant improvement in her symptoms was seen. The paediatrician attempted to get baby K to stop taking anti-reflux syrup, however, baby K's mother continued because of the persistent irritability symptoms.

Baby K was visited by the paediatrician at 24 days old. Although baby K was healthy, she was very hungry; she finished feeding in a couple of minutes, after which she would cry. Based on her symptoms, reflux was suspected. The paediatrician advised a switch to a thickened formula with the aim of lengthening the time of baby K's feed and alleviating her reflux symptoms. Therefore, an **AR formula with CBG*** was commenced. Alongside the change in formula, the paediatrician advised to slightly reduce the volume of feed and recommended that baby K was kept in an anti-reflux position during and after feeding (i.e. holding her upright) and whilst sleeping (i.e. on her back).

The **AR formula** was accepted well by baby K. For the first three weeks following the switch to the **AR formula** baby K's crying continued, particularly after her evening feed. However, gradually her crying reduced and at three months and ten days old baby K's crying was markedly improved and almost completely resolved (two to three crying episodes a week). Baby K presented with constipation however this was transient and resolved naturally after two weeks. Baby K's other symptoms such as back arching and irritability began to improve three to four weeks following the switch to the **AR formula**. Baby K's sleep also improved, which improved her parent's sleep quality.

*AR formula with carob bean gum, prebiotics scGOS/lcFOS (9:1) and postbiotics derived from the Lactofidus™ fermentation

DIAGNOSIS AND MANAGEMENT *continued*

Baby K continued to use anti-reflux syrup in combination with the **AR formula**. The anti-reflux syrup was then gradually reduced, and at four months and 18 days old it was stopped completely; the **AR formula** alone was sufficient in managing Baby K's symptoms. When baby K was reviewed at six months and five days old, she was switched onto a standard follow-on formula due to her age. However, baby K's crying recommenced with the follow-on formula, so she was switched back to the **AR formula.**

DISCUSSION

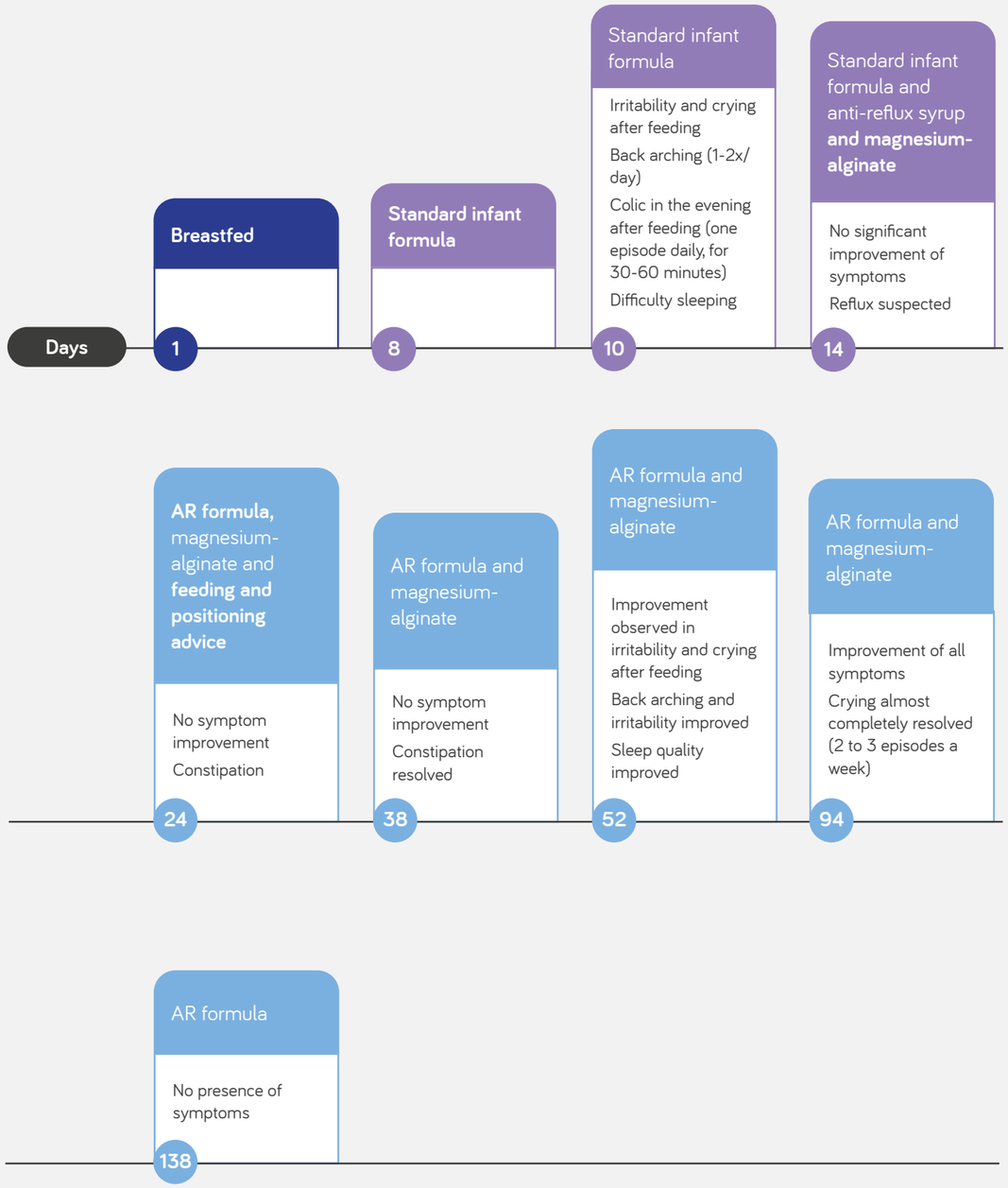
In this case, the AR formula was recommended by the paediatrician to manage baby K's reflux symptoms because it contains prebiotics and CBG. It was also chosen based on the paediatrician's clinical experience, as she found thickened formula often causes constipation, especially in the first days of life, but found that the use of the AR formula resulted in less constipation in infants. The presence of prebiotic galacto- and fructo-oligosaccharides (GOS/FOS) also played a role in the decision.

The main lesson from this case study is to listen clearly to what the infant's parents are reporting. Baby K experienced no vomiting or regurgitation and there were no concerns with her weight. However, baby K showed signs of pain, including back arching and crying, after feeding which led to reflux being suspected.

Following the switch to the AR formula, baby K's crying, irritability and back arching gradually reduced and were markedly improved. Baby K and her parents also all had improved sleep quality

Case study continues on the next page.

TIMELINE



FEEDING REGIMEN

AGE (DAYS)	FEED	NUMBER OF FEEDS PER DAY	TARGET VOLUME PER FEED (ML)	% OF TARGET VOLUMES ACHIEVED PER FEED
1	Breastmilk	On request		
7	Standard infant formula	7	90	100%
24	AR formula	6	120	100%
45	AR formula	6	120	100%
66	AR formula	5	150	100%
100	AR formula	5	150 x 3 + 180 x 2	100%
138	AR formula	5	180	100%

CONCLUSION

The use of the AR formula in this infant with suspected reflux left the paediatrician satisfied. Following the switch to the AR formula, baby K's crying, irritability and back arching gradually reduced and were markedly improved by three months and ten days old. Baby K and her parents also had improved sleep quality following the switch.

1. National Institute for Health and Care Excellence (NICE). Gastro-oesophageal reflux disease in children and young people: diagnosis and management. NICE guideline [NG1]. 2015 Jan. https://www.nice.org.uk/guidance/ng1/chapter/1-Recommendations#pharmacological-treatment-of-gord [Accessed December 2022].

Bristol Stool Chart and Adapted Vandenplas Scores scales

1. **Adapted Vandenplas score:** 0: 0-2 regurgitation episodes/day; 1: ≥3-≤5 episodes of small volume; 2: >5 episodes of >1 coffee spoon; 3 :>5 episodes of ±half of feedings in <half of the feedings; 4: Continuous regurgitation of small volumes >30 minutes after each feeding; 5: Regurgitation of half to complete volume of a feeding in at least half of the feedings; 6: Regurgitation of the “complete feeding” after each feeding.

2. **Bristol Stool Chart:**

	TYPE 1	Separate hard lumps	SEVERE CONSTIPATION
	TYPE 2	Lumpy and sausage like	MILD CONSTIPATION
	TYPE 3	A sausage shape with cracks in the surface	NORMAL
	TYPE 4	Like a smooth, soft sausage or snake	NORMAL
	TYPE 5	Soft blobs with clear-cut edges	LACKING FIBRE
	TYPE 6	Mushy consistency with ragged edges	MILD DIARRHOEA
	TYPE 7	Liquid consistency with no solid pieces	SEVERE DIARRHOEA

Adapted from: Cabot Health, Bristol Stool Chart - http://cdn.intechopen.com/pdfs-wm/46082.pdf, CC BY-SA 3.0

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