

Case Series

Evaluation of the safety and efficacy of herby angel tummy roll-on in managing infantile colic: a case series

Ajay Bajpai¹, Swathi Ramamurthy^{2*}, Arpitha C. Rao³

¹Department of Pediatrics, Royal Children Hospital, UP, India

²Research and New Product Development, Herbal Chakra Pvt Ltd., India

³Ayurveda, Herbal Chakra Pvt Ltd., India

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*Correspondence:

Dr. Swathi Ramamurthy,

E-mail: swathi@herbalchakra.in

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ABSTRACT

Infantile colic is a benign condition of the second or third week of life characterized by abdominal discomfort. Infantile colic is characterized by persistent and unconsolable crying in an otherwise healthy and well-fed infant. About 20% of the newborn babies and infants are affected by this condition. This condition distress and challenges caregivers, leading to 10% to 20% of paediatric provider visits during the first few weeks of their lives. Current management options are limited and often involve oral administration which can be challenging for the caregivers. This study evaluated the safety and efficacy of the Herby Angel Tummy Roll-On, a topical treatment containing natural ingredients like Asafoetida, Ajwain, Rock salt, etc., designed to alleviate colic symptoms through a non-invasive approach. Four infants with recurrent colic episodes were monitored over one month, assessing improvements using the FLACC scale and other parameters such as frequency of interruptions, episodes of colic, and skin reactions. Significant improvements in symptoms were observed within a short duration, with no adverse skin reactions. The findings of this study suggest that the product effectively alleviated abdominal distension and pain, leading to a marked reduction in sleep disturbances in infants. It has a positive short-term effect on infantile colic.

Keywords: FLACC scale, Herby angel, Infantile colic, Tummy roll-on

INTRODUCTION

Infantile colic is a benign process in which an infant has bouts of inconsolable crying for >3 hours a day, >3 days a week, and for >3 weeks.¹ It affects ~10% to 40% of infants' lives worldwide, peaking at approximately six weeks, with resolution by three to six months of age.² The incidence is equal between the sexes, and there is no correlation with the type of feeding (breast vs bottle), gestational age, or socioeconomic status. The cause of infantile colic is unknown; proposed causes include alterations in fecal microflora, intolerance to cow's milk protein or lactose, gastrointestinal immaturity or inflammation, increased serotonin secretion, poor feeding technique, and maternal smoking or replacement nicotine

therapy.² Crying associated with infantile colic can cause relationship stress, improper breastfeeding, postpartum depression, excess visits to doctors, and child abuse such as "Shaken baby syndrome".³ Colicky symptoms have been linked to feeding problems and disturbed sleep. Managing infantile colic poses significant challenges due to the limited availability of safe and effective options. Many conventional treatments involve oral administration, which can be difficult for caregivers to manage and may carry risks of side effects or overmedication. Additionally, accessibility to appropriate medications and waiting times for prescriptions can delay effective relief, further distressing both infants and caregivers. Herby angel tummy roll-on was selected for this study to address these challenges because it offers a

safer alternative due to its local application. This non-invasive approach minimizes the risk of systemic side effects. It allows parents to administer the remedy promptly at home, without the need to wait for a doctor's consultation or prescription. The safety of herby angel tummy roll-on was a key component of this trial, as the product was evaluated for any adverse effects when used by infants aged 1 week to 1 year. The safety assessment included monitoring skin reactions, irritations, or other side effects. It is administered whenever the baby experiences abdominal colic, and the study duration was one month.

Etiology

Even though infantile colic was described in the 1950s, the etiology is still unknown. Proposed causes include changes in fecal microflora, intolerance to cow's milk protein or lactose, immaturity or inflammation of the gastrointestinal tract, increased secretion of serotonin, improper feeding technique, and maternal smoking or replacement with nicotine.⁴

Pathophysiology

The episodes of colic have a distinct beginning and an end and happen during the evening. The behavior of the newborn/infant varies between being happy, sleeping, playing, or eating and the exact stimuli of these behaviors are not known. The cry associated with colic is typically louder and more urgent and is at times described as screaming. Less than 10% of infants with excessive and inconsolable crying have an organic cause and standard soothing techniques often do not work. Fortunately, most infants resolve colic spontaneously without any sequelae.⁴ This study aimed to investigate the effects and safety of the herby angel tummy roll-on in soothing infantile colic.

CASE SERIES

The case series includes 4 cases of infantile abdominal colic which was managed with an external application herby angel tummy roll-on for 1 month during the episodes. A specialized self-assessment questionnaire was developed to gather information, including demographic data, clinical presentations, feedback on product usage, no of application times in a day, and observed clinical improvements in symptoms.

Case 1

A 4-month-old male infant of 4.4 kg was brought in by his father with complaints of abdominal pain, loss of appetite, bloating, constipation, and refusal to breastfeed for the past 15 days. The symptoms occurred episodically, 2-3 times per week. According to the father, the baby's face flushed during colic episodes, and he was uncomfortable lying on his abdomen. The baby would cry and draw his legs towards his abdomen, passing stool

only once every 2-3 days. Despite frequent episodes and prior treatment with internal medication from a pediatrician, relief was only symptomatic. The parents sought alternative treatment involving only external applications, avoiding internal medications.

Case 2

A 20-day-old female infant, weighing 2.2 kg, presented with a history of recurrent abdominal colic, excessive sweating, bloating, and refusal to breastfeed over the past five days. These symptoms were accompanied by prolonged crying episodes lasting over three hours daily, predominantly in the late afternoon and evening. During these episodes, the infant often drew her knees to her chest. She was exclusively breastfed.

Case 3

A 4-month-old- male infant, weighing 4.4 kg, was presented with the symptoms of abdominal colic, continuous-intense crying episodes lasting 4-6 hours, occurring 3-4 times daily and disrupting sleep significantly. These episodes have persisted for over two weeks, occurring 3-4 days each week. On inspection, the infant showed signs of discomfort-drawing his leg towards the abdomen while crying and experiencing tenderness upon abdominal palpation. The episodes are accompanied by flushing of the face and warm skin with sweating over the abdomen. The infant has been refusing to breastfeed and appears uncomfortable lying flat, though some comfort is noted when placed on his abdomen. These symptoms have caused considerable distress for both the infant and the family, prompting the need for evaluation and intervention.

Case 4

A 6-month-old female infant, weighing 6.3 kg, presented with symptoms of abdominal colic, characterized by continuous crying episodes lasting 1 to 3 hours. These episodes occur 1 to 2 times daily and have persisted over the past two weeks, disrupting sleep on at least two days per week. During these episodes, the infant's abdomen was soft on palpation, and she displayed signs of discomfort by drawing her legs towards her abdomen while crying. There was noticeable facial flushing and severe perspiration, with skin over the abdomen feeling warm to the touch. She has not refused to breastfeed, lying on her abdomen provided some comfort. The persistent crying and associated symptoms have raised concerns for the parents, prompting further evaluation.

Inclusion criteria

Babies between the age group 1st week to 1 year of either sex. Infants diagnosed with infantile colic as per Rome IV criteria: Recurrent and prolonged periods of infant crying, fussing, or irritability reported by caregivers that occur without any apparent cause and cannot be

prevented or resolved by caregivers. No evidence of infant failure to thrive, fever, or illness. Parental reporting of crying more than 3 hours/day for at least 3 days/week. (Supplemented with a 24-hour diary at baseline). Mothers/caretakers who were literate enough to understand the essence of the study informed about the purpose of the study, and understand their rights.

Exclusion criteria

Children above 1 year of age will be excluded. Babies with known congenital anomalies or known chromosomal abnormalities contraindicating the inclusion into the study like diaphragmatic hernia. Abdominal colicky necessitating emergency intervention will be excluded. Abdominal colicky associated with any other systemic involvement or any other medical cause as found by the investigator at the time of examination necessitating the exclusion will be excluded. Infants with a disorder that might affect the bowel or urinary tract in any relevant way (such as scrotal and inguinal swelling, distended abdomen, etc). Infants receiving formula for particular medical purposes.

Assessment criteria

Subjective parameters

FLACC scale

The assessment will be based on the FLACC SCALE on Day 0—Before treatment (BT), 10 minutes, 20 minutes, and 30 minutes after applying the tummy roll-on.⁵

Scoring: Each category is scored on a 0-2 scale which results in a total score of 0-10

0= Relaxed and comfortable, 1-3= Mild discomfort, 4-6=Moderate pain, 7-10=Severe discomfort/pain.

Objective criteria

Safety study

The skin condition is evaluated regarding adverse reactions 24 hours after the application, such as erythema, itching, burning, scaling, and irritation. The site will be graded for irritation/reactions using the North American Contact Dermatitis Group (NACDG) grading scale. Sites will be adequately illuminated using lighting provided by a 60-watt incandescent blue daylight bulb.

Intervention

Herby angel tummy roll-on.

Method of application

Apply the roll-on around the navel area and gently massage for 2 to 4 minutes. Reapply as needed.

Duration of treatment

The duration of treatment was of 1 month.

Table 1: Showing FLACC scale.

Behaviour	0	1	2
Face	No particular expression or smile	Occasional grimace or frown, withdrawn, disinterested	Frequent to constant frown, clenched jaw
Legs	Normal position or relaxed	Uneasy, restless, tense	Kicking or legs drawn up
Activity	Lying quietly, normal position, moves easily	Squirming, shifting back and forth, tense	Arched, rigid, or jerking
Cry	No cry (Awake or asleep)	Moans or whimpers, the occasional complaint	Crying steadily, screams or sobs, frequent complaints
Consolability	Content, relaxed	Reassured by occasional touching, hugging, or being talked to, distractible	Difficult to console or comfort

Table 2: Frequency of interruption in 24 hours.

Sleep interruption	Score
No interruption	0
1-2 times/day	1
3-4 times/day	2
>4 times/day	3

Table 3: Episodes of abdominal colic in a week.

Episodes of abdominal colic in a week	Score
<1 week	0
2 weeks	1
3 weeks	2
>4 weeks	3

Table 4: Episodes of abdominal colic in a day.

Episodes of abdominal colic in a day	Score
1 time	0
2-3 times	1
4-5 times	2
5-7 times	3

Table 5: Skin on touch.

Skin on Touch	Score
Warm without perspiration	0
Cold/clammy	1
Warm with sweating	2
Severe perspiration	3

Table 6: Duration required to expel gas or stool after applying tummy roll-on.

Time duration	Improvement
<5 minutes	Significant improvement
5-10 minutes	Moderate improvement
15-30 minutes	Slight improvement
>1 hour	Delayed effect

Table 7: NACDG grading scale.⁶

Symptoms	Score
No reaction	0
Macular erythema	+0.5
Indurated erythema	+1
Erythema, infiltration, and vesicles	+2
Bullous reaction or ulcer	+3

DISCUSSION

Colic, a common issue in babies, often arises when they ingest excessive air during feeding, leading to intestinal contractions. Herby angel tummy roll-on is a blend of natural oils and soothing ingredients that are gentle on baby’s skin and provide instant relief. This traditional formulation incorporates a harmonious blend of natural ingredients such as asafoetida, ajwain, rock salt, and nourishing oils like coconut oil, castor oil, and peppermint oil.

Ferulic acid is the active constituent in asafoetida responsible for various health benefits. It has positive effects on aiding in digestive ailments. Its antispasmodic properties can help relax the muscles in the gastrointestinal tract. This can be particularly useful in alleviating the abdominal discomfort and cramps associated with colic.⁷

Ajwain contains essential oils containing thymol, carvacrol, and thymoquinone, which have anti-spasmodic properties. It inhibits cyclooxygenase-2 enzyme activity, which is responsible for the inflammatory processes in the body, and thereby acts as a pain-relieving ingredient.⁸

Table 8: Showing the results of the case series.

Parameter	Case 1		Case 2		Case 3		Case 4	
	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment	Before treatment	After treatment
FLACC scale	7-10	10 min	20 min	30 min	7-10	10 min	20 min	30 min
		4-6	1-3	0	7-10	4-6	1-3	0
Frequency of interruption in 24 hrs	2	1	2	1	2	1	1	0
Episodes of abdominal colic in a week	2	0	0	0	2	0	1	0
Episodes of abdominal colic in a day	1	0	2	0	2	0	1	0
Skin on touch	2	0	2	1	2	0	1	0
Time duration to expel gas/stool	-	<5 minutes, Significant improvement	-	15-30 minutes-Slight improvement	-	<5 minutes, Significant improvement	-	<5 minutes, Significant improvement
NACDG grading scale	-	0	-	0	-	0	-	0

Rock salt is considered the best among all the varieties of salt. Sodium chloride is the chief ingredient in rock salt. It also contains other trace minerals like iodine, zinc, lithium, magnesium, manganese, phosphorous, potassium, chromium, etc. It improves appetite, removes intestinal and abdominal gases, and cramps, and soothes abdominal colic. It is prized for its high laxative properties, which aid in regular bowel movement.⁹

Coconut oil is a rich source of antioxidants and anti-inflammatory compounds that can moisturize and protect a baby's skin from irritation and dryness. It contains lauric acid which eases digestion in infants. A gentle abdominal massage using warm coconut oil may help relax the baby and relieve abdominal discomfort associated with colic.¹⁰

Castor oil comprises beneficial components including omega 3 fatty acids, ricinoleic acid, flavonoids, vitamin E, phenolic acids, amino acids, terpenoids, and phytosterols. The anti-inflammatory action of this oil can help calm an upset stomach in babies. It helps to relieve the pain and distress caused by colic due to its analgesic and laxative properties.¹¹

Peppermint oil is commonly used for digestive problems and has been found to provide relaxing effects on gastrointestinal muscles. The menthol in peppermint oil helps decrease smooth muscle spasms, reducing colic and gas. It works by helping the muscles of the bowel wall to relax.¹² These components work synergistically to alleviate indigestion, soothe stomach cramps, and alleviate gas.

CONCLUSION

The findings of this case series indicate that herby angel tummy roll-on is effective in managing infantile colic by alleviating abdominal discomfort, reducing episodes of colic, and improving sleep patterns in infants. The non-invasive, topical application of this formulation, containing natural ingredients like asafoetida, ajwain, and rock salt, provides quick relief without systemic side effects, making it a practical and safe alternative for caregivers. Overall, herby angel tummy roll-on proves to be a promising remedy for infantile colic, offering significant short-term benefits in soothing abdominal pain and enhancing the well-being of infants.

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