

## Effects of Fumaria Extract on Colic Pain in 3-16 Weeks Infants

Sedigheh Montaseri<sup>1</sup>, Shahnaz Pourarian<sup>2</sup>, Hashem Montaseri<sup>3</sup>

*1*Fatemeh (P.B.U.H) College of Nursing &Midwifery, Shiraz university of Medical sciences, Shiraz, Iran

*2*Neonatal Research Center, School of Medicine, Shiraz University of Medical Sciences, Shiraz, Iran

*3*Department of Pharmaceutics, Faculty of Pharmacy, Shiraz University of Medical Sciences, Shiraz, Iran

### Abstract

#### Introduction

Infantile colic is somehow believed to be the worst pain a baby has thus experienced. It is usually manifested as an acute abdominal pain with intense spasmodic cramping accompanied by intense crying lasting for more than 3 hours a day during at least a three days period. Accordingly, this study is aimed to investigate the effects of Fumaria on such pain in 3-16 weeks-old infants.

#### Materials and Methods

A double-blind clinical trial has been conducted on 60 newborns. The cases were selected through simple random sampling and divided into two groups, namely control and treatment group and given 2.5cc placebo or Fumaria extract. Daily symptoms were gathered and recorded via a specially designed questionnaire. Chi-squared test was used to analyze the mustered data.

#### Results

Out of the 60 cases, 50 newborns completely participated in the study. This study revealed a significant difference between the two aforementioned study groups as regards to the length and frequency of crying periods and the number of times an infant would wake up due to colic pain ( $P<0.05$ ).

Concerning the demographic characteristics, there was no statistically significant difference between the control and the treatment group ( $p>0.05$ ).

#### Conclusion

It was revealed that Fumaria extract is of great help in reducing the colic pain in 3-16 week-old infants.

#### Key words

Infantile colic, Fumaria, Infant

### Introduction

Infantile colic, as a behavioral syndrome, is one of the most important and meanwhile the most common disorders in the first few weeks to four months of an infant's life and rarely does it endure past six months of age (1). Hockenberry *et al.* have reported the prevalence of this disorder to be 15 to 40 percent (2) while Talachian *et al.* have reported a 20 percent occurrence among the Iranian infants and newborns (3). In fact, colic pain in infants and newborns is identified as intense crying accompanied by physical symptoms such as facial redness, bending the knees up toward the stomach, and finger gripping for three or more hours per day, at least three times a week, within a three weeks period (4). Such symptoms may lead to physical disorders, distress, and sleeping disarrays in children (5). Furthermore, they may as well create

numerous physical, emotional, and psychological problems in parents which can lead to child abuse or even disregarding the newborn (6,7). Based on theories, colic is believed to occur due to various factors, such as the infant's being fed quickly, swallowing air while feeding, inappropriate position of the infant while being fed and the mother's having emotional as well as nervous tensions. In general, colic is defined as a multifactorial disorder [2]. Several studies conducted on the issue have revealed the impact of both chemical and herbal medicines on decreasing this disorder in infants as well as newborns (7,8). Fumaria is one of such herbal medicines, which has a long background in the traditional medicine. Other than having beneficial features such as anti-microbial, antioxidant, and anti-inflammatory effects, Fumaria is known as an antispasmodic

herbal medicine for the gastrointestinal system (9,10). Brinkan *et al.* conducted a study on the effects of Fumaria on the inflammatory bowel syndrome in 2005 and showed that taking 1500 mg Fumaria, three times a day for eight weeks had a considerable effect in reducing the pain resulting from this syndrome (5). Likewise, the results of a study conducted by Henschel *et al.* revealed the antispasmodic effect of Fumaria on the gastrointestinal system (11). Comparing to chemical medicines which have more side effects and the high cost of production, Fumaria can be used as a natural cost-effective treatment which has no side effects. Therefore, the present study aims to investigate the effects of Fumaria on sedating the colic pain in infants as well as reducing the parents' and particularly the mothers' dilemma in taking care of such infants.

### Methods

The present study conducted a double-blind clinical trial in six cluster selected clinics affiliated to Shiraz University of Medical Sciences. The population of the study was selected through the simple random sampling method. Thus, among the 3-16 weeks infants referred to the outpatient clinic in the selected centers, sixty who were suffering from colic pain were selected and examined by a physician in order to confirm colic pain and the lack of other disorders. Infants who suffered from other problems were excluded from this study. Fumaria extract and the placebo were prepared and encoded according to the table of random numbers. These codes were kept secret up to the end of the data collection by a pharmacist and were revealed after performing the analysis and preparing the report on the labels. After obtaining written informed consents from the infant's mothers, control and treatment groups were established based on these labels. A questionnaire including maternal age, occupation, education and also baby's demographic information such as the age, sex, birth weight and status of the colic pain, frequency and duration of crying, bowel status and possible predisposing factors in creating the colic pain was designed and filled out. For medicine and placebo prescription, the cases were introduced to the pharmacy of the same clinic, and 2.5 cc

of the Fumaria extract was prescribed for the infants to be taken three times a day for a week. Meanwhile, the mothers were required not to use any other types of medicines or treatments in this period. They were also given a booklet for daily recording of the colic symptoms. Finally, they were asked to refer to the clinic after the treatment period in order to hand in the booklet and, at the same time, evaluate the colic pain in the infants. In order to investigate the progression of the effect of the medicine, the information recorded by the mothers in the period of one week, including the frequency as well as the length of crying and the frequency of waking up due to the colic pain per day, were assessed. The study protocol was approved by the Ethics Committee of Shiraz University of Medical Sciences. The data were analyzed by descriptive statistics method using SPSS (version 15). Descriptive data were presented as mean standard deviation. P values less than 0.05 were considered statistically significant and the Chi-square test was used to analyze the data.

### Results

Out of the total 60 samples, 26 samples of the treatment group and 24 samples of the control group were enrolled in this study. There were approximately % 17 reductions in numbers of samples due to not referring to the clinic or not completing the booklet. The demographic characteristics revealed an equal proportion of male and female infants in both treatment and control groups. The mean birth weight was measured to be  $1.96 \pm 0.77$  kg and  $1.75 \pm 0.89$  kg in the study and control groups as well respectively. In addition, 50% of the cases in the treatment group and %58 of the control group cases were the first children of their families. The most frequent age group was related to 2-month infants in both treatment and control groups. Regarding the demographic characteristics of the mothers, the results showed that the mothers in the treatment group were mostly 20-30 years old (77%) housewives (88%), 61% of whom had high school education. In the control group, 87% of the mothers were 20-30 years old, 91% were housewives and 41% had high school education. Nevertheless, the results of Chi-

square and Fisher tests showed no statistically significant difference between the demographic characteristics of the control and the treatment group ( $p>0.05$ ) (Table 1,2).

Concerning the specific goals and outcomes of the present study, the results of Chi-square test showed that after using the

Fumaria extract, the frequency, length of crying and the occurrence of waking up due to colic pain were decreased in the study group, while they either remained unchanged or increased in the control group and there was a statistically significant difference between them. ( $P<0.05$ ) (Table 3).

Table 1: frequency Distribution of Demographic characteristics of 4-16 week in infant with colic pain

Group		Treatment group				Control group				Pvalue	
Frequency	Variable	Female		Male		Female		male		P =1	
		Number	Percent	Number	percent	Number	Percent	Number	Percent		
Sex		13	50	13	50	12	50	12	50		
Age	Group	Number		Percent		Number		Percent		P =0.08	
	1-2m	9		34		7		29			
	2-3m	13		50		12		50			
	3-4m	4		16		5		21			
Birth order	First	Second		More them second		First	Second		morthea		P=0.13
	N*	P**	N	P	N	P	N	P	N	P	
	13	50	10	38.5	3	11.5	14	58	8	33	
Birth weight	200-2500gr	2500-3000 gr		> 3000-2500gr		200-2500gr	2500-3000 gr		> 3000 gr		P= 0.12
	N	P	N	P	N	P	N	P	N	P	
	7	27	11	42	8	30	2	8	12	50	

\*N= Number

\*\*P= Percent

Table 2: frequency Distribution of some demographic characteristics of mother with colicky infant

Group Frequency Variable	Treatment group		Controle group		p. value
	Number	Percent	Number	percent	
	O1				
Age (20-30 y/o)	20.26	77	21	84	P= 0.06
Job (housewife)	23	88	22	61	P=0.76
Education (high school)	16	61	10	41	P=0.26

Table 3: Comparison of colic criteria in treatment &amp; control group after intervention

Group variable	Treatment group						Control group						P. Value
	< 1 hour		1-3 hour		> 3 hour		< 1 hour		1-3 hour		> 3 hour		
Duration Of crying	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	Number	Percent	p≤0.00 1
	24	92	2	8	0	0	8	33	11	46	5	21	
Frequenc y Of crying	19	73	7	27	0	0	4	17	18	75	2	8	p≤0.00 1
Frequenc y Of wakingup	19	73	5	19	2	8	6	26	9	37	9	37	p≤0.00 1

Table 4: comparison of colic criteria in treatment &amp; control Group

Group variable	Treatment group						Control group						P value
	< 1 hour		1-3 hour		> 3 hour		< 1 hour		1-3 hour		> 3 hour		
	N	P	N	p	N	P	N	p	N	P	N	p	
Duration of Crying	7	26.9	8	30.8	11	42.3	4	16.7	10	41.7	10	41	P=0.4
	1 Episode		1-3 Episode		> 3 Episode		1 Episode		1-3 Episode		> 3 Episode		P=0.62
	N	P	N	p	N	P	N	p	N	P	N	p	
	4	15.4	10	38.5	12	46.2	4	16.7	8	33.3	12	50	
Frequency of crying	1 Episode		1-3 Episode		> 3 Episode		1 Episode		1-3 Episode		> 3 Episode		P=0.66
	N	P	N	p	N	P	N	p	N	P	N	p	
	5	19.2	10	38.5	11	42.3	3	12.5	9	37.5	12	50	

### Discussion

Considering the significant difference between the two groups regarding the frequency, length of crying and the occurrence of waking up due to colic pain - as the three major criteria for confirming the existence of colic pain-reported in the present study, one can claim that using the Fumaria extract can have a major effect on reducing the colic pain in the infants. Various studies conducted on the issue have also confirmed the remedy effects of this plant on animals. The studies performed on animals have claimed Fumaria to be an effective medicine for treating the spasmogenic processes. For instance, Rao *et al.* conducted a study on mice and reported both antispasmodic and anti-inflammatory effects for Fumaria extract (11,12). In another survey, Angha *et al.* carried out a research and showed that both the extract and oil of Fumaria have antibacterial effects (13). In addition, comparing the effect of Fumaria with other similar herbal medicines depicts the superior effects of Fumaria on reducing the length as well as the frequency of crying and occurrence of due waking ups in infants. For instance, Garner *et al.* conducted a study on a specific type of tea including Chamomile, Vervain, Licorice and Lemon balm and concluded that this type of tea would not affect the frequency of waking ups, while it would reduce the other symptoms in the infants (14). Another study was conducted on the effects of Fennel seed oil on reducing the colic pain

in the newborns which showed that although the compound could let to the reduction of the colic pain, it would decrease the rate of the crying times in the infants of the study group (7). Acupuncture, considered to be a new treatment for colic is proved to be less effective by Lungern *et al.* in a study in 2011 which revealed that this treatment had no impacts on reducing the frequency of the infant's waking up due to colic pain (15). Considering the 15%-40% prevalence of colic in the infants and, consequently, the increase of its due problems for the child as well as their families (2), the Fumaria extract which has antispasmodic effects according to Gilani *et al.* (16), can be introduced as an effective herbal medicine for reducing such problems.

### Conclusion

The Fumaria extract, as a cost-effective traditional medicine, can be highly effective in treating the colic pain in the newborns.

### Acknowledgments

The authors would like to thank the office of the Vice Chancellor of Shiraz University of Medical Sciences for financial support. Research Improvement Center of Shiraz University of Medical Sciences and Ms. A. Keivanshekouh are appreciated for improving the use of English in the manuscript. Also, the authors would like to thank Dr. Zareh at Research Improvement Center of Shiraz University of Medical Sciences for statistical assistance. Special

thanks must also go to OPD clinic's personnel for their full cooperation.

### References

- 1- Wyllie R & Hyams J. Pediatric Gastrointestinal and Liver Disease: Pathophysiology, Diagnosis, Management. 3<sup>rd</sup>. ed. Saunders CO; 2006:171-172.
- 2-Hockenberry M & Wilson D. Wong's Nursing Care of Infants and Children. 8<sup>th</sup> ed. Elsevier Health Sciences; 2011:32-3.
- 3.Talachian E, Bidari A, Rezaie MH. Incidence and risk factors for infantile colic in Iranian infants. World J Gastroenterol. 2008 Aug 7;14(29):4662-6
4. Wessel M, Cobb J, Jackson E, Harris Jr G, Detwiler A. Paroxysmal fussing in infancy, sometimes called "colic". Pediatrics. 1954;14(5):421.
- 5.Brinkhaus B, Hentschel C, Von Keudell C, Schindler G, Lindner M, Stützer H, et al. Herbal medicine with curcuma and fumitory in the treatment of irritable bowel syndrome: a randomized, placebo-controlled, double-blind clinical trial. Scand J Gastroenterol. 2005;40(8):936-43.
- 6.Howard CR, Lanphear N, Lanphear BP, Eberly S, Lawrence RA. Parental Responses to Infant Crying and Colic: The Effect on Breastfeeding Duration. Breastfeed Med. 2006;1(3):146-55.
- 7.Alexandrovich I, Rakovitskaya O, Kolmo E, Sidorova T, Shushunov S. The effect of fennel (*Foeniculum Vulgare*) seed oil emulsion in infantile colic: a randomized, placebo-controlled study. Altern Ther Health Med. 2003;9(4):58-61.
8. Weizman Z, Alkrinawi S, Goldfarb D, Bitran C. Efficacy of herbal tea preparation in infantile colic. J Pediatr. 1993 Apr;122(4):650-2.
- 9.Bowcher, A. & Condon, K. Fumitory update, Cooperative Research Centre for Australian Weed Management (Weeds CRC). 2005; Available at <http://www.murrumbidgee.cma.nsw.gov.au/Fumitory.Fumitory-Murrumbidgee Catchment Management Authority>
- 10.Blumenthal M(Ed). The complete German Commission E Monographs. Therapeutic Guide to Herbal Medicines. American Botanical Council.Austin,TX.1998;Available at <http://www.Herbalgram/issue44/article1309.html> 1998-10-01.
11. Hentschel C, Dressler S, Hahn EG. *Fumaria officinalis* (fumitory) clinical applications. Fortschr Med. 1995; 10:113(19):291-2.
- 12.Rao CV, Verma AR, Gupta PK, Vijayakumar M. Anti-inflammatory and anti-nociceptive activities of *Fumaria indica* whole plant extract in experimental animals. Acta Pharm. 2007;57(4):491-8.
- 13.Owngh A, Majdani R , Yaghobzadeh N, Niazi M. Antibacterial and anti fungal effects of fumitory oil on gram positive & gram negative bacteria and fungi in vitro. Iran J. Veterin Med. 2008 Vol. 1.
- 14.Crotteau CA, Wright ST, Eglash A. Clinical inquiries. What is the best treatment for infants with colic? J Fam Pract. 2006 ;55(7):634-6.
- 15.Landgren K, Kvorning N, Hallström I. Acupuncture reduces crying in infants with infantile colic: a randomised, controlled, blind clinical study. Acupunct Med. 2010;28(4):174-9.
16. Gilani AH, Bashir S, Janbaz KH, Khan A. [Pharmacological basis for the use of \*Fumaria indica\* in constipation and diarrhea.](#) J Ethnopharmacol. 2005; 96(3):585-9.