# Interaction of functional gastrointestinal disorders with postpartum conditions related to mother and baby

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#### **ABSTRACT**

**Background.** Functional gastrointestinal disorders (FGID) may affect or may be affected by postpartum depression (PPD), mode of feeding and postpartum life quality. We aimed to evaluate the interaction between FGID and these parameters in infants.

**Methods.** The study group consisted of babies attending our outpatient clinics. There were three age groups: 4-6 weeks, 3-4 months and 6-7 months. Demographic data of the babies and mothers, and data of feeding were collected. For the diagnosis of FGID, Rome III criteria were used. Mothers were screened with the Edinburgh Depression Scale. Quality of life (QoL) scores were obtained by using the "Maternal Postpartum Quality of Life Questionnaire". Factors affecting the presence of FGID, PPD and quality of life were analyzed.

**Results.** Two hundred thirteen infants were enrolled during the study period. FGID was present with similar rates in both genders and was lower (31.5%) in the 6-7 month-old group (p=0.001). Infantile colic was higher in girls (68.6% vs. 31.4%, p=0.016). In 4-6 week-old infants with infantile dyschesia, the delivery route was mostly cesarean (83.3% vs. 16.7%, p=0.006). Similarly, regurgitation was more frequent in 6-7 month-old infants born by cesarean (88.9% vs. 11.1%, p=0.035), and was more frequent in infants being exclusively breastfed (60.9%, p=0.037). QoL scores were lower in mothers with depression (20.9 $\pm$ 3.4 vs. 23.9 $\pm$ 3.6, p=0.003). Infantile colic was higher in mothers with depression, but not significantly (29.3% vs. 11.4%, p=0.057).

**Conclusions.** Caesarian section delivery and breastfeeding were influential on infantile dyschesia and regurgitation subgroups. No other studied factor seemed to affect FGID.

Key words: functional gastrointestinal disorders, infants, breastfeeding, postpartum depression, life quality.

Functional gastrointestinal disorders (FGID) in infants are chronic or recurrent symptoms that are age-dependent, and cannot be explained by structural or biochemical problems. Regurgitation, rumination syndrome, cyclic vomiting syndrome, infantile colic, functional diarrhea, infant dyschesia and functional constipation are defined under this group of disorders. These symptoms may be a

component of normal development or an inappropriate response to different stimuli.¹ Biopsychosocial model is commonly accepted to explain the etiology of FGID.² In this model genetics, environment, life stress, psychological state, coping, social support, motility and gut hypersensitivity have reciprocal interaction with symptoms.² The effect of parent's psychological state and behaviors are emphasized in many studies.³ These studies are mostly performed in older children. During infancy, some conditions like postpartum depression (PPD), mode of feeding, postpartum life quality may affect or may be affected by FGID.

PPD is an important, frequent and chronic problem if untreated.<sup>5</sup> It affects 9.1-19.2% of mothers in the first months after birth.<sup>6,7</sup> Stressful

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Received 5th June 2020, revised 30th July 2020, 11st November 2020, accepted 15th November 2020.

This study was presented at the 12th Pediatric Gastroenterology, Hepatology and Nutrition Congress, İzmir, Turkey, April 18-21, 2018.

life events, poor social support, infant health problems, low income and education, previous history of depression are risk factors for PPD.<sup>8</sup> It has been shown that PPD lowers life quality significantly. Mothers with PPD displayed lower quality of life (QoL) scores especially in emotional well-being, mostly at the 2<sup>nd</sup> and 4<sup>th</sup> months postpartum.<sup>9</sup> This situation may affect the whole family along with the mother in psychological and physical ways. For example, maternal PPD and attachment problems of the mother and the baby are suggested as reasons for infantile colic.<sup>10-13</sup> However, no data is present with regard to PPD and other infant FGID.

Diet is an important factor in FGID etiopathogenesis. Symptoms are reported to be food-related in most of the children with FGID.<sup>14</sup> Consuming foods like milk, spicy foods, pizza, sodas, fried foods and fast foods may exacerbate the symptoms of FGID in older children.<sup>15,16</sup> This may be explained by foods' ability to alter gut motility, sensitivity and microbiota.<sup>14</sup> There may be a similar effect in FGID of infants. The relationship between infantile colic and breastfeeding is well studied. In these studies, it has been demonstrated that exclusive breastfeeding reduces infantile colic.<sup>17,18</sup> However its effect is not clear in other FGID.

FGID do not only affect the infant's health but also the emotional status and daily life of the family. Parents miss workdays and have less ability to concentrate at work.<sup>19</sup> Infantile colic lowers QoL scores of mothers, especially in physical and social functioning domains.<sup>20</sup> However, data concerning the effects of other FGID on life quality is scarce.

In this study, we aimed to evaluate the interaction between FGID, PPD, maternal quality of life and breastfeeding in infants.

### Material and Methods

This study was designed as a cross-sectional study. The study group was selected from three

outpatient clinics (pediatric gastroenterology, social pediatrics, general pediatrics). The sample size for a CI level of 95% and 80% power was calculated to be 189 children with regard to infantile FGID incidence of 77%. <sup>21-24</sup> Considering a 10% sample loss we decided to have a sample size of 200. Data was collected between February and December 2013.

We had three age groups for the sample: infants between 4-6 weeks, 3-4 months and 6-7 months. We aimed to study children under 6 months as this age is the limit for exclusive breastfeeding. The 4-6-week-old group was chosen as this age is the only appropriate time to perform the maternal postpartum QoL scale.25 As PPD is highest at 3 months after birth we chose 3-4 months old as the second group.26 All children within the age range of groups were considered for the sample. The questionnaires were filled at the first visit, if a baby was admitted more than once they were not reenrolled to the study for older age groups. Exclusion criteria were severe conditions that require urgent intervention, chronic illnesses and babies brought to the hospital without their mother. Organic diseases presenting like FGID were excluded via history, physical examination and absence of alarm signs.

Demographic data collected for the babies were age (in months), sex, birth weight (as appropriate for gestation or small for gestation), socioeconomic status (SES) (low, intermediate, high) and family type. SES was grouped using a classification developed by Nesanir and Eser.<sup>27</sup> This classification uses the maternal level of education and the occupation of the father. Family types were classified as nuclear or extended. Variables related to the mother and birth were maternal age (in years), maternal education level, type of delivery (caesarian (c) section or vaginal), presence of miscarriages (absent or present) and parity (first or multiple). According to education level, mothers were divided into three groups. First group was illiterate and literate but did not finish elementary school; second group was consisted of elementary school graduates and

the last group was for women who graduated from secondary school or higher.27 We also collected data on feeding. These were; type (breast milk or other) and time (within 1st hour, after 1st hour within 1st day, later than 1st day) of the first feeding following birth, the current type of feeding (breastfeeding, mixed or nonbreastfeeding), presence of breastfeeding problems and use of bottle and/or pacifiers. Any problem interfering with breastfeeding like fissures of areolas, rejection of breastfeeding was included under this title. We asked an openended question concerning how well mother and baby were coping with breastfeeding. Anything declared as a problem by the mothers was noted as a breastfeeding problem.

Rome III criteria were used for FGID diagnosis.¹ Emotional status of the mother was screened with Edinburgh Depression Scale validated for Turkish.²8 Cut-off score for PPD was set as 10 points as recommended by the original scale.²9 Mothers were referred for the evaluation of depression if their score was above 10. QoL scores were obtained by using the "Maternal Postpartum Quality of Life Questionnaire", which is validated for Turkish.²5 The scale was scored between 0-30. Higher scores demonstrated a better life quality. This scale was given only to the mothers in the 4-6-week-old baby group as this was the age recommended by the authors.²5

Statistical analysis was done by using SPSS software. Mean values were given as mean+/standard deviation. When the distribution of the groups was not normal, Mann-Whitney U and variance analysis were used. Chi-square and t-test were used where distribution was normal to analyze factors affecting the presence of FGID, PPD and low scores on quality of life scores. P value <0.05 was accepted as significant. Ethics Committee approval was obtained from Dr. Behcet Uz Children's Ethics Committee (B-10-4-ISM-4-35-65-72, 28.02.2013). Informed consent was taken from all parents.

#### Results

Two hundred thirteen infants were enrolled during the study period. Of the study group, 108 (50.7%) were male. Children were grouped as follows; 4-6 weeks old (n=61, 28.6%), 3-4 months old (n=85, 39.9%) and 6-7 months old (n=67, 31.5%). The mean age of the mothers was 27.7±5.2 years. More than half of the mothers (n=116, 54.5%) had multiple parities, and 45 (21.1%) had a history of miscarriage. The mode of delivery was C-section in 120 (56.6%) mothers. Generally, babies had birth weights appropriate for gestational age (n=203, 96.2%). All the infants were born full term. Most (n=166, 78%) of the families were of intermediate socioeconomic status. Thirty-two (15%) families had high and 15 (7%) had low socioeconomic status. Approximately half of the mothers (n=116, 54.5%) had graduated from secondary school or above, while 17 (8.0%) were illiterate or literate but did not finish elementary school. Most of the babies (n=133, 62.3%) within six months were exclusively breastfed. In the babies older than six months 79.1% were still breastfed besides complementary feeding. Breast milk was the first food given to 165 (77.5%) babies. The first breastfeeding was performed in the first hour of birth in 122 (57.5%) and on the first day of birth in the other 67 (31.6%) babies. One baby was not breastfed at all. A breastfeeding problem was present in 70 (33.3%) mothers. Pacifier/bottle usage rate was high in our study group (n=150, 70.8%). The demographic data are given in Table I.

A FGID was present in 44.1%. The most common FGID was regurgitation (21.6%), infantile colic (16.4%) and infantile dyschesia (11.7%). Two babies (0.9%) had infant rumination syndrome, one baby (0,5%) had cyclic vomiting syndrome, six babies (2.8%) had functional constipation and none had functional diarrhea. FGID was present with a similar rate in both genders (p=0.492), and with a lower rate (13.8%) in the 6-7 month-old group (p=0.001) (Table I).

Table I. Demographic data of the children.

	Total group	Postpartum	depression	Quality of life score	FGID	
		Present	Absent		Present	Absent
Gender	n=213	n=99	n=114	n=53	n=94	n=119
Female	49.3%	47.5%	50.9%	23.0±4.5	46.7%	53.3%
Male	50.7%	52.5%	49.1%	22.4±3.2	41.7%	58.3%
Age groups	n=213	n=99	n=114	n=53	n=94*	n=119*
4-6 weeks	28.6%	25.3%	31.6%	22.7±3.8	31.9%	26.0%
3-4 months	39.9%	41.4%	38.6%	-	54.3%	28.6%
6-7 months	31.5%	33.3%	29.8%	-	13.8%	45.4%
Miscarriage	n=213	n=99	n=114	n=53	n=94	n=119
Present	21.1%	20.2%	21.9%	21.8±4.2	18.1%	23.5%
Absent	78.9%	79.8%	78.1%	22.9±3.7	81.9%	76.5%
Parity	n=213	n=99	n=114	n=53	n=94	n=119
One	45.5%	43.4%	47.4%	23.1±3.8	48.9%	42.9%
Multiple	54.5%	56.6%	52.6%	22.3±3.8	51.1%	57.1%
Birth weight	n=211	n=99	n=112	n=52	n=93	n=118
AGA	96.2%	96.4%	96.0%	22.7±3.9	96.8%	95.8%
SGA	3.8%	3.6%	4.0%	21.2±0.0	3.2%	4.2%
Mode of delivery	n=212	n=99	n=113	n=53	n=93	n=119
c/s	56.6%	52.5%	60.2%	22.8±3.1	59.1%	54.6%
Vaginally	43.4%	47.5%	39.8%	22.5±4.6	40.9%	45.4%
Maternal age groups	n=213	n=99	n=114	n=53	n=94	n=119
≤18 years	1.9%	2.0%	1.8%	22.0±0.0	2.1%	1.7%
19-35 years	90.6%	90.9%	90.4%	22.5±3.7	89.4%	91.6%
>35 years	7.5%	7.1%	7.8%	24.8±5.5	8.5%	6.7%
Maternal education level	n=213	n=99*	n=114*	n=53	n=94	n=119
Illiterate/literate	8.0%	3.0%	12.3%	21.2±0.8	10.6%	5.9%
Elementary school	37.5%	39.4%	36.0%	23.7±4.0	31.9%	42.0%
Secondary school or above	54.5%	57.6%	51.7%	22.4±3.9	57.5%	52.1%
Socioeconomic status	n=213	n=99*	n=114*	n=53	n=94	n=119
Low	7.0%	2.0%	11.4%	21.2±0.8	10.6%	4.2%
Intermediate	77.9%	78.8%	77.2%	23.0±4.0	75.6%	79.8%
High	15.0%	19.2%	11.4%	22.4±4.0	13.8%	16.0%
Nuclear family	n=213	n=99	n=114	n=53	n=94	n=119
Yes	83.1%	86.9%	79.8%	22.7±3.6	81.9%	84.0%
No	16.9%	13.1%	20.2%	22.4±5.0	18.1%	16.0%
First consumed food at birth	n=213	n=99	n=114	n=53	n=94	n=119
Breast milk	77.5%	80.8%	74.6%	22.6±4.0	79.8%	75.6%
Other	22.5%	19.2%	25.4%	23.1±2.2	20.2%	24.4%

<sup>\*</sup>p<0.05

AGA: appropriate for gestational age, SGA: small for gestational age FGID: functional gastrointestinal disorders, c/s: cesarean section

Table I. Continued.

	Total group	Postpartum depression		Quality of life score	FGID	
		Present	Absent		Present	Absent
First breastfeeding time	n=212	n=98	n=113	n=53	n=93	n=118
1st hour	57.5%	54.1%	61.1%	22.8±4.3	50.6%	63.6%
1 <sup>st</sup> day	31.6%	35.7%	28.3%	22.5±3.3	37.6%	27.1%
Later than 1st day	10.4%	10.2%	10.6%	22.9±2.9	11.8%	9.3%
Feeding type	n=212	n=99	n=113	n=52	n=93*	n=119*
Breastfeeding	44.4%	37.4%	50.5%	22.5±4.3	54.8%	36.1%
Non-breastfeeding	10.8%	12.1%	9.7%	-	7.5%	13.4%
Mixed	44.8%	50.5%	39.8%	23.0±3.2	37.6%	50.4%
Breastfeeding problem	n=210	n=98	n=112	n=52	n=93	n=117
Present	33.3%	38.8%	28.6%	22.2±3.3	29.0%	36.8%
Absent	66.7%	61.2%	71.4%	22.9±4.0	71.0%	63.2%
Pacifier/bottle usage	n=212	n=99	n=113	n=52	n=93	n=119
Present	70.8%	69.7%	71.7%	22.7±3.2	68.8%	72.3%
Absent	29.2%	30.3%	28.3%	22.7±4.8	31.2%	27.7%

<sup>\*</sup>p<0.05

AGA: appropriate for gestational age, SGA: small for gestational age FGID: functional gastrointestinal disorders, c/s: cesarean section

The education level of the mother or family socioeconomic status was not related to FGID frequency (p=0.203 and p=0.185, respectively). FGID was more frequent in exclusively breastfed infants (54.8% vs 36.1%, p<0.05) (Table I). Other demographic data, maternal, birth or feeding related variables were not related to FGID as given in Table I.

Regarding the FGID subgroups, infantile colic was seen mostly in girls (68.6% vs. 31.4%, p=0.016). No difference was present with regard to gender in other subgroups. Infantile colic and dyschesia were more frequent (2.4 ± 1.0 vs.  $4.3 \pm 2.2$  months, and  $2.3 \pm 1.5$  vs.  $4.2 \pm$ 2.1 months, respectively) in younger infants (p<0.05). Regurgitation frequency was not different with regards to age. Variables related to birth such as the number of miscarriages, parity and birth weight did not have an effect on FGID subgroups. In the 4-6 week-old infants with infantile dyschesia, the delivery route was mostly C-section (83.3% vs. 16.7%, p=0.006). Similarly, regurgitation was more frequent in 6-7 month-old infants born by C-section (88.9% vs. 11.1%, p=0.035). Maternal education level or family type had no effect on FGID subgroups. Infantile dyschesia was less frequently (17.5%) seen in families with intermediate SES (p=0.044) in 4-6 week old infants. Type of first consumed food or starting time of breastfeeding did not have an effect on FGID subgroups. Regurgitation was more frequent in infants being exclusively breastfed compared to other types of feeding (breastfed 60.9%, mixed 30.4%, non-breastfed 8.7%, p=0.037). Infants with regurgitation had less breastfeeding problems (82.6% vs. 17.4%, p=0.013). Bottle/pacifier usage did not affect FGID subgroups either.

PPD was detected in 46.5% of the mothers. The rate of depression was not different between age groups or genders (p=0.591, p=0.681). In mothers with depression quality of life scores were lower (20.9±3.4 vs. 23.9±3.6, p=0.003). Infantile colic was seen higher in the presence of depression, but this was not significant (29.3% vs. 11.4%, p=0.057). Edinburg depression scale scores were higher in the presence of infantile colic as well (11.6±5.6 vs. 8.3±4.7, p=0.015). (Table II). PPD was significantly lower in mothers with low education levels (illiterate and literate but

**Table II.** Relation of FGID with postpartum depression and life quality.

	Postpartum	depression	Edinberral Casas	O 1:1 (1:6	
	Present	Absent	— Edinburgh Score	Quality of life score (n=53)	
	(n=99)	(n=114)	(n=213)		
FGID					
Present	46.5%	42.1%	9.7±5.2	22.0±3.0	
Absent	53.5%	57.9%	8.9±5.6	23.3±4.4	
Regurgitation					
Present	20.2%	22.8%	8.9±4.8	-	
Absent	79.8%	77.2%	9.4±5.6	22.7±3.8	
Infantile colic					
Present	21.2%	12.3%	11.0±5.2*	21.8±3.0	
Absent	78.8%	87.7%	8.9±5.4*	23.0±4.0	
Dyschesia					
Present	9.1%	14.0%	9.6±6.3	21.9±3.1	
Absent	90.9%	86.0%	9.2±5.3	23.0±4.1	

FGID: functional gastrointestinal disorder

did not finish primary school) and in families with low SES (p=0.046 and 0.012, respectively). Any other demographic data or variables related to the birth, mother or feeding were not related to PPD (Table I). The mean QoL score was 22.7±3.8. The scores were not different with regards to FGID presence, demographic data, mother, birth or feeding variables (Table I and II).

## Discussion

FGID's are chronic problems that affect the life of patients in many ways. There are also many factors like genetics, environment, life stress, psychological state, motility and gut hypersensitivity that may be related to these disorders.<sup>2</sup> The effect of parent's psychological state and behavior are also emphasized.<sup>3,4</sup> We found that FGID are common in infants; regurgitation, infantile colic and infantile dyschesia being the most common ones. Gender did not have an effect on FGID, except infantile colic. Infantile colic was mostly seen in girls, and it seems to be relevant to PPD.

In Izmir, which is the biggest city in the Aegean region, women are mostly elementary

school graduates and the SES of the families is intermediate or high.<sup>30</sup> SES and vital parameters of our study were similar to the Aegean region. Some birth parameters were better in our study group compared to Turkey, such as miscarriage and being small for gestational age.30 It is assumed that breastfeeding might take a role in FGID as it is a determinant of microbiota.31 Shorter duration of breastfeeding might cause multiple FGIDs.32 We found higher exclusive breastfeeding rates (44.8%) compared to Turkish data.<sup>30</sup> This may be due to our approach as a baby-friendly hospital. Additionally, Izmir is a baby-friendly province. Bottle-feeding was reported in 39.7% of the babies younger than 6 months.30 Bottle or pacifier usage was found in 70.8% of our study group. This rate may be higher due to pacifier usage. Using pacifiers is a factor increasing bottle usage. In time, this increases breast rejection and eventually bottlefeeding.33 Other data about feeding was similar to Turkish data.30

FGID is seen in 27.1% of infants/toddlers between 0-3 years old. It may be as high as 67-87% in 2-4 months of age.<sup>21-24</sup> Regurgitation (25.9%), colic (5.9%) and functional constipation (4.7%) are the most common disorders.<sup>21</sup> In

<sup>\*</sup>p<0.05

our study group FGID rate was high (44.1%). Regurgitation, infantile colic and dyschesia were the most frequent disorders with similar rates reported in a review as 17.3-26.0%, 6-19% and 2-5.6%, respectively.<sup>34</sup> Even though FGID frequency did not differ with regard to sex, infantile colic was mostly seen in girls in our study. No gender difference is reported for FGID or infantile colic in the literature.<sup>21,35</sup>

4-6 week-old infants with dyschesia and 6-7 month-old infants with regurgitation were mostly born by cesarean. This may be due to the microbiota differences between vaginal and cesarean delivery. The effect of delivery mode on infant microbiota is well defined. 32,36 It is also documented that microbiota is an important factor in the genesis of FGID.37 Breastfeeding may also have an impact on FGID by affecting microbiota.35 One study demonstrated the relation of a shorter duration of breastfeeding and the development of irritable bowel syndrome in adult life.37 We could not find any relation between FGID and feeding parameters. FGID, predominantly regurgitation, was more frequent in breastfed infants in our study which was contradictory to the literature. 38,39 On the other hand, even regurgitation was higher in breastfed infants, infants with regurgitation had fewer breastfeeding problems. As proposed, infants with regurgitation should continue breastfeeding.38,39

PPD is a common disorder affecting almost 9.1-19.2% of mothers.<sup>6,7</sup> In our study we found a much higher frequency than reported earlier in Turkey, which was 23.8%.40 Many factors are known to affect the incidence. Even though the sex of the baby was not associated with PPD in our study, it is accepted as a factor by some authors.41 Socioeconomic factors such as low income are also associated with PPD.42 In our study group, PPD was lower in families with low SES. When analyzed further we saw that depression was less in mothers with a lower educational level. Higher education levels may raise awareness. We speculate that a raise in awareness may lead to an increase in anxiety, which is questioned in the Edinburgh Depression Scale.<sup>28</sup> This might explain lower depression rates in mothers with lower education levels. No other factor was found to influence PPD. Maternal depression was found to influence life quality as expected and has also been presented in previous studies.<sup>9,43</sup>

Regarding the FGID subgroups, infantile colic was related to PPD. This finding is in concordance with other studies. In the presence of infantile colic, PPD frequency is higher indicating an interaction.<sup>20</sup> Behavioral symptoms like depression and anxiety of the mother might cause infantile colic and infantile colic might affect parents negatively leading to maternal depression.<sup>3,10</sup> Depressed mothers may have a lower interaction with their infants and they might not respond to their infants' needs appropriately. When the needs of the infants were not met they may respond by crying to this distress. This may increase the occurrence of infantile colic.<sup>10</sup> In the biopsychosocial model, life stress, psychological state and coping, are some factors that interact with symptoms. As suggested in this model, the psychological state of the baby may influence FGID.2 PPD was not related to any other FGID subgroup.

Giving birth to a child might cause some physical and psychological changes in mothers' lives. These changes lead to changes in life quality.9 In our study, QoL scores were 22.7±3.8. The scores are expected between 0-30 on the scale we used. Therefore, scores in our study are not low. On the other hand, QoL scores were lower in depressed mothers with babies 4-6 weeks-old. This result supports the negative effect of PPD on life quality as discussed above.<sup>9,43</sup> However, the life quality of the mothers did not affect or was not affected by the presence of FGID and subtypes in 4-6 week old infants. There is only one study evaluating the life quality of infants with FGID. This study revealed that FGID, especially if there is more than one, lowers life quality of the infant.32 However, the effect of FGID on mothers' life quality is still not known. Therefore, more studies are needed to evaluate the relation of life quality and FGID, especially in different age groups.

There are some limitations to our study. First of all, our sample was selected from patients admitted to a tertiary level hospital. The SES of the families was above the average in Izmir. Since the sample was not population based, it may have a weakness in representing the population. Secondly, all data was obtained by questionnaires. However, we tried to minimize this limitation by questioning face to face. However, this still might lead to recall bias especially concerning feeding data of the older babies.

In conclusion, FGID (especially regurgitation, infantile colic and infantile dyschesia) and PPD are common problems in early infancy. From the FGID, infantile colic was related to PPD. Another influential factor on some FGID subgroups was C-Section delivery and breastfeeding in our study group. No other factor seems to affect FGID. Environment, life stress, parent's psychological state are some factors suggested to being responsible for the pathogenesis of FGID in older children. However, we suppose that other factors may be responsible for FGID in infancy. More studies are needed to enlighten this issue.

# **Author contribution**

The authors confirm contribution to the paper as follows: study conception and design: Özlem Bekem , İlker Günay, data collection: Özlem Bekem, İlker Günay, Filiz Çelik, Hurşit Apa; analysis and interpretation of results: Özlem Bekem, İlker Günay; draft manuscript preparation: Özlem Bekem, İlker Günay, Hurşit Apa.

All authors reviewed the results and approved the final version of the manuscript.

## **Ethics approval**

Approval was obtained from the ethics committee of Dr. Behcet Uz Children's Ethic Committee (B-10-4-ISM-4-35-65-72, 28.02.2013). The procedures used in this study adhere to the tenets of the Declaration of Helsinki.

## Source of funding

None declared.

### **Conflicts of Interest**

The authors declare that they have no conflict of interest.

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