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EFFECTIVENESS OF REFEZO IN INFANTS WITH FUNCTIONAL GASTROINTESTINAL DISORDERS

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ABSTRACT

The article describes the experience of using Refezo (domperidone) in suspension in young children with regurgitation syndrome. The study group consisted of 60 patients aged 1 month to 1 year who experienced vomiting, regurgitation, flatulence and GER in somatic diseases (pneumonia, bronchiolitis, obstructive bronchitis, sepsis). Group I consisted of 30 children with functional gastrointestinal disorders (FGD), who received basic therapy including the prokinetic drug Refezo. Group II consisted of 30 children with FGD who received only basic therapy. In children with FGD treated with Refezo, the drug was effective in 96% of children, and there were no side effects in the form of individual intolerance, allergic manifestations and neurological disorders.

INTRODUCTION

Functional gastrointestinal disorders (FGD) occupy a leading place in the structure of diseases of the digestive system in childhood, occurring with the greatest frequency in the first years of life [5,7]. According to modern concepts, FGD is a broad group of pathological conditions characterized by changes in any of the functions of the digestive tract: motility, secretion, digestion, absorption, state of microflora, immune system activity, etc. in the absence of organic changes [3,9].

One of the most common FGDs in newborns and children under 1 year of age is regurgitation (regurgitation) - the passive throwing of small amounts of food (uncurdled or partially curdled milk) from the stomach into the esophagus, pharynx and oral cavity, combined with the release of air. Regurgitation can be observed in healthy children, but it is infrequent, with a small (up to 3 ml) volume of regurgitated contents. According to S.V. Bellmer [2], 67% of children under 4 months of age burp at least once a day. In most babies, regurgitation disappears on its own by the end of the first year of life. The occurrence of regurgitation is predisposed by the anatomical and physiological features of the structure of the upper parts of the digestive tract in newborns and children of the first year - the spherical shape of the stomach and its small volume, delayed emptying, relative weakness of the lower esophageal sphincter, immaturity of the regulation of the system of moving food through the gastrointestinal tract (GIT) , immaturity of enzymes, etc. [6,10].

Functional gastrointestinal disorders lead to a decrease in the child's quality of life, and pathological conditions such as gastroesophageal reflux, FD and irritable bowel syndrome are associated with a high risk of developing GERD, gastritis and colitis, respectively. In children, especially young children, physiological GER occurs more often than in adults. Basically, GER in children in the first months of life has no clinical consequences and quite often goes away spontaneously when an effective antireflux barrier is gradually established. However, the primary failure of antireflux mechanisms in young children may also be based on disturbances in the regulation of the esophagus by the autonomic nervous system, caused by hypoxia of the fetal or newborn brain [4].

Regurgitation often occurs in children with intrauterine growth restriction and premature infants. Along with the above anatomical and physiological features of the gastrointestinal tract, this group of children has a slow development of the process of coordinated sucking, swallowing and breathing, which lasts for 6-8 weeks. Persistent regurgitation can be observed in children with connective tissue dysplasia (CTD), perinatal damage to the central nervous system (CNS), etc. Vomiting is an indirect cause of a large number of hospitalizations, especially in infants. According to a US cohort study (2014), about 3% of emergency department visits are due to vomiting, with 75% of these visits among children under 5 years of age [9]. The most common causes of vomiting in infants are functional (due to respiratory diseases, fermentopathy, neonatal jaundice, PDCNS) and organic gastrointestinal disorders (pyloric stenosis, pylorospasm, chalasia, achalasia of the esophagus, etc.) [8].

The pathogenesis of vomiting syndrome is quite complex. It is controlled by serotonergic, dopaminergic, histamine and muscarinic receptors. For this reason, the mechanism of action of numerous antiemetics is different. There are antagonists of serotonin (ondansetron), histamine (promethazine), dopamine (metoclopramide and trimethobenzamide) receptors. Treatment of regurgitation and vomiting in accordance with the recommendations of the working group of the European Society of Gastroenterology and Nutrition should be carried out in several successive stages: “positional treatment”, nutritional therapy, drug therapy, surgical methods. In the standards of specialized medical care for children with frequent vomiting and other dyspeptic symptoms due to various somatic diseases, two drugs are recommended as antiemetic drugs: domperidone and metoclopramide [1]. But metoclopramide has side effects such as drowsiness, extrapyramidal reactions (opisthotonus, muscle hypertonicity), hallucinations, seizures and neuroleptic malignant syndrome. When using domperidone, unlike

metoclopramide, the development of side effects associated with blockade of 5HT4 receptors is not typical. Domperidone, unlike other prokinetics, acts selectively - mainly on D-2 receptors. The antiemetic effect of domperidone is due to a combination of gastrokinetic action and blockade of chemoreceptors of the trigger zone of the vomiting center. The effectiveness and safety of the use of Domperidone was studied in the treatment of children with regurgitation syndrome, which occurs in 20-50% of children in the first 6 months of life (with an active survey of mothers - in 85% of children), in which passive involuntary reflux of food into the oral cavity is noted [1,4] . Despite the basic treatment tactics for FGD, which includes normalization of the psycho-emotional background, postural therapy, normalization of the daily routine and rational nutrition, in most cases there is a need to prescribe drug therapy with prokinetics. It is prokinetics, such as domperidone, that act as agents that are primarily used to treat functional disorders of gastrointestinal motor function. Therefore, the correct approach to the choice of therapy determines the positive outcome of treatment. But there is no proper assessment of the effectiveness and safety of domperidone in infants with functional disorders of the gastrointestinal tract due to somatic diseases.

In this case, we used a new domestic drug produced in the Republic of Uzbekistan, Refezo (domperidone), the main ingredient of which is widely used in clinical practice. The active ingredient of this drug is domperidone. Domperidone is a dopamine receptor antagonist, prokinetic. It blocks to a greater extent peripheral and to a lesser extent central (in the trigger zone of the vomiting center) dopamine receptors, eliminates the inhibitory effect of dopamine on the motor function of the gastrointestinal tract, and increases the evacuation and motor activity of the stomach. Penetrates poorly through the blood-brain barrier. Has no effect on gastric secretion. According to the instructions, the drug is approved for use from the neonatal period. The suspension form is convenient for administering to children from the first days of life.

Purpose of the study. To evaluate the effectiveness and safety of Refezo in infants with functional disorders of the gastrointestinal tract due to somatic diseases.

Material and research methods. The study was conducted in the neonatal pathology department of the TMA multidisciplinary clinic. The study included children aged 1 month to 1 year with FGD who experienced vomiting, regurgitation, flatulence due to somatic diseases (pneumonia, bronchiolitis, obstructive bronchitis, sepsis). Our study group included 60 children - 32 (53.3%) boys and 28 (46.7%) girls. All children underwent clinical, laboratory and instrumental studies (ultrasound of the pyloric stomach to exclude organic pathology). The effectiveness of the drug was monitored by comparative analysis of information (dynamics of complaints and objective data) obtained initially and over the next 10 days. During treatment, the presence and severity of side effects were recorded. The results obtained were processed by classical mathematical methods of variation statistics using the Statistica 6.0 application package.

Research results. All children were divided into 2 groups. Group I consisted of 30 children with FGD who received basic therapy including the prokinetic drug Refezo. Refezo suspension was prescribed according to the instructions at 0.25 mg (0.25 ml) suspension per 1 kg of child's body weight 3 times a day 15 minutes before meals for 5-7 days. Control group II included 30 children with FGD who received only basic therapy.

When studying the perinatal history of the examined children, it was revealed that the mothers of 13 (21.6%) of 60 children had various pregnancy pathologies documented - early and late gestosis, threat of miscarriage, etc. 17 children (28.3%) were diagnosed with asphyxia of varying degrees . 38 (63.3%) had perinatal pathology of the central nervous system. In 32 (53.3%) patients, clinical symptoms of rickets of varying severity were observed; 20 (33.3%) patients had atopic dermatitis; 21 (35.0%) children had deficiency anemia. It was noteworthy that 5 (8.3%) patients had grade I-II thymic hyperplasia, and 8 (19.0%) children had nutritional disorders. Today, the presence of concomitant diseases in children is important in the course of childhood illnesses, and we analyzed the effect of the drug Refezo on the clinical symptoms of functional gastrointestinal disorders in children without and with concomitant pathologies. When analyzing the dynamics of the disappearance of the main clinical symptoms of functional gastrointestinal disorders in children with and without concomitant pathology in the form of nausea, vomiting, regurgitation and flatulence, patients with various somatic diseases against the background of basic therapy with the inclusion of Refezo, prescribed in our hospital, it was found that the functional manifestations were stopped comparatively faster in children without concomitant pathology. However, by the end of the first week of treatment with Refezo, the main clinical symptoms of the disorder also disappeared in the group with concomitant pathology, which confirms the fairly high effectiveness of the drug (figure 1).

All children from both observation groups were mixed-fed and received complementary foods according to their age.

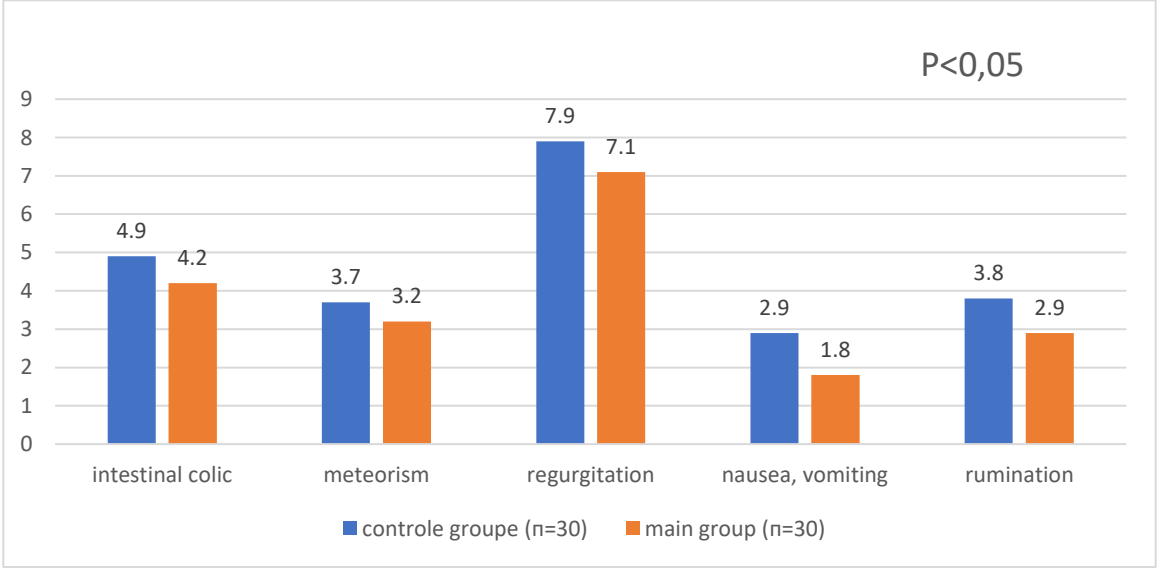

Fig.1. Average duration of clinical symptoms of functional disorders of the gastrointestinal tract in children with various somatic diseases, depending on the therapy (days)

When analyzing the dynamics of the disappearance of the main clinical symptoms of functional gastrointestinal disorders in children in the form of nausea, vomiting, regurgitation and flatulence, patients with various somatic diseases against the background of basic therapy with the inclusion of Refezo, prescribed in our hospital, it was found that the functional manifestations were stopped relatively faster than the control group. Thus, treatment of infants with FGR syndrome using the drug Refezo in suspension was characterized by an earlier onset

of positive dynamics of well-being, a decrease in the frequency and volume of regurgitation, nausea and vomiting within 3 days, weight gain, and normalization of physiological functions in comparison with the control group. On the 5th day of treatment in the main group there was a significant positive dynamics of clinical manifestations; the number of children who continued to have these complaints was significantly less than in the comparison group. A similar trend was observed when analyzing blood dynamics (Table 1).

Table 1

Characteristics of general and biochemical blood test indicators

Indicators	Main group		Control groupe	
	Before treatment (n=30)	After treatment (n=30)	Before treatment (n=30)	After treatment (n=30)
Нв	93,7±4,58***	99,3±6,37***	92,5±4,58***	93,4±5,3***
Er.	3,1±0,09	3,5±0,14*	3,4±0,09	3,4±0,14
CI	0,85±0,024	0,89±0,03*	0,88±0,02	0,86±0,02*
L	8,3±0,24***	7,2±0,28***	9,02±0,26***	8,6±0,24**
Lymphocytes	28,6±0,76***	37,7±1,47***	30,6±0,78***	36,4±1,07**
Monocytes	4,4±0,12	4,3±0,17	4,1±0,14	4,2±0,07
ESR	16,4±0,60***	14,1±0,60***	16,8±0,50***	15,02±0,60***
AsT AlT	0,48±0,019***	0,25±0,007*	0,42±0,016***	0,28±0,006*
AlT	0,26±0,010**	0,27±0,007**	0,24±0,12***	0,22±0,007***
Potassium	3,8±0,12*	4,20 ± 0,17*	3,6±0,14*	3,9 ± 0,17*
Sodium	112±4,6*	145±2,3*	114±4,2	116±1,6
Total protein	52±3,12**	62±2,8**	54±3,14	56±1,8

Note * - the differences relative to the healthy data are significant (* - P<0.05, *** - P<0.001).

As can be seen from the table, in children with regurgitation and vomiting syndrome during therapy with Refezo (domperidone), blood counts improved in almost all parameters. Thus, basic therapy with the use of the drug Refezo is characterized by significantly greater effectiveness compared to the control group without the prescription of a prokinetic agent. In children with FGD, this drug was effective in 96% of children, and there were no side effects in the form of individual intolerance, allergic manifestations and neurological disorders.

CONCLUSION

The presented data indicate that the domestic drug Refezo has a beneficial effect, improving the patient's well-being, reducing the severity of regurgitation and vomiting, weight gain, physiological functions and normalizing clinical manifestations. When analyzing the dynamics of the disappearance of the main clinical symptoms of functional disorders of the gastrointestinal tract in children with various somatic diseases and concomitant pathologies against the background of prokinetic therapy, the signs of FGD stopped significantly faster and the effectiveness of the drug Refezo was established. The form of release of the drug in the form of a suspension in unidoses is optimal and convenient for use in young children.

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