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# Comparison the Effect of Omeprazole, Esomeprazole and Lansoprazole on Treatment of Gastroesophageal Reflux Disease in Infants

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## ABSTRACT

**Aims** Gastroesophageal reflux Disease (GERD) results impairment in the quality of life of the infants. Various studies have shown that proton pump inhibitors have a beneficial effect on the treatment of GERD. The aim of this study was to compare the effect of omeprazole, esomeprazole, and lansoprazole in the treatment of GERD in infants.

**Materials & Methods** This study is a randomized double blinded clinical trial that was conducted on 2-24-month-old infants with GERD referred to the Shahid Mofatteh clinic in Yasuj, Iran in 2016. 90 samples were selected by purposive sampling method and randomly assigned to three intervention groups including lansoprazole, omeprazole and esomeprazole (30 subjects per group). Infants in each group daily received 1mg/kg body weight of their prescription drugs. Before and after two and four weeks of treatment, the GERD-Q questionnaire was completed. Data were analyzed by SPSS 21 software using statistical tests.

**Findings** There was no significant difference in the severity of GERD among the 3 groups before and 2 and 4 weeks after the intervention. Although, esomeprazole had a greater and faster effect on recovery. The symptoms of GERD in esomeprazole group were similar to the other two groups, but this difference was not significant. However, each of the three interventions alone improved GERD.

**Conclusion** All three drugs, lansoprazole, omeprazole, and esomeprazole, are effective on GERD recovery. In comparison, although there is no significant difference among these 3 drugs, However esomeprazole appears to have a better clinical effect.

**Keywords** Gastroesophageal Reflux; Esomeprazole; Omeprazole; Lansoprazole; Infants

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## Introduction

Gastroesophageal reflux Disease (GERD) is a common digestive disease which refers to reflux of the stomach contents through the lower esophageal sphincter into the esophagus. This causes incidence of disease symptoms and stimulation of the esophagus tissue [1]. In most cases, reflux in children is physiological and does not lead to complications. However, in some cases, if not treated, it results in a wide range of pathological and clinical findings in esophagus, whose diagnosis is mostly based on clinical symptoms [2].

GERD in children brings about high prevalence as well as high treatment costs and complications [3, 4]. In investigations conducted in the Western references, reflux symptoms occur daily, weekly, and monthly in 7, 14-19, and 40% of cases, respectively [5]. GERD disease incurs a staggering financial load to the healthcare systems of countries. Reflux disease may be associated with complications such as esophageal ulcer, peptic stricture, Barrett's esophagus, and extra esophageal symptoms such as asthma, chronic coughing, hoarseness, and laryngeal inflammation, which makes it difficult to diagnose and treat [6].

Physiological reflux is typically observed during infancy period especially during the first six months in many infants [7]. In most cases, some symptoms are resolved at 12-24 months of age, but if GERD is developed in infants, treatment should be started. Because if left untreated, the disease will lead to a series complications in infants [8]; such as Esophagus inflammation (Esophagitis), GI bleeding and Barrett's esophagus. Other complications are extra GI such as growth disorder, frequent pulmonary infections and dental decay. These mentioned complications have been frequently reported in infants with gastroesophageal reflux disease, and presence of such symptoms will compel physician to treat the patient [9, 10].

The pharmacological treatment of GERD involves $H_2$ receptor antagonists such as ranitidine and proton pump inhibitors including omeprazole, esomeprazole, and lansoprazole. Furthermore, medications such as baclofen, domperidone, and some herbal compounds such as aloe Vera are also used. As the last resort, for the children who do not respond to pharmacotherapy and experience serious complications, surgical anti reflux methods are used [11, 12]. Proton pump inhibitors are indicated for short-term and long-term treatment of reflux. Among the medications of this group, omeprazole and lansoprazole are the most common drugs used in children with FDA (Food and Drug Administration) approval. Compared to H2 receptor antagonists, these medications are more preferred and inhibit acid secretion more [10, 13]. This group of medications are different in terms of pharmacokinetic properties such as bioavailability as well as economic load [14].

In adults, comparative studies have been conducted to compare the therapeutic effect of esomeprazole, omeprazole, and lansoprazole in relieving symptoms of reflux, suggested that esomeprazole has more control over gastric acid secretion and a better therapeutic effect on esophagitis [15]. There have been limited studies in this area in children, and recommendations are often based on adult studies [16, 17].

Orenstein *et al*. investigated the effect of lansoprazole in the treatment of infantile reflux. Results showed that lansoprazole was more effective than placebo in reducing clinical symptoms of reflux [18]. Chen *et al*. investigated the efficacy of esomeprazole in the treatment of gastro esophageal reflux disease infants aged 6 months to 24 months. Their study showed 80% efficacy of esomeprazole compared to 40% placebo [19]. In the study of Winter *et al*. in infants from one month to eleven months with reflux symptoms, the results also showed 81 children of 98 (82%), after two weeks of treatment with esomeprazole compared to placebo (48%) showed significant improvement in reflux symptoms [20]. In a systematic study of Higginbotham on the efficacy and safety of proton pump inhibitor drugs in the treatment of infants with gastro esophageal reflux disease, a number of studies have shown that treatment with proton pump inhibitors is not an effective treatment to ameliorate the common symptoms of reflux disease in infants. A comparative study of the effects of these three drugs on infantile reflux disease was not found [14].

High prevalence of complications and heavy treatment costs of the disease highlight the necessity of conducting studies to examine the causes and treatment approaches for reflux. With regards to treatment, most studies have dealt with investigating the therapeutic effects of medications or their safety. However, since in clinical practice it seems that the effect of esomeprazole is different from that of the two other medications in children, and no comparative study has been conducted in the group of children, hence in this regard, a comparative research was performed between the three medications.

The aim of this study was to compare the effect of omeprazole, esomeprazole, and lansoprazole in the treatment of reflux disease in infants.

## Materials and Methods

This study is a randomized double blinded clinical trial that was conducted on 2-24-month-old infants with GERD referred to the Shahid Mofatteh clinic in Yasuj, Iran in 2016.

The inclusion criteria included the absence of active underlying disease including liver, kidney, lung diseases, obstructive diseases of the digestive system,

metabolite diseases, digestive ulcers, history of receiving antiacid and antireflux drugs over the past 24 hours. Exclusion criteria were: lack of companion or caregiver, lack of parental cooperation to complete the reflux questionnaire, and non-correct use of the medication by parents with arbitrary use of the drug. To do the study, 2-24-month-old infants who were diagnosed with GERD were referred to the researcher by a pediatrician. Then, after completing the demographic information questionnaire and GERD questionnaire, if they gained a score above 16, entered the study. In this way, 90 samples were selected by purposive sampling method and randomly assigned to three intervention groups including lansoprazole, omeprazole and esomeprazole (30 subjects per group). But during the treatment phase, 7 participants, including one in the esomeprazole group, one in the lansoprazole group, and 5 in the omeprazole group withdrew treatment. Due to the ethical codes and free exit of individuals at each stage of the study, they were excluded from the final analysis.

To determine the severity of reflux in infants, a 12-question GERD-Q questionnaire was used which has been standardized according to previous studies. Its total score is 44. Scores of 16 and under are considered disease-free and 17 to 19 with mild reflux, 20 and 21 with moderate reflux, and 22 and above with severe reflux [18].

In order to evaluate the reliability of the questionnaire, Cronbach alpha method was used. Furthermore, to examine the validity of the questionnaire, since standard combinational questions has been used, face validity determination method was employed.

Infants in each group daily received 1mg/kg body weight of their prescription drugs including esomeprazole, omeprazole, and lansoprazole (Abidi Co; Iran). After two and four weeks of treatment, the patients revisited and the questionnaire was recompleted.

Before the study, written consent was received from all participants. The parents were free to leave the study anytime they desired without mentioning any reason. Maintaining patients' privacy and not imposing additional costs on patients were other ethical considerations.

At first, the normality of the data distribution was evaluated by Kolmogorov-Smirnov test. Then the data were analyzed by SPSS 21 software using one-way analysis of variance, paired-samples t-test, and chi-square test.

## Findings

83 infants with reflux disease were studied. The mean age of infants was 5.23±2.99 months and in the esomeprazole, omeprazole, and lansoprazole groups was 5.00±2.64, 5.13±3.06, and 5.57±3.30 months, respectively. There was no significant difference among studied groups in term of the mean age (t=0.29; p=0.75).

Also, there was no significant difference among studied groups in term of the sex and the kind of feeding (Table 1).

The most common symptoms observed in the studied infants in order of prevalence were regurgitation (60.3%), hiccups (47.2%), bridging (41.1%), and constant restlessness (36.2%).

There was no significant difference in reflux intensity scores among studied groups at the beginning of the study (p>0.05). In the second week after the treatment, the mean score of reflux was higher in the omeprazole group than in esomeprazole and lansoprazole groups. However, four weeks after the treatment, best outcome was observed in the esomeprazole group. The mean reflux severity in all three groups showed a decreasing trend and the rate of reduction was better in the esomeprazole group than the other two groups, but the difference among the groups was not statistically significant (p>0.05; Table 2 and Diagram 1).

Frequency of response to treatment was higher in the esomeprazole and lansoprazole groups than in the omeprazole group. Esomeprazole also showed a faster response than the lansoprazole and omeprazole (Table 3).

**Table1)** Distribution of absolute and relative frequency of participants' demographic information at start time of study by Chi square test (30 samples in each group; the numbers in parentheses are percentage)

| Demographic Information | Esomeprazole Group | Omeprazole Group | Lansoprazole Group | Total | P. value |
|---|---|---|---|---|---|
| **Sex** | | | | | |
| Male | 16 (53.3) | 14 (46.7) | 20 (66.7) | 50 (55.6) | 0.28 |
| Female | 14 (46.7) | 16 (53.3) | 10 (33.3) | 40 (44.4) | |
| **Feeding** | | | | | |
| Breast | 21 (70.0) | 23 (76.7) | 21 (70.0) | 65 (72.2) | 0.8 |
| Formula | 9 (30.0) | 7 (23.3) | 9 (30.0) | 25 (27.8) | |

**Table 2)** Comparing the mean intensity of reflux in the before and after treatment among the studied groups

| Groups | Before treatment | Two weeks after treatment | Four weeks after treatment |
|---|---|---|---|
| Esomeprazole | 23.70±4.04 | 13.87±3.24 | 11.27±2.67 |
| Omeprazole | 22.57±5.85 | 15.23±3.06 | 12.23±2.93 |
| Lansoprazole | 22.97±4.43 | 14.30±3.37 | 12.20±2.60 |
| Total | 23.08±4.80 | 14.47±3.24 | 11.90±2.75 |

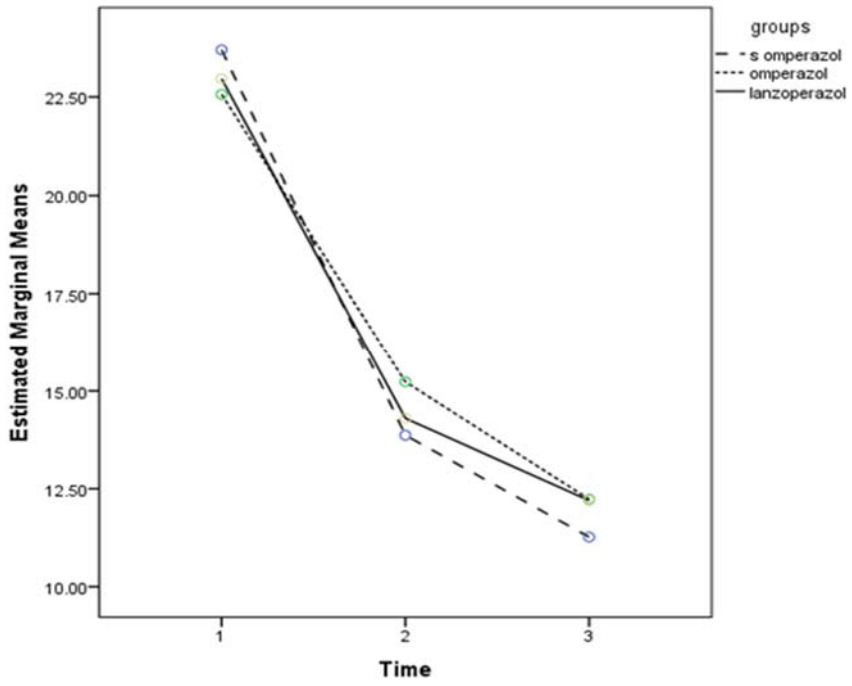


**Diagram 1)** The trend of the time effect of esomeprazole, lansoprazole, and omeprazole on mean intensity score of reflux in under study participants

**Table 3)** Frequency distribution of response to treatment based understudy groups (the numbers in parentheses are percentage)

| groups | Total No. | TWM[1] | FWM[2] | No Response | P. value |
|---|---|---|---|---|---|
| Esomeprazole | 29 | 21 (72.4) | 27 (93.1) | 2 (6.9) | |
| Lansoprazole | 29 | 20 (69.0) | 27 (93.1) | 2 (6.9) | 0.03 |
| Omeprazole | 25 | 10 (40.0) | 21 (84.0) | 4 (16.0) | |

1: Two weeks after treatment; 2: Four weeks after treatment

## Discussion

The aim of the present study was to compare the effect of omeprazole, esomeprazole, and lansoprazole on clinical symptoms of GERD in 2-24-month-old infants.

The obtained results have suggested that infants with GERD improved by esomeprazole, and this medication are effective to treat GERD among 2-24-month-old children. The results of this study are in line with those obtained by Sahara *et al*., Winter *et al*., and Tolia *et al*. [16, 20, 21].

Infants with GERD improved after going through treatment course by omeprazole, and this medication is also effective in treating GERD among 2-24-month-old children. The results of this study are congruent with those obtained by Omari *et al*. [22].

Infants with GERD improved after going through treatment course by lansoprazole, and this medication is also effective in treating GERD among 2-24-month-old children. The results of this study are congruent with the theoretical principles and previous studies including Khoshoo and Dhume [23] in a study examining the effect of lansoprazole in treating reflux in 3-month-to-2-year-old children. Also, the study by Tighe *et al*. examining the effect of lansoprazole in treating infantile reflux [24] produced similar results to the present study.

The mean degree of reflux across all of the three groups based on the scores acquired in the basic mean degree of reflux into three groups has been of severe type (above 20 in all of the groups). However, after two and four weeks of treatment, the mean degree of reflux decreased.

Compared to omeprazole, esomeprazole and lansoprazole significantly reduced the symptoms of reflux, and the effect of esomeprazole on reflux after the second week was greater than omeprazole and lansoprazole, although the differences were not significant. Thus, despite no significant differences among the three drugs, esomeprazole may be clinically better than the other two drugs due to a further decrease in the severity of reflux disease.

This result is similar to the results of the Naseri Moghaddam *et al*. study [25] that the efficacy of esomeprazole and omeprazole was similar to that of pantoprazole, but the difference was that lansoprazole was not studied in this study. It was also consistent with a study by Richter *et al*. which showed that esomeprazole had a greater effect on reflux than omeprazole after 4 and 8 weeks. In our study, symptoms decreased more than two weeks after four weeks. But in a Richter study, the effect of the drug on reducing reflux symptoms after 8 weeks was also examined.

In Zheng's study, which compared the effects of omeprazole, lansoprazole, pantoprazole, and esomeprazole in reducing symptoms of esophageal reflux, there was no significant difference in

symptom reduction between esomeprazole and other proton pump inhibitors. But this symptom reduction had occurred over a shorter period of esomeprazole users [27], which was similar to the result of our study.

However, Rohss *et al.*'s study found that esomeprazole had a better effect than other drugs, such as omeprazole, lansoprazole, and pantoprazole on reducing gastric acid and reducing clinical symptoms [28]. This is different from our study, but this may be due in part to the higher age of the study population. But the results of studies by Richter *et al*. [26] and Higginbotham [14], which investigated the efficacy of proton pump inhibitors in children with reflux disease, confirmed that these drugs were not effective in infants, which is contrary to our results.

In our study, no specific complication was observed among drug users during the period of use. In a study by Tjon *et al*., which looked at the efficacy and safety of proton pump inhibitor drugs in children, it was observed that few of the reviewed articles reported minor side effects of these drugs. But in general its benefits are greater [29].

One of limitations of this study is that only four weeks after the intervention, the therapeutic effect of the drugs was evaluated, while other studies measured the therapeutic effect of the drugs for up to eight weeks.

It is recommended that further studies are carried out with more patients and longer follow-up to better evaluate the efficacy of drugs and the potential side effects of proton pump inhibitors.

## Conclusion

Lansoprazole, omeprazole and esomeprazole medications can each significantly improve the symptoms of gastro esophageal reflux disease (GERD) in infants alone. A four-week use of the drug has a better effect than a two-week dose. But their effect is no different from one another.

Our recommendation is to use esomeprazole in infants with reflux disease, because it is able to reduce gastro esophageal reflux disease (GERD) severity score based on the gastro esophageal reflux disease questionnaire compared to other drugs.

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