Critically Appraised Topic: Gastroesophageal Reflux Disease Treatment in Infants

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Clinical Scenario:
A mother presents with her one month old infant to the clinic. She states that he screams for one hour after his feedings, has been spitting up large amounts, and has frequent hiccups. She states this has been going on for approximately one week now. She is wondering what can be done to help him with these symptoms.

Clinical Question:
Would the use of anti-reflux medications in infants with gastroesophageal reflux disease be appropriate in alleviating symptom versus a nonpharmacological approach?

Articles:


Summary and Appraisal of Key Evidence:

Study Design:
- Orenstein et al., (2009), performed a multicenter, double-blind, randomized, placebo controlled trial. This study provided a grade A level 2a of evidence (CEBM, 2011).

- The study conducted by Orenstein & McGowan (2008), multicenter, double-blind, randomized, placebo controlled trial. This study also provided a grade A level 2a of evidence (CEBM, 2011).

Sample:
- Orenstein et al., (2009), included infants with persistent symptoms of gastroesophageal reflux disease (GERD). This study included 16 different centers within the United States and Poland. There were 216 infants that were screened for this study. Of those 216 there were 162 that met the criteria and were then randomized. These infants were enrolled with informed consent from parents or guardians. The infants were between the ages of 28 days to less than 12 months.
• Orenstein & McGowan (2008) used 50 infants that were screened to meet the inclusion and exclusion criteria. These 50 infants were found at 5 different outpatient pediatric sites in the United States. Of the 50 infants there were 40 that met the criteria for the study. There were 37 infants that returned after the two weeks for follow up. Of this 37 there were 59% that were male and 41% that were female.

Procedure:

• Orenstein et al., (2009) study included infants with symptoms of GERD that have persisted after using nonpharmacological therapy for greater than one week. These infants were treated with lansoprazole or placebo for 4 weeks and the symptoms were tracked through daily diaries and weekly appointments. The I-GERQ-R which is a reflux questionnaire was used to diagnose the infants with reflux disease.

• In the study conducted by Orenstein & McGowan (2008), informed consent from the parent or guardian was first obtained following by a medical history intake, physical examination, and baseline chemistry labs. The parents then completed a I-GERQ-R, which is a reflux questionnaire. Infants with a score greater than 16 were eligible for the study. The parents were instructed on conservative therapy treatment and not to take any PPI, H2 blockers, or antacids. Conservative therapy included feeding modifications, positioning, and tobacco smoke avoidance. They then returned in 2 weeks to have the parents fill out another I-GERQ-R.

Outcome(s) Measured:

• In the study by Orenstein et al., (2009) efficacy of the medication was defined by a greater than 50% reduction in symptoms. The safety of the medication was assessed by the occurrence of adverse events. The daily diary served as a baseline for efficacy comparison. Documented in the diary was the number and duration of crying episodes during or less than one hour after a feeding.

• They study by Orenstein & McGowan (2008) utilized a 12 item questionnaire used for diagnostic purposes as well as tracking changes in symptoms of GERD. The scores of this questionnaire range from 0 to 42 with a cutoff of greater than 16 indicating the presence of GERD. A reduction in score of 5 to 6 points is considered clinically significant.

Results:

• The results of the study by Orenstein et al., (2009) stated that there were no significant differences between the placebo and lansoprazole in analyzing the efficacy. During the double blind treatment there were 62% of the lansoprazole treated subjects that experienced one or more emergent adverse events versus 46% of the infants taking the placebo. Serious adverse events included lower respiratory tract infections that occurred in a total of 12 infants.
• Results of the study conducted by Orenstein & McGowan (2008) indicated an improvement in conservative treatment for GERD. The median initial score was 23 with scores ranging from 16 to 36. At the end of the two weeks the median score was 18 with scores ranging from 7 to 34. Approximately 59% of the infants improved beyond the 5 points and 24% became normal. Individual scores for regurgitation, crying, and arching improved significantly.

Strengths and Limitations:

• In the study conducted by Orenstein et al. (2009), the strengths included the design, large number of infants, and predetermined power analysis. Some possible limitations included the fact that crying is not necessarily related to GERD, the prerandomization acid suppressing treatment may have had nonresponders, and aspects of treatment including dose and duration.

• A limitation of the study conducted by Orenstein & McGowan (2008) includes the uncertainty of which interventions produced a benefit in the infants. Another limitation could be the lack of a control group that were not instructed on conservative therapy.

Clinical Bottom Line:

• According to the study conducted by Orenstein et al., (2009) there is no difference in efficacy between lansoprazole and placebo for symptoms related to GERD in infants. This randomized double blinded study found that adverse effects including lower respiratory infections occur more frequently with lansoprazole than the placebo.

• In the study by Orenstein & McGowan (2008) two weeks of conservative therapy did show an improved difference in treating the symptoms of GERD in infants. The conservative treatments most beneficial include lying the baby prone, specific feeding volumes, thickening of formula with dry rice cereal, and decreasing smoke exposure.

Relevance in Clinical Practice:

As future healthcare providers we will strive to provide and treat our patients with the most up to date information in regards to their family’s health. This will include the most cost-effective and successful treatment to our knowledge. It is our job to stay knowledgeable on the most effective treatment for our patients. In regards to this study on anti-reflux medication, the most cost effective treatment would be to use conservative strategies in preventing and treating reflux in infants. Not only is this more cost effective but it also has been proven that in many cases there is no difference between using anti-reflux medication or not. Also, medications such as lansoprazole have been shown to increase the chances of lower respiratory infections. This is something the parents of these infants should be educated on and it is our job to inform them of this.
References

