

Antidepressant and placebo are equally effective in child pain relief

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When used "off-label," the antidepressant amitriptyline works just as well as placebo in treating pain-predominant gastrointestinal disorders in children, according to a new study in *Gastroenterology*, the official journal of the American Gastroenterological Association (AGA) Institute.

"Many pharmaceutical products are prescribed for off-label use in children due to the lack of clinical trials testing the efficacy of the drugs in children and adolescents. Therefore, the pediatric gastroenterologist frequently has to make treatment decisions without the evidence of how drugs work in children," said Miguel Saps, MD, of Children's Memorial Hospital and lead author of the study. "The high [placebo](#) effect we identified in this study suggests that further studies of the use of certain [antidepressants](#) in children with functional bowel disorders are needed. While several trials have demonstrated a beneficial effect of antidepressants, including amitriptyline, for the treatment of [irritable bowel syndrome](#) (IBS) in adults, more research is needed to determine how effective this drug is, if at all, in children."

Amitriptyline (Elavil®) is used to treat symptoms of depression, however, it is often times prescribed to children for pain relief from pain-predominant functional gastrointestinal disorders (FGIDs). Pain-predominant FGIDs are among the most common causes for medical consultation in children. Such disorders include three common conditions: IBS, [functional dyspepsia](#) and functional abdominal pain.

Video: Dr. Miguel Saps discusses his manuscript Multicenter, Randomized, Placebo-Controlled Trial of Amitriptyline in Children With Functional Gastrointestinal Disorders.

Doctors designed a large prospective, multicenter, randomized placebo-controlled trial in which children, ages eight to 17, with IBS, functional abdominal pain or functional dyspepsia were randomized to four weeks of placebo or amitriptyline.

Of the 83 children who completed the study, 63 percent of those who took amitriptyline reported feeling better, while 5 percent reported feeling worse. Of the patients who were given a placebo, 57.5 percent felt better, while 2.5 percent felt worse. Pain relief was excellent (7 percent), good (38 percent) in children on placebo and excellent (15 percent), good (35 percent) in children on amitriptyline. Both amitriptyline and placebo were associated with excellent therapeutic response, although patients with mild to moderate intensity of pain responded better to treatment. There was no significant difference between amitriptyline and placebo after four weeks of treatment.

In children, the use of drugs to treat pain-predominant FGIDs is mostly empirical and based on adult data. There have been only a few small randomized clinical trials evaluating the efficacy of drugs for the treatment of pain-predominant FGIDs in [children](#).

Source: American Gastroenterological Association ([news](#) : [web](#))

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