

## DOMPERIDONE ON ABDOMINAL PAIN- PREDOMINANT FUNCTIONAL GASTROINTESTINAL DISORDERS IN CHILDREN: RANDOMIZED, DOUBLE-BLIND, PLACEBO- CONTROLLED TRIAL

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### Introduction:

The therapeutic effect of the prokinetic drug, domperidone was assessed on children with AP-FGIDs aged 5-12 years.

### Methods:

100 Children fulfilling Rome III criteria for AP-FGIDs were randomized into 8 weeks of placebo or domperidone. Primary outcomes defined were cure (abdominal pain less than 25mm on the visual analogue scale and no impact on daily activities) and improvement (pain relief and sense of improvement recorded on global assessment scales). Secondary outcomes were significant improvement in symptoms, gastric motility, quality of life (QoL) and family impact. Symptom severity was recorded on a validated 100mm visual analogue scale. Translated and validated PedQL Generic Score Scale version 4.0 and Family Impact Module were used. Gastric motility was assessed using a validated ultrasound method.

### Results:

One hundred children were enrolled and 89 completed the trial (Placebo 42 [20 boys], domperidone 47[14boys]). While comparing primary outcomes, domperidone group had significant improvement (37 [78.7%] vs. 25 [59.5%] in placebo group,  $p=0.04$ ), while no such difference was observed in cure. When assessing secondary outcomes, domperidone group reported significant reduction in abdominal pain severity (70.8% vs. 48.2%,  $p =0.03$ ) and improvement in motility index (29.3% vs. 8.6%,  $p=0.04$ ) after intervention. No such difference was seen in improvement of QoL and family impact ( $p>0.05$ ).

### Conclusion:

Domperidone has a favourable therapeutic effect on improvement AP-FGIDs in children aged 5-12 years. It causes significant reduction in abdominal pain and improvement in motility of the gastric antrum. However, it has no significant effect on improvement of QoL and family impact.