DOMPERIDONA (MOTIULIUM/DISKINETON®) – SELECTIE STUDII CLINICE (PUBMED.COM)
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DOMPERIDONA IN BRGE:

1. Pharmacological treatment of children with gastro-oesophageal reflux/disease (GOR/GORD)
   (AUTHORS’ CONCLUSIONS: Moderate evidence was found to support the use of PPIs, along with some evidence to support the use of H₂ antagonists in older children with GORD, based on improvement in symptom scores, pH indices and endoscopic/histological appearances. However, lack of independent placebo-controlled and head-to-head trials makes conclusions as to relative efficacy difficult to determine. Further RCTs are recommended. No robust RCT evidence is available to support the use of domperidone, and further studies on prokinetics are recommended, including assessments of erythromycin. Pharmacological treatment of infants with reflux symptoms is problematic, as many infants have GOR, and little correlation has been noted between reported symptoms and endoscopic and pH findings. Better evidence has been found to support the use of PPIs in infants with GORD, but heterogeneity in outcomes and in study design impairs interpretation of placebo-controlled data regarding efficacy. Some evidence is available to support the use of Gaviscon Infant (®), but further studies with longer follow-up times are recommended. Studies of omeprazole and lansoprazole in infants with functional GOR have demonstrated variable benefit, probably because of differences in inclusion criteria. No robust RCT evidence has been found regarding treatment of preterm babies with GOR/GORD or children with neurodisabilities. Initiation of RCTs with common endpoints is recommended, given the frequency of treatment and the use of multiple antireflux agents in these children.)

2. Gastroesophageal reflux (GER): natural evolution, diagnostic approach and treatment (Extract from abstract: Symptoms due to GER are troublesome when they have an adverse effect on the well-being of the pediatric patient. In regurgitating infants, decreasing the amount of regurgitation is often seen by the parents as the most welcomed intervention that physicians can provide. Many medications have been attempted to overcome GER in infants, each with their own advantages and limitations.)

DOMPERIDONA IN DUREREA ABDOMINALA DE CAUZE FUNCTIONALE:

1. OP-7 THERAPEUTIC EFFECTS OF DOMPERIDONE ON ABDOMINAL PAIN-PREDOMINANT FUNCTIONAL GASTROINTESTINAL DISORDERS (AP-FGIDs): RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED TRIAL (Conclusion: Domperidone has a favorable 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 quality of life and family impact.

2. Prokinetics prescribing in paediatrics: evidence on cisapride, domperidone, and metoclopramide (OBJECTIVES: Domperidone and metoclopramide are prokinetics commonly prescribed off-label to infants and younger children in an attempt to treat gastro-esophageal reflux symptoms. Another prokinetic drug, cisapride, was used but withdrawn in 2000 in the United Kingdom because of serious arrhythmic adverse events. Medicines and Healthcare Products Regulatory Agency issued safety
warnings for domperidone in May 2012 and restricted its indications. We report here national primary care prescribing trends and safety signals of these drugs in children. **RESULTS:** The proportion of children <2 years old being prescribed one of the medications doubled during the study period. Prescriptions of domperidone increased 10-fold, mainly following the withdrawal of cisapride in 2000. Prescriptions of metoclopramide did not change significantly. Despite the increase in prescriptions of domperidone, no new safety signals were identified. **CONCLUSIONS:** These data showed dramatic changes in prescribing of cisapride and domperidone despite the lack of good-quality supporting evidence. It is possible that these prescribing trends were influenced by published guidelines. Even if produced without robust efficacy and safety evidence, published guidelines can influence clinicians and consequently affect prescribing. Therefore, improving the evidence base on prokinetics to inform future guidelines is vital. The lack of new safety signals during this period would support the development of suitable powered clinical studies.

**DOMPERIDONA SI SECRETIA LACTATA (la femei, dar si la copii [adolescenti]):**

1. **Enhancing Human Milk Production With Domperidone in Mothers of Preterm Infants** *(Conclusion: A greater number of mothers experienced a 50% or more increase in human milk volume, but the absolute increase in milk volume was modest.)*

2. **Should Domperidone be Used as a Galactagogue? Possible Safety Implications for Mother and Child** *(Conclusion: Domperidone has repeatedly been shown to produce sudden cardiac death, starting at 30 mg/day. Because of this known cardiac effect, the use of domperidone to increase breast milk production may not be justified.)*

3. **Euprolactinemic galactorrhea secondary to domperidone treatment** *(Abstract: Milk leakage from the breast, which is known as galactorrhea, can be caused by a number of pharmacological, physical, and tumoral factors. Galactorrhea is a well-known side effect of domperidone, and is usually associated with hyperprolactinemia. However, euprolactinemic galactorrhea secondary to domperidone is very rarely seen and has yet to be reported in children before. Here, we report an adolescent with euprolactinemic galactorrhea caused by domperidone.)*

**DOMPERIDONA IN GASTROENTERITA ACUTA:**

1. **Oral Ondansetron versus Domperidone for Acute Gastroenteritis in Pediatric Emergency Departments: Multicenter Double Blind Randomized Controlled Trial** *(Conclusion: Ondansetron reduced the risk of intravenous rehydration by over 50%, both vs placebo (RR 0.41, 98.6% CI 0.20-0.83) and domperidone (RR 0.47, 98.6% CI 0.23-0.97). No differences for adverse events were seen among groups. In a context of emergency care, 6 out of 10 children aged 1-6 years with vomiting due to gastroenteritis and without severe dehydration can be managed effectively with administration of oral rehydration solution alone. In children who fail oral rehydration, a single oral dose of ondansetron reduces the need for intravenous rehydration and the percentage of children who continue to vomit, thereby facilitating the success of oral rehydration. Domperidone was not effective for the symptomatic treatment of vomiting during acute gastroenteritis.)*
2. Randomized study of ondansetron versus domperidone in the treatment of children with acute gastroenteritis (METHODS: Seventy-six Thai children under the age of 15 with AGE were randomized to receive either ondansetron or domperidone. The primary outcome of the study was the proportion of the patients in each group who had no episode of vomiting 24 hours after the start of treatment. RESULTS: Primary outcome was met in 62% of patients in ondansetron group and 44% of patients in domperidone group (P = 0.16). Patients in domperidone group received more doses of the drug within 24 hours after the start of the treatment compared to ondansetron group (P = 0.01). No adverse effect was observed in any of the two groups. CONCLUSIONS: Ondansetron can be considered a safe comparable alternative to commonly-used domperidone in Thai children who suffer from symptoms of gastroenteritis. Larger clinical trials are needed to further explore the effectiveness of the two medications.)

DOMPERIDONA IN CONSTIPATIA CRONICA:

1. Oral domperidone has no additional effect on chronic functional constipation in children: a randomized clinical trial (METHOD: A total of 105 children with chronic functional constipation (according to Rome III criteria) who were referred to the Pediatric Gastroenterology Clinic were recruited in this double-blind randomized clinical trial. The study subjects were randomly divided into two groups, the first of which received polyethylene glycol (PEG) solution 0.6 g/kg/day two times a day for 6 months and domperidone syrup 0.15 mL/kg three times a day for 3 months (case group) while the second one received PEG with the same dose for 6 months and placebo for 3 months with the same dose (control group). The two groups were compared regarding their symptoms and Rome III criteria through 1, 3, and 6 months following therapy. Primary outcome was response to treatment, and a response was defined as decrease in signs and symptoms that did not fulfill Rome III criteria. Secondary outcome measures were side effects during the course of treatment. RESULTS: A significant difference was observed both before and after PEG and domperidone treatment and before and after PEG and placebo treatment regarding Rome III criteria. There was no significant difference in response to treatment between the two study groups during 1 (p = 1), 3 (p = 0.799), and 6 (p = 0.403) month follow up periods. Also, the two groups were not significantly different regarding the Rome III criteria during the mentioned follow up periods. There were no side effects during the course of treatment. CONCLUSION: There was no additional effect of domperidone as adjunct to PEG in the treatment of children with constipation.)

DOMPERIDONA – EFECTE ADVERSE:

1. Domperidone-Associated QT Interval Prolongation in Non-oncologic Pediatric Patients: A Review of the Literature (Conclusion: Of the 5 studies meeting the inclusion criteria (n = 137 patients), one reported a statistically significant change in the corrected QT (QTc) interval, but the clinical significance was unclear. Most of the studies reported rare occurrences of pathological QTc intervals in a limited number of patients. However, confounding factors (e.g., abnormal electrolyte level or concurrent medications) were not consistently considered. Potential bias might have been alleviated by blinding of electrocardiogram (ECG) assessors; however, this was not consistently implemented. The designs of the included studies did not allow assessment of causality. The results should be interpreted with caution. CONCLUSIONS: Although the available evidence is limited, pathological QTc intervals were noted among a small number of infants, which supports the possibility of domperidone-associated risk of
prolonged QTc interval. Because of the potential severity of QT interval prolongation, individual assessment and routine ECG monitoring should be implemented for patients receiving domperidone.)

2. **Adverse effects reported in the use of gastroesophageal reflux disease treatments in children: a 10 years literature review** (Conclusion: Adverse effects have been reported in at least 23% of patients treated with histamine H2 receptor antagonists (H2 RAs) and 34% of those treated with proton pump inhibitors (PPIs), and mostly include headaches, diarrhoea, nausea (H2 RAs and PPIs) and constipation (PPIs). Acid suppression may place immune-deficient infants and children, or those with indwelling catheters, at risk for the development of lower respiratory tract infections and nosocomial sepsis. Prokinetic agents have many adverse effects, without major benefits to support their routine use.)

3. **Domperidone-induced dystonia: a rare and troublesome complication** (Abstract. Domperidone is a commonly prescribed antiemetic drug but its side effects are rarely seen. Extrapyramidal side effects are a very rare complication of the drug occurring in 1/10,000 population. They usually occur in infants and very young children due to a poorly developed blood-brain barrier. We report a case of acute dystonia in a 13-year-old boy induced by domperidone. The boy was treated for viral fever and was started on domperidone 30 mg/day, sustained release form (0.7 mg/kg/day), for persistent vomiting along with other supportive treatment. On the fourth day of treatment, although the fever and vomiting subsided, the child developed oromandibular dystonia despite giving the drug in the recommended dose. Fortunately, drug-induced dystonias are a reversible condition and the child improved in 7-8 days after discontinuation of the drug. There was no recurrence at 1 month follow-up. Usually, dystonic reactions do not threaten life but are troublesome and life altering, so judicious use of the drug is advised.)

4. **Cardiac safety concerns for domperidone, an antiemetic and prokinetic, and galactogogue medicine** (EXPERT OPINION: The data from preclinical studies are unambiguous in identifying domperidone as able to produce marked hERG channel inhibition and action potential prolongation at clinically relevant concentrations. The compound’s propensity to augment instability of action potential duration and action potential triangulation are also indicative of proarrhythmic potential. Domperidone should not be administered to subjects with pre-existing QT prolongation/LQTS, subjects receiving drugs that inhibit CYP3A4, subjects with electrolyte abnormalities or with other risk factors for QT-prolongation. With these provisos, it is possible that domperidone may be used as a galactogogue without direct risk to healthy breast feeding women, but more safety information should be sought in this situation. Also, more safety information is required regarding risk to breast feeding infants before domperidone is routinely used in gastroparesis or gastroesophageal reflux in children.)

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**ALTE STUDII DOMPERIDONA:**

1. [Observation the clinical curative effect of children's laryngopharyngeal reflux and sleep apnea hypopnea syndrome]
2. The use of domperidone increases the completion rate of small bowel capsule endoscopy: does this come at the expense of diagnostic yield?