Mebeverine for Pediatric Functional Abdominal Pain: A Randomized, Placebo-Controlled Trial

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Introduction:
Few studies are conducted on the efficacy of antispasmodics in the treatment of functional gastrointestinal disorders in children. We evaluated the effectiveness of a smooth-muscle relaxant (mebeverine) in the treatment of childhood functional abdominal pain (FAP).

Materials and Methods:
Children (n=115, aged 6-18 years) with FAP were randomized to receive mebeverine 135 mg twice daily or placebo for 4 weeks. Response was defined as ≥ 2 point reduction in the 6-point pain rating scale or "no pain". Secondary outcome measures were physician-assessed global severity and improvement. Patients were followed for 8 weeks after medication period.

Results:
Eighty seven patients completed the trial (44 in the mebeverine group). Response rate in the mebeverine and the placebo group was 54.5% and 39.5% at week 4 (P=0.117) and 72.7% and 53.4% at week 12 (P=0.050), respectively. No significant difference was observed between the two groups in change of the global severity or improvement at week 4 (P=0.723 and 0.057) or at week 12 (P=0.870 and 0.183), respectively. In regression analysis, male gender (Beta=3.470, P=0.025) and baseline pain score (Beta=3.665, P<0.001) were associated with response at week 4, but the association of mebeverine was not significant (Beta=2.585, P=0.078). At week 12, mebeverine was non-significantly associated with response (Beta=2.616, P=0.0503).

Conclusions:
Mebeverine seems to be effective in the treatment of childhood FAP, but our study was not able to show its statistically significant effect over placebo due to high placebo response and limited sample of the study. Further trials are recommended in this regard (ACTRN12613000158763).

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