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Evaluation of Plasma Cholecystokinin (CCK) Levels and Gallbladder (GB) Functions in Hyperemesis Gravidarum

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Background: The pathophysiology of hyperemesis gravidarum (HG) remains poorly understood. A multifactorial origin, including infective, anatomical and psychological factors, and hormonal changes of pregnancy has been proposed. Altered cholecystokinin (CCK) levels may have potential consequences on gastric emptying, which may be related to nausea and vomiting. In this context, alterations in CCK secretion in women diagnosed with HG have been previously reported, and alterations in CCK levels lead to impaired gallbladder (GB) functions.

Objective: In this study, we aimed to evaluate fasting and post-prandial CCK levels, and GB function in HG patients.

Design: Prospective cohort study

Methods: HG patients who present before the end of the 14th week of gestation at our obstetrics outpatient clinic, with persistent vomiting and routine prenatal visits, will be recruited. The required evaluations, including the collection of venous blood samples and sonographic evaluation of GB functions, will be performed at the initial assessment.

After a 12-hour overnight fasting period, venous blood samples will be collected for routine haematological, biochemical, hormonal tests and CCK levels. Transabdominal ultrasonography (US) will be performed to assess GB functions. Subsequently, a fatty test meal (100 g of milk chocolate) will be administered to the patients. The postprandial CCK concentrations at 15 min after meal intake will be measured. The postprandial GB volume (PGv) will be measured using the same US equipment by the same radiologist for each patient at the 45th minute after the meal

Statistical analysis:

Statistical analyses will be performed using SPSS for Windows, version 22.0 (SPSS Inc., Chicago, IL, United States). Since this is the first study comparing both CCK levels and GB functions in patients diagnosed with HG and healthy pregnant women, a power analysis is not feasible. The distribution of continuous variables (normal or skewed) will be determined with the Shapiro-Wilks test. Levene's test will be used for the evaluation of the homogeneity of variances. Unless specified otherwise, continuous data will be described as mean ± SD for normal distributions, and median (inter-quartile range) for skewed distributions. The two groups will be compared with Student's t-test for normally distributed variables and the Mann-Whitney U test for the data that were not normally distributed. Degrees of relation between the variables will be evaluated with the Pearson or Spearman correlation analysis. A p value of <0.05 will be accepted as significant in all statistical analyses.