临床研究

李东垣消痞丸治疗难治性功能性消化不良餐后不适综合征 33 例*

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摘 要:目的 评价消痞丸方治疗难治性功能性消化不良餐后不适综合征的临床疗效。**方法** 采用随机、双盲、安慰剂平行对照的方法,把难治性功能性消化不良餐后不是综合征患者随机分为消痞丸组和安慰剂组,分别予消痞丸免煎颗粒和安慰剂颗粒,疗程均为 4 周。观察指标为临床症状总积分和单项临床症状积分。主要疗效指标为临床症状总有效率,次要疗效指标为单项临床症状消失率和症状积分改善率。**结果** 共纳入 66 名患者,消痞丸组和安慰剂组各 33 例,两组各脱落 3 例,各实际完成 30 例。消痞丸组和安慰剂组的临床症状总有效率的 FAS 和 PPS 分析分别为 66.7% vs 36.7% (P = 0.02) 和 60.61% vs 33.33% (P = 0.014)。消痞丸组餐后饱胀、早饱感和中上腹不适症状的消失率和改善率的 FAS 和 PPS 分析均高于安慰剂组($P < 0.05$)。消痞丸组无不良事件发生,安慰剂组有 3 例不良事件,两组间差异无统计学意义($P > 0.05$)。**结论** 消痞丸方能有效改善难治性功能性消化不良餐后不适综合征的临床症状且安全性较好。

关键词:消痞丸方;难治性功能性消化不良;餐后不适综合征;临床研究
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A Clinical Study on 33 Cases with Refractory Functional Dyspepsia Postprandial Discomfort Syndrome Treated by Li Donghuan Xiao Pi Pill

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Abstract: Objective To evaluate the clinical effect on treating Refractory Functional Dyspepsia Postprandial Discomfort Syndrome by Li Donghuan Xiao Pi Pill. **Methodology** The patients with Refractory Functional Dyspepsia Postprandial Discomfort Syndrome are divided into two groups which are treated by Xiao Pi concentrated granules and the placebo granules respectively for a period of 4 weeks by means of the random, double - blind, and placebo control lab experiment. The observation index includes the overall clinical syndrome score and single clinical syndrome score. The main outcome measurement is the overall clinical syndrome effective rate, and the secondary is the single clinical syndrome disappearance rate and the improvement rate of symptom score. **Result** Among 65 cases, 33 are divided into Xiao Pi Pill and placebo group with 3 detached for each group, thereby 30 cases are actually accomplished in each group. The analysis of overall effective rate for each group is 66.7% vs 36.7% (P = 0.02) and 60.61% vs 33.33% (P = 0.014) respectively by means of FAS and PPS. Xiao Pi Pill Group is significantly higher than its counterpart in terms of the disappearance and improvement rate of the postprandial fullness, fullness in the morning and the discomfort in upper - middle abdomen($P < 0.05$). No adverse event occurs to the Xiao Pi Pill group, by contrast, 3 with the placebo group thws, there is no statisti-

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