

青岛大学附属医院医学伦理委员会审批件

伦审批件号: QYFYWZLL 2023

项目名称:

Coca-Cola Consumption versus Fragmentation in the Management of Patients with Phytobezoars: A Prospective Randomized Controlled Trial

承担单位: The Affiliated Hospital of Qingdao university

项目负责人: Lingyun Zhang

项目简介: A total of 160 consecutive patients were enrolled in the study by doctors in the outpatient department and randomly assigned at a 1:1 ratio to either the control group, which underwent emergency fragmentation with gastroscopy, or the intervention group, which consumed Coca-Cola in the endoscopy center. The enrollment period spanned from January 1st, 2018, to December 1st, 2022. Randomization was conducted by the investigator using a web-based computer-generated random number system (www.randomization.com). In the intervention group, patients consumed Coca-Cola to treat GPBs. The amount consumed was 250 ml-500 ml every 2 hours until bedtime, tailored to individual health conditions and lifestyle habits. Close attention was given to the patients' bowel movements to assess the excretion of bezoars (which are usually harder than normal stool and not scattered by flushing water). The duration of Coca-Cola ingestion was 7 days for the intervention group. Upon completion of the Coca-Cola therapy, patients underwent another endoscopy because endoscopy can observe the mucosa of the stomach directly and further intervention if fragmentation was necessary. The endoscopist recorded all images for every patient. The volume of GPBs was estimated under endoscopy and the evaluation for gastric ulcer was performed in the first endoscopy. Prior to endoscopy, all patients provided digital informed

consent.

Equipment and consumables

The following instruments and materials were used in this study: CV-290 (Olympus Co. Ltd), GIF-Q260J (Olympus Co. Ltd), the WF-DTH fragmentation kit (Wilson Shanghai Co. Ltd), disposable snares (Micro-Tech Nanjing Co. Ltd), and Coca-Cola.

医学伦理委员会意见:

该计划项目中，受试者权力和利益得到充分保护，符合医学伦理委员会要求。同意研究方案。

医学伦理委员会(盖章):

