THE ABDOMINAL DRAIN AFTER GASTRECTOMY (ADiGe) TRIAL: A MULTICENTER NON-INFERIORITY RANDOMIZED TRIAL INVESTIGATING THE ROLE OF PROPHYLACTIC DRAIN IN THE MANAGEMENT OF POST-OPERATIVE COLLECTIONS.

Autori

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Introduction: Evidence suggests that prophylactic abdominal drainage after gastrectomy for cancer may reduce postoperative morbidity and hospital stay, although this evidence comes from small studies with a high risk of bias. However, the primary purpose of drains is to identify and manage postoperative intraperitoneal collections without the need for reoperation or additional percutaneous drainage.
Objective: The Abdominal Drain in Gastrectomy (ADiGe) Trial was designed to determine whether avoiding routine abdominal drainage increased postoperative invasive procedures.
Methods: This is a multicenter prospective randomized non-inferiority trial, where participated eleven centers within the Italian Research Group for Gastric Cancer, encompassing both academic medical centers and community hospitals. Patients with gastric cancer undergoing subtotal or total gastrectomy with curative intent were eligible. Enrollment spanned from December 2019 to January 2023. The patients were randomized 1:1 into prophylactic drain (Group A) or no drain (Group B) arms. The primary endpoint was a modified intention-to-treat analysis (mITT) measuring reoperation or percutaneous drainage within 30 postoperative days (PoD). The null hypothesis was rejected when the 90% confidence interval upper limit of the proportion difference did not exceed 3.56%. The calculated sample size to achieve 80% power with a 10% dropout rate was 404 patients (202 in each group). Surgeons and patients were blinded until gastrointestinal reconstruction.
Results: A total of 404 patients were randomized. Intraoperative identification of non-resectable disease occurred in 14 patients, leading to their exclusion from the study, leaving 390 patients.
In the mITT analysis, 14 (7.7%) Group A patients needed reoperation/percutaneous drainage by PoD 30, versus 28 (15%) in Group B, favoring Group A (7.3% difference, 90% CI: 2.2-12.4, p=0.020). Of note, the difference in the primary composite endpoint was entirely due to a similar difference in reoperation (p=0.012). Drain-related complications were limited to 4 patients, all belonging to Group A.
Conclusions: Refraining from prophylactic drain use after gastrectomy heightens the risk of postoperative invasive procedures, discouraging its avoidance. Future studies identifying high-risk groups could optimize prophylactic drainage decisions.
Trial registration: ClinicalTrials.gov Identifier: NCT04227951.