The Drain Debate: Reevaluating Prophylactic Drains in Total Gastrectomy- A Controlled Trial on the Use of Prophylactic Drains in Total Gastrectomy for Gastric Cancer (DRAG Study)

Trial registration: Clinical Trials.gov NCT 04288661

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STUDY PROTOCOL

The DRAG (DRains After Gastrectomy) Trial is a prospective, non-randomized, controlled clinical trial involving patients diagnosed with gastric neoplasm. All surgeries were performed by a single, highly experienced surgeon in the 1st Propaedeutic Surgery Department at Hippocration General Hospital in Athens, Greece. The patients underwent open total gastrectomy with D2 lymph node dissection, followed by Roux-en-Y gastrointestinal tract reconstruction, in accordance with a predefined, ERAS-compliant perioperative departmental protocol. Our institution's protocol does not routinely incorporate exploratory laparoscopy or peritoneal cytology.

The participants were divided into two groups. The first group followed the department's standard practice, with a drain placed near the esophagojejunal anastomosis (drain group). In contrast, the second did not have a drain placed (non-drain group). The decision to place a drain was based on the following criteria:

a) Pulmonary diseases under oxygen therapy
b) Chronic oral steroid use (≥5mg/day prednisone equivalent for >1month)
c) Intraoperative hemodynamic instability requiring vasopressors
d) Intraoperative blood loss exceeding 250 mL
e) Vessel injury (celiac axis or its branches)
f) Injury to adjacent structures (pancreas, spleen, duodenum)
g) Tension of the anastomosis
h) Uncertainty regarding duodenal stump integrity due to either staple misfire or tissue quality issues

Per our departmental protocol, patients were gradually mobilized starting directly after surgery, when feasible. On the second postoperative day, an oral gastrografin study was conducted for each patient to detect any early anastomotic leaks. Following a normal radiological study, patients were initiated on a liquid diet, which was then advanced to pureed food on the third postoperative day, and a soft diet on the fourth day. For patients in the drain group, the drain was removed on the fifth postoperative day, provided that the drainage volume was less than 50 mL over the preceding 48 hours, in line with departmental protocol. A descriptive timeline of the protocol is presented in the the table below.

a) Appendix 1. Timeline of study protocol

STUDY PERIOD									
	ENROLLMENT DAYS		**DAY OF SURGERY**	**POSTOPERATIVE DAYS**					
TIMEPOINT	-7 TO -2	-1	0	1	2	3	4	5	Ω
ENROLLMENT									
PATIENT SELECTION	X								
PREOP CHECK	X								
CONSENT SIGN		X							
PROTOCOL EDUCATION		X							
INTERVENTION									
DRAIN PLACEMENT			X						
INTRAOPERATIVE DATA RECORDING			X						
MONITORING									
CLIN. EXAMINATION &VITALS				X	X	X	X	X	X
LABS				X	X	X	X	X	X
DRAIN CONTENT MONITORING			X	X	X	X	X	X	X
ORAL CONTRAST STUDY					X				
PONV				X	X	X	X	X	
PAIN (VAS SCORE)			X	X	X	X	X	X	
SSI				X	X	X	X	X	
MOBILIZATION				X	X	X	X	X	
ORAL FEEDING				X	X	X	X	X	
GUT MOTILITY				X	X	X	X	X	X
EXTRAABDOMINAL COMPLICATIONS				X	X	X	X	X	
LOS				X	X	X	X	X	X
MORTALITY				X	X	X	X	X	X
READMISSIONS				X	X	X	X	X	X
REOPERATIONS									

b) LOS: length of stay, SSI: surgical site infection, VAS score: visual analogue score

c) Ω*: time between POD#5 and discharge*

This study was conducted in accordance with the principles outlined in the Helsinki Declaration of Human Rights and with the Guidelines of Good Clinical Practice. The final study protocol and the informed consent form for participant inclusion received approval from the Institutional Review Board (IRB). The IRB also conducted regular assessments, as required, to ensure the ongoing compliance with lawful medical practice throughout the trial.

The statistical analysis was performed using the R software (R foundation for Statistical Computing) version 4.3.0 for Windows. Descriptive characteristics for the quantitative data were expressed as median and Quartile 1 (Q1) to Quartile 3 (Q3) range and for completeness reasons the mean ± standard deviation (SD), for the qualitative data was reported the frequency of occurrence and the relevant percentage. Comparisons were preformed between patients with drainage and those without drainage; for the qualitative parameters statistical tests were performed via the chi-square test (and if required a Fisher exact test) and for the arithmetic data (as normality was not possible to be ensured using the Shapiro Wilk test), were applied not parametric tests, specifically the Mann Whitney U test. The significance level (p-value) was set to 0.05, thus statistically significant difference between compared groups was for $p<0.05$ and all tests were two sided.