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Utility of Abdominal Drain in Gastrectomy (ADiGe) Trial: study protocol for a multicenter non-inferiority randomized trial

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Study protocol

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Abstract

Background: Prophylactic use of abdominal drain in gastrectomy has been questioned in the last 15 years and a 2015 Cochrane meta-analysis on four RCTs concluded that there was no convincing evidence to the routine drain placement in gastrectomy. Nevertheless the Authors evidenced the moderate/low quality of the included studies and highlighted how 3 out of four came from Eastern countries. After 2015 only retrospective studies have been published, all with inconsistent results.

Methods: ADiGe (Abdominal Drain in GastrEctomy) Trial is a multicenter prospective randomized non-inferiority trial with a parallel design. It aimed to verify whether avoiding routine use of abdominal drain is burdened with complications, particularly an increase in postoperative invasive procedures. Patients with gastric cancer, scheduled for subtotal or total gastrectomy with curative intent, are eligible for inclusion, irrespective of previous oncological treatment.

The primary composite endpoint is reoperation or percutaneous drainage procedures within 30 postoperative days. The primary analysis will verify whether the incidence of the primary composite endpoint is higher in the experimental arm, avoiding routine drain placement, than control arm, undergoing prophylactic drain placement, in order to falsify or support the null hypothesis of inferiority. Secondary endpoints assessed for superiority are overall morbidity and mortality, Comprehensive Complications Index, incidence and time for diagnosis of anastomotic and duodenal leaks, length of hospital stay, readmission rate.

Assuming one-sided alpha of 5%, and cumulative incidence of the primary composite endpoint of 14.5% in control arm and 9% in the experimental one, 256 patients allow to achieve 80% power to detect a non-inferiority margin difference between the arm proportions of 4.5%. Considering a 15.5% drop-out rate, 304 patients are needed. In order to have a balanced percentage between total and subtotal gastrectomies, recruitment will end at 152 patients for each type of gastrectomy. The surgeon and the patient are blinded until the end of the operation, while postoperative course is not blinded to patient and caregivers.

Discussion: ADiGe Trial could contribute to critically re-evaluate the role of prophylactic drain in gastrectomy, a still widely used procedure.

Trial registration: Retrospectively registered on 01/10/2020 at Clinicaltrials.gov with the identifier NCT04227951, https://clinicaltrials.gov/ct2/show/NCT04227951.

Introduction

Background and rationale

Prophylactic drain placement after gastrectomy has been advocated until the last few years as the main tool for early diagnosis and treatment of surgical intra-abdominal complications, especially as regards anastomotic or duodenal stump leakages. Evidence against routine drain use after colorectal resection [1,

2] raised the interest on this argument also in upper gastrointestinal surgeons and, in 2015, a Cochrane meta-analysis [3] on four RCTs concluded that there was no convincing evidence to the prophylactic drain placement after gastrectomy. Nevertheless, the Authors evidenced the moderate/low methodological quality of the included studies and highlighted how 3 studies out of 4 came from Eastern countries [3]. Moreover, randomization was never mentioned in one of the four articles, classified as RCTs. After 2015 other retrospective studies have been published, but most of them included small number of patients and heterogeneous types of surgery, including multi-visceral and R2 resection [5, 6, 7, 8]. Our study group recently published an updated metanalysis including both RCTs and cohort studies comparing the use of prophylactic drain with drain avoidance [9]. The results suggest that skipping drainage can reduce morbidity and length of stay, without affecting other major surgical outcomes. However, as for the Cochrane meta-analysis, the strength of this evidence is blunted by the limited quantity and quality of data available.

Objectives

Aim of the study is to evaluate whether avoiding prophylactic drain placement in gastrectomy results in an increase of postoperative invasive procedure (reoperation or percutaneous drain placement) compared with routine procedure, i.e. prophylactic drain placement. If this inferiority hypothesis were rejected, avoiding drain placement would be favored as drain placement is a possible harmful procedure. Moreover, the study will be performed on Western patients, who have been less extensively studied so far than Eastern patients.

Trial design

The design is a multicenter non-inferiority randomized controlled trial with a parallel design, conducted on behalf of the Italian Research Group for Gastric Cancer (GIRCG). The study has been approved by the Research Ethics Board at the central coordinating center and has to be approved at each of the participating sites. The ADiGe trial was registered at ClinicalTrials.gov #NCT0422795. The protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials (SPIRIT) guidelines (see Supplementary File 1 for the SPIRIT checklist).

Methods: Participants, Interventions And Outcomes

Study settings

All hospitals belonging to the Italian Research Group for Gastric Cancer are eligible to participate in the ADiGe Trial, irrespective of their hospital volume. A total of 9 Centers applied to participate, and the study has already been approved by the local Ethics Committee of four centers (Verona University Hospital, the leading Center, Orbassano Hospital of Turin, San Raffaele Hospital of Milan, Morgagni Hospital of Forlì).

Eligibility criteria

All consecutive patients that undergo total (TG) or subtotal gastrectomy (STG) with curative intent, for histologically proven gastric cancer or esophago-gastric junction cancer (Siewert type II or III), in participating centers from the beginning of the study until reaching the accrual number.

Inclusion criteria:

- Esophageal involvement <= 2 cm
- Patients planned for upfront surgery or treated with a neoadjuvant/perioperative chemotherapy or chemo-radiotherapy
- Open, hybrid, laparoscopic or robotic approach
- All types of anastomoses (circular stapled, linear stapled, hand sewn)

Exclusion criteria:

- Refuse to sign informed consent
- Age <18
- severe heart disease (Heart failure New York Heart Association - NYHA Class IV)
- severe liver disease (Child >= B7)
- Pregnancy
- Metastatic disease
- Emergency surgery
- Palliative surgery
- Operation different from total or subtotal oncological gastrectomies (e.g. pylorus preserving, proximal gastrectomy)
- <D1 lymph nodal dissection
- Reconstruction different from Roux-en-Y or Billroth II
- Multiple organ resection (except for cholecystectomy)
- Gastric cancer with duodenal involvement
- Intraoperative Hyperthermic Intraperitoneal Chemotherapy (HIPEC)

Compared to three RCTs already published on this topic [10,11,12], we include also patients that undergo neoadjuvant/perioperative therapies, as these treatments are currently the standard of care for locally advanced gastric tumours. Moreover, considering that minimally invasive and open surgery outcomes are nowadays comparable, we decided to include both type of approaches.

Who will take informed consent

Patients eligible for participation are informed about the trial by one of the surgeons during the preoperative visit at the outpatient clinic. Patients can agree to participate until the day before the operation by signing the informed consent.

Interventions

Intervention description

Operation and Intraoperative drop out

Randomized patients included in the control group (Group A) receive one abdominal drain (any type of drainage is allowed) placed below the liver, passing by the duodenal stump with the apex posterior to the esophago-jejunal or gastro-jejunal anastomosis. No drainage is placed in patients assigned to the experimental group (Group B). Towards the end of the operation the leading surgeon can classify a patient as an intraoperative drop out before knowing the randomisation arm, if one or more of the following criteria are met:

- Intraoperative finding of non-radically resectable disease (R2 resection)
- Need for unplanned multiple organ resection (except for cholecystectomy)
- High risk anastomosis defined as: intraoperative test (e.g. methylene blue or pneumatic test) positive for leak or intraoperative evidence of a positive resection margin.
- Other intraoperative complication that has to be specified on the case report form (unintended intraoperative damage to major vessels and/or organs requiring reconstruction or resection, intraoperative bleeding requiring urgent transfusion, unexpected medical conditions interrupting or changing the planned procedure [13]).

Postoperative procedure

All patients follow the usual postoperative pathway of each participating center except for abdominal drain management. Prophylactic drain in group A patients is daily evaluated checking for suspicious debt. In patients with a normal debt, a methylene blue test (200 ml of water/tea with 5 ml of methylene blue) is performed on postoperative day (POD) 4 and the test is considered negative if no blue staining of drain output is apparent within 60 minutes. After the blue test is confirmed as negative, the drain can be removed. Each Center is allowed to remove drain on whatever POD after a negative test. Drain management in patients with a suspicious debt or positive blue test is left to Center preference. Postoperative complications are recorded until POD 30 or in hospital if hospital stay is longer than 30 days.

Reoperation under general anaesthesia and/or percutaneous abdominal/thoracic drain placement during the first 30 PODs for any cause related to the previous gastrectomy are considered as an event in both groups. After discharge, patients are evaluated in the outpatient clinic on POD 30 or in the subsequent week. Follow up calls are conducted by authorised medical or nursing staff at POD 60 and 90 in order to assess patient’s clinical status.

Outcomes

The primary composite endpoint is the cumulative incidence of reoperation and/or percutaneous drainage placement by the 30th postoperative day.

Secondary endpoints are:

- Incidence, severity and time to diagnosis of anastomotic and duodenal leak;
- Length of hospital stays;
- Overall 30 days morbidity or in hospital if longer than 30 days;
- Overall 90 days mortality;
- 30 days readmission rate.

Length of hospital stay is considered from the day of operation until discharge at home or at other facilities, or death. Postoperative complications, including anastomotic and duodenal leak, are classified according to the International Consensus on a Complications List After Gastrectomy for Cancer [13] and stratified by severity using the Clavien-Dindo classification [14].

Prophylactic drain related complications observed in drain group, such bleeding from drain site, will be considered both apart from and together with overall complications.

Participant timeline

The timeline of study events is displayed in Fig.1 and Fig.2. After patient's inclusion, a medical authorized staff member randomizes the participant using an online secure module on the International Gastrectomy Complications Database website (www.gastrodata.org), the day before the operation. Upon filling out the randomization form, an immediate reply is obtained, containing the study group. "Group A" includes patients with prophylactic drain placed at the end of the operation, "Group B" includes patients without any abdominal drain at the end of the operation. The ratio 1:1 is obtained using a computer-generated randomization scheme, equally stratified (1:1 ratio) for type of surgery (STG or TG). Enrolment type is competitive.

Sample size

According to a systematic review conducted by our Center in January 2019 the cumulative incidence of reoperation was 11.9% (95% CI 8.8-15.6%) in the drain group and 5.6% (95% CI 2.9-9.6%) in the no drain group. Cumulative incidence of additional drain was 3.7% (95% CI 2.8-4.8%) in the drainage group and 10.7% (95% CI 8.5-13.1%) in the no drain group. Assuming a 70-75% of overlap between the two procedures in the drain group, the estimated proportion of the composite outcome is 14.5%, while assuming a 30-35% overlap in the no drain group, the estimated proportion of the composite outcome is 9%.

Hence, we assumed a reference group proportion of 14.5%, and a treated group proportion of 19% under the null hypothesis of inferiority and 9% under the alternative hypothesis of non-inferiority. Sample sizes

of 128 in group one and 128 in group two (256 patients) achieve 80% power to detect a non-inferiority margin difference between the group proportions of 4.5% (= 19-14.5 %), with a one-sided significance level of 5%. Considering a 15.5% drop-out rate, 304 patients (152 in each group) are needed. In order to have a balanced percentage between total and subtotal gastrectomies, recruitment will end at 152 patients for each type of gastrectomy.

Assignment of interventions

Sequence generation and concealment mechanism

Randomization plan has been generated using www.randomization.com program and no one of the investigator has access to the list. Participants are randomized in a 1:1 ratio, using a secure web based randomization system to receive either intervention or routine care, stratified by type of gastrectomy.

Blinding

The leading surgeon and the patient are blinded to the arm assigned until gastrointestinal reconstruction is completed (and anastomosis integrity test is done, if applicable). Before discovering the arm assigned, the surgeon will decide whether the patient meet or not the dropout criteria. There is no blinding for the patient, care providers, or coordinating researcher after the operation.

Data Collection and management

Data is collected via a secured Internet module and each participating center has in custody the informed consents on paper. A secured and anonymized online module has been especially designed for the ADiGe trial, in collaboration with the Gastrectomy Complications Consensus Group on www.gastrodata.org. Every patient will be identified by a numeric unique code. Data are collected until POD 91. Before recruitment process starts, investigators from each participating Center will practice with the Leading Center data manager in order to increase proficiency in data entry. The Leading Center will monitor the quality of data collection of all included patients and regular audit will be held with all participating Centers.

Statistical methods

Analysis population

The primary analysis will be performed on a modified Intention To Treat (mITT) population, including all randomized patients who have undergone gastrectomy. Patients will be analyzed according to the treatment assigned at pre-operative randomization.

A sensitivity analysis will be performed on the As Treated Population, including the same patients enclosed in the mITT population, classified according to whether they actually underwent the prophylactic drain placement or not.

A secondary analysis will be carried out on the Per Protocol (PP) population, including only patients undergoing surgery according to the arm assigned at randomization, and followed-up for at least 30 days.

Statistical analysis

Categorical variables will be presented as absolute and percent frequencies, continuous variables as mean and standard deviation when normally distributed and as median and interquartile range otherwise.

The proportion of patients undergoing re-intervention or percutaneous drain placement (primary endpoint) will be computed for each group with the corresponding 95% confidence interval. The difference between the primary end-point proportion in the treated group and in the control group will be computed with the corresponding confidence interval. If the upper limit of the 90% confidence interval of this proportion does not exceed the non-inferiority margin difference of 4.5%, the null hypothesis of inferiority will be rejected.

Further statistical analysis on the primary endpoint will follow a hierarchical approach: if the non-inferiority null hypothesis will be rejected, significance of differences in the primary endpoint between control and experimental arms will be further investigated with a Fisher's exact test. The relation between the primary endpoint and treatment (drain placement or avoidance) will be further investigated using a multivariable logistic model, adjusting for center, sex, age, tumor site and histology, tumor stage, type of gastrectomy (total/subtotal).

To evaluate significance of differences between control and experimental arms, Fisher's exact test or chi-square test will be used for nominal variables (reoperation, placement of additional percutaneous drain, anastomotic or duodenal stump fistula, postoperative mortality, hospital readmission), Wilcoxon-Mann-Whitney test for ordinal variables (fistula or complication severity), and t test (or the corresponding non-parametric test) for continuous variables (length of hospital stay, time from surgery to fistula detection). Statistical significance will be set at $p<0.05$. Statistical analyses will be performed using Stata®/IC 16.0 for windows (StataCorp LLC, College Station, Texas, USA).

Oversight and monitoring

A data monitoring Committee has not been established nor interim analysis have been planned due to the short expected duration and minimal calculated risks of the Trial.

As all the participating Centers are part of GIRCG quality of surgery and postoperative care were considerate adequate for this Trial according to our previous studies [15,16].

As both arms include treatment commonly applied in daily clinical practice (drain placement and drain avoidance), the standard hospital insurance was considered acceptable. Nonetheless, adverse events related to drain placement/avoidance from the day of operation until the end of the follow up period (91 POD) will be recorded. Investigators will determine the correlation of an adverse event to the study

variable based on timing, type of complication and probability of cause-effect relationship between the event and drain placement/avoidance. Moreover, any adverse event that meets the following criteria will be recorded as “serious adverse event” and reported to the local institutional review board: life threatening condition; severe or permanent disability, prolonged hospitalisation.

Ethical Committee approval

The design of ADiGe Trial was approved by the scientific committee of GIRCG. The Ethical Committee for Clinical Trial (CESC) of Verona has approved the present protocol with the following code: 2245CESC. Prior to implementation, any protocol amendment will be approved by GIRCG scientific committee and CESC of each participating Center. Study information in ClinicalTrials.gov will be updated accordingly.

Dissemination policy

Results of this trial will be published in a peer-reviewed journal. The abstract will be submitted for presentations at different congresses. Within 6 months of completion of the trial, the ClinicalTrials.gov site will be updated to include summary results.

Authorship is granted to authors who make important contributions to the creation of the final publication in accordance with recommendations from the International Committee of Medical Journal Editors and GIRCG group internal policy. Authors can contribute via written or physical help in this clinical trial.

The datasets used during the current study will be available from the corresponding author on reasonable request within 1 year after completion of the Trial.

Discussion

Prophylactic drain in gastrectomy is still widely applied, even if some evidence against its routine use have been reported in four RCTs [10, 11, 12, 17]. Nevertheless, as highlighted in Cochrane meta analysis, these studies lack in methodological quality and mainly come from Eastern countries [3].

So far, the only Western RCT has been published in 2005 by Alvarez and included 60 patients that underwent total gastrectomy [10]. The Author reported a significantly longer hospital stay (18.8 vs 12.9 days) and higher morbidity rate (37.9% vs 9.7%) in drain group. Reoperation rate was rather high in both groups, with a trend in favour of no drain population (9.7% vs 24.1%). However, the results of this study are jeopardised by the small sample size, unclear primary outcome and inclusion of multivisceral resection.

The largest Eastern RCT has been published by Jiang and included a total of 170 patients treated with total or subtotal gastrectomies aimed to compare complication rate between drain and no drain groups [11]. The trial resulted in a comparable morbidity rate with a total of three patients with intra-abdominal abscess (one in drain, two in no drain group) that required ultrasound guided percutaneous drainage.

A multi-institutional analysis from US on 344 patients that underwent total gastrectomy observed no differences in overall complication rate and 30 day mortality. Need for secondary drain placement (10% vs 9%) or reoperation (13% vs 8%) were also comparable [7].

Based on these limited evidences we designed the ADiGe Trial aiming to contribute to a critical re-evaluation of the role of prophylactic drain placement in gastrectomy. Of note, ADiGe Trial is the first RCT studying the use of prophylactic drain in gastrectomy in a large cohort of Western patients. The wide inclusion criteria and the balancing between type of resection aim to result in a trial as close as possible to the everyday Western clinical practice.

Trial status

Protocol Version: 2 (20/10/2019)

Recruitment began: December 23rd, 2019

Approximate date of recruitment completion: December 31st, 2021

Abbreviations

STG
Subtotal gastrectomy
TG
Total gastrectomy
ADiGe
Abdominal Drain in Gastrectomy

Declarations

- Ethics approval and consent to participate: The ADiGe Trial was approved by the Ethical Committee for Clinical Trial (CESC) of Verona with the follow protocol code: 2245CESC. All the participant of the study will be informed and an informed consent will be obtained.
- Availability of data and material: The full data set will be hosted in the www.gastrodata.org site. All principal investigators will be given access to their own site's data sets, access to other sites data upon request only will be granted only after the completion of the recruitment phase. Data will be coded so that anonymity is preserved. The data will be kept in storage for 15 years.
- Consent for publication: available on request. Note that each CESC will revise and adapt according to their own institution's guidelines.
- Competing interests: the authors have no competing interests.
- Funding: The ADIGe Trial has received funding from the RicerChiAmo Onlus to assess the randomization website. The funders of the study had no role in the study design, data analysis,

manuscript preparation and publication decision.

- Authors' contributions: JW, VM and GdM designed the protocol; VM and AV review the literature and wrote the ethical board preposition; GV took care of the statistical analysis. JW, VM, AV, GLB, SG, GV and GdM contributed to the writing of the study protocol. All authors read and approved the final manuscript.
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Figures

		STUDY PERIOD							
	Enrolment	Day of Operation	Post-operative						Close-out
TIMEPOINT	$-t_1$	0	*Day 1*	*Day 2*	*Day 3*	*Day 4*	*Day 5 +*	*Day 30*	*Days 60 and 90*
ENROLMENT:									
Eligibility screen	X								
Informed consent	X								
Randomization	X								
INTERVENTIONS:									
Group A		abdominal drain placed							
Group B		No abdominal drain placed							
ASSESSMENTS:									
Outcomes assessment (see Figure 2 for detailed timeline)			X	X	X	X	X	X	X

Figure 1

Flow-chart of the study.

	STUDY PERIOD							
	Day of Operation	Post-Operative						
TIMEPOINT	Day 0	Day 1	Day 2	Day 3	Day 4	Day 5 +	Day 30	Days 60 and 90
GROUP A	abdominal drain placed	check for suspect debt	check for suspect debt	check for suspect debt	methylene blue test: if negative the drain can be removed	Patient can be discharged	follow up outpatient visit to assess patient clinical status and any related problem	Follow up calls to assess patient clinical status
		Any postoperative complications, additional percutaneous drain or reoperation are registered within POD 30 or in hospital if hospital stay is longer than 30 days						
GROUP B	No abdominal drain placed					Patient can be discharged	follow up outpatient visit to assess patient clinical status and any related problem	Follow up calls to assess patient clinical status
		Any postoperative complications, additional percutaneous drain or reoperation are registered within POD 30 or in hospital if hospital stay is longer than 30 days						

Figure 2

Schedule of outcomes data collection

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- SPIRITChecklistADiGe.doc