Mid- and long-term surgical and oncological outcomes of total laparoscopic gastrectomy for gastric cancer: A prospective study.

November 25, 2020

STUDY PROTOCOL

1. Background and current status of the issue: the laparoscopic approach for gastric carcinoma (GC) is being increasingly implemented by digestive surgeons. Although recent evidence suggests that this surgical approach is associated with improvements in short-term outcomes, mid- and long-term outcomes have not been well studied.

2. Study justification: laparoscopic gastrectomy for GC is widely employed in eastern Countries. But there is a lack of data on its use and results in Western countries, where the incidence of this pathology is lower.

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3. Goals: This study aimed to evaluate the mid- and long-term outcomes of laparoscopic gastrectomy (LG) with D1-D2 lymph node dissection for all stages of GC in a western country.

4. General objectives: to establish a program for the laparoscopic treatment of GC.

5. Specific objectives: determine the short, medium and long-term results of the program.

6. Hypothesis: the results should be similar to those reported by eastern centers.

7. Methodology: prospective observational study.

8. Reference and study population: patients diagnosed of GC and fits for surgery.

9. Inclusion criteria:

a. Patients diagnosed with gastric adenocarcinoma and operated by a laparoscopic approach.

b. Acceptance the proposed technical procedure by the patient.

c. No anesthetic contraindication for the laparoscopic technique.

10. Exclusion criteria:

a. Patients lost to follow-up.

b. Patients unfit for surgery.

c. Palliative surgery.

d. T4b lesions or gastric neoplasms other than adenocarcinoma

11. Sample size: 100-150 cases.

12. Variables:

a. Demographic data.

b. Operative morbidity and mortality.

c. Disease-free survival at 3, 5, and 10 years.

d. Overall survival at 3, 5 and 10 years.

e. Neoadjuvant and / or adjuvant treatment.

13. Data collection and information sources: The data obtained will be collected in an ANONYMOUS database and guarded by the main researcher and the researchers signing the project, respecting at all times Organic Law 15/1999, of December 13, on the Protection of Personal Data.

14. Analysis of data: The statistical program IBM SPSS Statistics 25.0 will be used. A descriptive analysis of the collected data will be carried out, based on survival or mortality during the follow-up period and, later, it will be made with a Cox regression, a univariate and multivariate analysis, with the in order to determine the risk factors for mortality at one year, three, five and ten years of follow-up