THE IMPACT OF SARCOPENIA, BODY COMPOSITION AND OTHER BIOMETRIC PARAMETERS ON THE POSTOPERATIVE OUTCOMES OF PATIENTS UNDERGOING LIVER RESECTION FOR DIFFERENT INDICATIONS

- Study Protocol -

BACKGROUND

Surgical treatment with negative margins is the mainstay for most gastrointestinal malignancies as it offers long-term survival as compared to locoregional or systemic therapies(1-3).

Besides, abdominal surgery is associated with both postoperative mortality and morbidity depending on patient's conditions and type of intervention. Despite significant improvements in perioperative management and surgical techniques, hepatobiliary surgery still holds a high morbidity and mortality risk, reaching rates of 20-50% as reported in the literature (4-6). Liver resections are to be considered major surgeries, often requiring large incisions, extensive mobilizations, long operative times, bleeding risks and a delicate postoperative course. Furthermore, patients with liver malignancies often present with impaired liver function due to cirrhosis, neoadjuvant chemotherapy and cholestasis, increasing the chance of unexpected postoperative events (7, 8). It is therefore necessary to accurately select patients scheduled for liver surgery, to provide the best oncological treatment while minimizing the risk of complications. Sarcopenia is defined as the degenerative loss of muscle mass, strength and function, and its prevalence among cancer patients ranges between 30% and 74%. (9, 10). Previous studies have highlighted that an impaired muscle mass significantly affects both postoperative and oncological outcomes following surgery for hepatocellular carcinoma (HCC) and colorectal liver metastases (CRLM) (11, 12). Although the prognostic role of sarcopenia in the treatment of liver malignancies has been somehow anticipated, the available studies are limited by the heterogeneity of results, the retrospective design and the lack of standardized measurements of this variable, hampering therefore its applicability in current clinical practice (10, 11).

Due to the lack of high-quality evidence, the aim of this study was to investigate the role of sarcopenia as a predictor of postoperative outcomes after liver resections for malignancies, in a prospective observational study.

STUDY DESIGN

- Prospective, single center observational study

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POPULATION

Patients undergoing liver resection for benign and malignant indications with CT scan imaging availability within 30 days before surgery. Of all the patients included in the study muscle function tests will be collected including handgrip strength, gait speed and fat composition. Preoperative antropometric, biochemical and disease presentation characteristics will be collected as well as operative details and postoperative outcomes.

Inclusion Criteria:

1. Patients undergoing open or laparoscopic liver resection
2. Patients undergoing major or minor liver resection
3. Patients undergoing liver resection for primary or secondary liver malignancies
4. Patients undergoing liver resections for benign diseases (cysts, adenoma, focal nodular hyperplasia, hemangioma)

Exclusion Criteria:

1. Patients undergoing extrahepatic resection
2. Patients undergoing cyst fenestration or biopsies without liver resections
3. Patients with extrahepatic metastases
4. Patients undergoing explorative laparoscopy or laparotomy without parenchymal transection -

END-POINTS

Primary Outcome: *90-Day Morbidity*
Secondary Outcomes: *90-Day Mortality, readmission rate*

STATISTICAL PLAN

According to the null hypothesis, no difference in postoperative morbidity between the two groups would be expected. To calculate sample size, a 42% morbidity rate would be expected in sarcopenic patients

while a 22% rate would be expected in the non-sarcopenic group. Considering a two-sided $\alpha=0.05$ and $\beta=0.1$, the minimal sample size required to achieve statistical significance was 224 subjects. Considering a 10% drop-out rate of patients undergoing explorative laparoscopy or laparotomy without parenchymal resection a total of 249 patients will be required for completion of the study.

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