Reviewer’s report

Title: DISSECTION OF THE INFERIOR MESENTERIC VEIN VERSUS OF THE INFERIOR MESENTERIC ARTERY FOR THE GENITOURINARY FUNCTION AFTER LAPAROSCOPIC APPROACH OF RECTAL CANCER SURGERY: A RANDOMIZED CONTROLLED TRIAL.

Version: 0  Date: 07 Jun 2019

Reviewer: G. P. Sao Juliao

Reviewer's report:

Thank you for the opportunity of reviewing this interesting study protocol.

This is the description of a randomized trial of patients with rectal cancer that will be submitted to total mesorectal excision by two different approaches to the inferior mesenteric vessels. The aim of this study is to prove that there is a difference in the rate of sexual dysfunction related to each surgical technique.

I have a few comments for the authors:

1) I would like to recommend the authors to instead of including patients with rectal cancer up to 15 cm, to include patients with rectal cancer that will be submitted to total mesorectal excision. Some patients with higher tumors may ultimately have a partial mesorectal excision performed and this may impact on the results.

2) It would be interesting to know the number of surgeons enrolled in the protocol that will perform the operations. Did they have training on both techniques?

3) I would recommend to record the surgeon's impression on autonomic nerve preservation during the procedure. Some patients may need the nerve resection for oncological purposes. This information may be relevant in the final analyses.
4) I am not comfortable with the criteria for withdrawal - when the dissection cannot be performed or the surgical anatomy cannot be identified is because this is a very difficult case. This can drastically impact on your results as they are at increased risk for nerve injury irrespective of the technique used. Let's say that the only ones that will be removed are those randomized to the intervention group, the control group will have more difficult cases included in the analyzes and consequently worst results.

5) It would be interesting to know the expected range of time to recruit all patients.

6) Finally, including patients submitted to different operations is an important bias. Quality of life and sexual dysfunction rates are not similar among patients submitted to LAR and Miles. One can argue that even different approaches to the same operation may have different outcomes (laparoscopic, robotic, taTME). I would like to recommend the authors to do not include patients submitted to Miles and only those submitted to LAR. This would avoid major bias.

I would like to congratulate the authors, and wish success during this study.

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