Author’s response to reviews

Title: Effect of laparoscopy by single-port endoscopic access in benign adnexal surgery: study protocol for a randomized controlled trial

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Author’s response to reviews:

Subject: Revisions of the manuscript TRLS-D-17-00742

Title: Benefits of laparoscopy by single-port endoscopic access in benign adnexal surgery: a randomized prospective study

Dear Editor,

Please find enclosed the revised version of the article entitled “Benefits of laparoscopy by single-port endoscopic access in benign adnexal surgery: a randomized prospective study” which we submitted to you for publication in your journal.
We took into account the editor’s comments and reviewer's comments. You shall find the revised manuscript and a second file with changes (Yellow highlighted). Each of the authors has read and concurs with the content of this manuscript.

We would be thankful if you would reconsider this article for publication in your journal.

Sincerely yours,

Aubert AGOSTINI

Associate Editor Comments:

- Title: change "benefits" to "effect" or other word which is not pre-supposing the outcome of the study.

Title: since all randomized studies are prospective, change "randomized prospective study" to "randomized clinical trial"

P1L3-4: This terms have been changed and the title is: “Effect of laparoscopy by single-port endoscopic access in benign adnexal surgery: a randomized clinical trial”
Abstract: include population/surgery being studied in the Introduction

Abstract: change D7 to "day seven"

Abstract and throughout: change "main assessment criterion" to "primary outcome"

Abstract: be specific about how postop pain will be assessed at 24 h. Will this be a numeric rating scale? VAS?

Abstract: change "rate" to "incidence" of complications, unless you really are describing a rate (i.e., events per unit time)

- P2L42-44: The population studies is now in the introduction.

- P2L47-54": The terms have been changed and pain assessment is specified:

“The perioperative data up to 24 h after the intervention, as well as the postoperative data at day seven and at one month from the intervention will be collected. The primary outcome for the study will be the postoperative pain at 24 h ± 2 hours after the intervention. The pain will be assessed by a numeric rating scale going from 0 to 10.

Other outcomes will also be assessed such as pain at other times, the consumption of analgesics, the operative time, perioperative bleeding, the number of additional trocars in the two groups, the incidence of laparoconversion, the esthetic criteria of the scar at one month, the incidence of complications, and the quality of life at one month.”

- P5L11: change to "endoscope"

P5L60: change "paroi" to the correct English word ("wall")?

P6: do you mean "Fallopian tube" rather than "Eustachian"?

P6: change "a curare" to "a non-depolarizing neuromuscular blocking drug"

The terms have been changed:
- P5L135: “An endoscope of 10 mm with an angulation of 0 degrees will be used to visualize the abdominopelvic cavity.”

- P5L162: “If necessary hemostatsis of the wall will be performed with bipolar energy.”

- P6L168: “The connection of the uterine horn will then be able to be controlled by coagulation/sectioning of the utero-ovarian connection and of the Fallopian tube.”

- P6L176-177: “The general anesthesia will comprise 0.2 mcg/kg of Sufentanil, 3 mg/kg of Propofol, a non-depolarizing neuromuscular blocking drug, and oro-tracheal intubation.”

- P6: is it your standard of care not to use local anesthesia for the port site(s)? If so, please state this as it IS standard of care at many institutions and this is a salient difference in your care compared to other centres

We add explanation for not using local anesthesia.

-P6L183-184: “There will be no local infiltration of the trocar orifices with analgesics as this procedure is not a standard of care in your department.”

- randomization: mention mode of allocation concealment (envelope, central, etc)

We have added:

P7L223-224: “The mode of allocation concealment is two pack of numeroted envelopes for the stratification.”

- P8: since a VAS is a “distance” measurement, include the unit ("cm") here. Since you are collecting some of this information by phone, please be sure you do not instead mean a numeric rating scale where a patient says her pain is “7 out of 10”. The latter is NOT a VAS.

P7L229: Indeed, the pain will be assessed by a numeric rating scale going from 0 to 10.
- if you are measuring a NRS, provide a reference for treating this ordinal scale as a continuous dependent variable

The average values of pain at 24 hours will be compared between the two groups using a Student’s t-test or a Mann-Whitney test, as appropriate. The average values of pain for the other evaluation times will also be compared between the two groups. This analysis will be carried out through use of a mixed model for the longitudinal data that takes the different times of the pain evaluation into consideration.

-P11L340-341: “This ordinal scale is treated as a continuous dependent variable in all comparative studies of the same type, such as the Hoyer Sorensen study (1).”


- P10L47: change "our" to "out"

statistics: change "ANOVA and Kruskal-Wallis" to "t test and Mann-Whitney test" since you only have two groups

The terms have been changed.

-P11L343: “The criteria will also be compared between the two groups: the proportions with the Chi-2 test (complications, etc.), the quantitative variables using t-test and Mann-Whitney test (different durations, bleeding, etc.).”

- provide a "Current Status" section stating when randomization started and how many patients have been randomized until now

This section have been provide.
“Current Status

The randomization started on 09/06/2016 and 60 patients have been randomized to date 05/11/2017.”

Reviewer reports: Reviewer #1:

1. Declaration of Helsinki: there is no statement whether the study will be conducted in accordance with the Declaration of Helsinki.

We specified:

-P11L351: “This study will be conducted in accordance with the declaration of Helsinki.”

2. Primary outcome measure (main assessment criterion): the main assessment criterion for the study will be the postoperative pain at 24 h ± 2 hours after the intervention. Please clarify how strong this criterion will relate to the disease process as it requires subjective assessments by the investigator using a VAS. In other terms, how would you address the disadvantages of choosing a "soft" endpoint instead of a "hard" one?

We are agree with you concerning subjectivity of VAS evaluation. However, today it’s the main tool used in the literature. The second criteria which is often used is painkillers consumption. We used this criterion as second measure in this study.

Add in the text

-P9L270-272: “The choice to evaluate pain from a numeric rating scale is based on the fact that this evaluation method remains consensual in the literature even though this evaluation especially by phone is subjective.”