Protocol

Low-pressure pneumoperitoneum reduces influence on ovarian hormones in infertile women

Background: Pneumoperitoneum is commonly used in laparoscopic gynecological surgery. This study investigated the effect of carbon dioxide (CO_2) pressure on ovarian hormones following laparoscopic surgery.

Methods: A total of 424 infertile patients were randomly allocated to 4 groups to undergo laparoscopic surgery at different CO_2 pneumoperitoneum pressures. Complications and the levels of serum hormones were observed and measured.

Discussion: The use of CO_2 for pneumoperitoneum affects the levels of E2, LH, and FSH during the first menstruation after laparoscopic surgery in a pressure-dependent manner and the impact vanishes by the third menstruation.

Trial registration：http://www.chictr.org.cn/index.aspx(Supplementary Registration)

Keywords: Carbon dioxide (CO_2); pneumoperitoneum; laparoscopic surgery; ovarian hormones

Introduction

Background it is very important for gynecologists to fathom the effect of pneumoperitoneum pressure on reproductive-age patients.

Objectives The purpose of our study was to evaluate the effect of CO_2 pneumoperitoneum pressure on ovarian hormones in infertile women.

Trial design

Women diagnosed infertile at the Institute were enrolled and investigated the effect of carbon dioxide (CO_2) pneumoperitoneum pressure on ovarian function.

Methods: Participants, criteria and outcomes

Participants

From April 2009 to May 2013, a total of 424 women diagnosed infertile at the Institute of Obstetrics and Gynecology were screened for this study.

Cretiea: Patients were included if their infertility was caused by pelvic adhesions, tubal factors, or unexplained, and were followed up for 3 menstrual cycles following surgery.

Patients with endocrine-related diseases, such as endometriosis and polycystic ovary syndrome (PCOS), were excluded. Participants who dropped out during the course of study were also excluded.

Outcomes

The excluded cases were as follows: 106 were diagnosed with endometriosis upon surgery; 80 were diagnosed with PCOS, 50 had ovarian cysts detected during surgery (ovarian endometrial cyst, 26 cases; teratoma, 18 cases; corpus luteum cyst, 6 cases). A total of 120 cases were excluded who did not undergo blood draw or ultrasound examination.

Interventions

A total of 118 patients (aged 18–39 years) undergo laparoscopic surgery applied with different CO_2 pressure.

Outcomes

Primary outcome :Ovarian hormone

Secondary outcome:mean ovarian volume (MOV), maximal ovarian volume (MaxOV), mean follicle number (MFN), and maximal follicle diameter (MFD).

Other outcome:Length of menstrual cycle

Participant timeline，Sample size and Recruitment

From April 2009 to May 2013, a total of 424 women diagnosed infertile at the Institute of Obstetrics and Gynecology were screened for this study.

Data collection and management

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This study was approved by Supervised by the Ethics Committee and Institutional Review Board of Maternal and Child Hospital (No. 81), Guiyang and written consent was provided by every participant.

Statistical methods

Statistical methods: Means were compared using the Student's *t*-test or 2-way analysis of variance (ANOVA) with the corresponding post-test. All data were analyzed using the software SPSS 19.0 (SPSS, Inc., IBM, Chicago, IL, USA).

Discussion

Trial status

Chinese Clinical Trial Registry, ChiCTR

Abbreviations

serum estradiol (E2), progesterone (P), luteinizing hormone (LH), testosterone (T) mean ovarian volume (MOV), maximal ovarian volume (MaxOV), mean follicle number (MFN), and maximal follicle diameter (MFD).

Declarations

Authors' contributions

Juan Qin and Guoling Song are the Chief Investigators; They conceived the study, led the proposal and protocol development. Yao Jiang and Qin Liu contributed to study design and to development of the proposal.Hong Lin was the lead trial methodologist. All authors read and approved the final manuscript.

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Written informed consent was provided by every participant and the study protocols were approved by the Ethics Committee and Institutional Review Board of the Maternal and Child Hospital, Guiyang.

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