

Wide excision of soft tissues adjacent to the ovary and fallopian tube does not impair the ovarian reserve in women undergoing prophylactic bilateral salpingectomy: results from a randomized, controlled trial

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Objective: To study the effects of the wide excision of soft tissues adjacent to the ovary and fallopian tube on ovarian function and surgical outcomes in women undergoing laparoscopic bilateral prophylactic salpingectomy.

Design: Randomized, controlled trial.

Setting: Teaching hospital.

Patient(s): One hundred eighty-six women undergoing laparoscopic surgery for uterine myoma (n = 143) or tubal surgical sterilization (n = 43).

Intervention(s): Patients were randomly divided into two groups. In group A (n = 91), standard salpingectomy was performed. In group B (n = 95), the mesosalpinx was removed within the tubes. Prior to and 3 months after surgery, antimüllerian hormone (AMH), FSH, three-dimensional antral follicle count (AFC), vascular index (VI), flow index (FI), vascular-flow index (VFI), and OvAge were recorded for each patient.

Main Outcome Measure(s): Ovarian reserve modification (Δ) before and after surgery was assessed as the primary outcome. Operative time, variation of the hemoglobin level (Δ Hb), postoperative hospital stay, postoperative return to normal activity, and complication rate were assessed as secondary outcomes.

Result(s): No significant difference was observed between groups for Δ AMH, Δ FSH, Δ AFC, Δ VI, Δ FI, Δ VFI, and Δ OvAge. Moreover, the groups were similar for operative time, Δ Hb, postoperative hospital stay, postoperative return to normal activity, and complication rate.

Conclusion(s): Even when the surgical excision includes the removal of the mesosalpinx, salpingectomy does not damage the ovarian reserve. Moreover, wide salpingectomy with excision of the mesosalpinx did not alter blood loss, hospitalization stay, or return to normal activities.

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Key Words: Wide salpingectomy, ovarian reserve, surgical outcomes, ovarian cancer prevention, prophylactic surgery





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Reprint requests: Roberta Venturella, M.D., Department of Obstetrics and Gynecology, "Magna Graecia" University, Viale Europa, Loc. Germaneto, 88100 Catanzaro, Italy (E-mail: rovefa@libero.it).

Fertility and Sterility® Vol. 104, No. 5, November 2015 0015-0282/\$36.00 Copyright ©2015 American Society for Reproductive Medicine, Published by Elsevier Inc. http://dx.doi.org/10.1016/j.fertnstert.2015.08.004 pithelial ovarian cancers (EOCs) account for 3% of all female cancers and represent the fifth leading cause of cancer death in the Western world (1, 2). Because of the aggressiveness of these tumours and a delayed diagnosis in 75% of cases, ovarian cancer is the gynecologic cancer with the highest mortality rate (3).

To date, an effective screening strategy for the early diagnosis of EOC does not exist, so prophylactic salpingooophorectomy has been considered the only available tool to reduce its incidence and mortality rate. It is now recognized, however, that prophylactic oophorectomy in premenopausal women significantly increases the risk of total mortality (hazard ratio [HR] 1.12; 95% confidence interval [CI] 1.03–1.21) through the increase in the long-term risk of lethal and nonlethal cardiovascular disease (HR 1.17; 95% CI 1.02–1.35) and stroke (HR 1.14; 95% CI 0.98–1.33) (4).

Considering the new histopathologic classification of EOC proposed by Kurman and Shih (5) and based on new insights into the pathogenesis and origin of these tumours, there is growing evidence to support the idea that most high-grade serous cancers develop from the neoplastic progression of the epithelial cells of the fallopian tubes (FTs).

This new theory has led to an opportunity to prevent EOC by the addition of the prophylactic bilateral salpingectomy (PBS) in all surgical procedures performed in women with benign diseases who have achieved their reproductive goals. The PBS, in place of the current standard procedure (bilateral salpingo-oophorectomy), could reduce the risk of cancer while improving quality of life and reducing the risk of premature death due to cardiovascular disease seen in women subjected to salpingo-oophorectomy before the onset of natural menopause.

Both the American Cancer Society and the American College of Obstetricians and Gynecologists recently shared this opinion (6, 7), declaring in their guidelines that salpingectomy can be considered in average-risk women undergoing hysterectomy, other pelvic surgeries, or sterilization after childbearing.

This declaration was possible because of preliminary data regarding the safety of PBS (8-10), which showed that if the bilateral salpingectomy is performed with attention to ovarian blood flow, no patient had negative effects in terms of ovarian function. In addition, no perioperative complication seemed to be attributable to the salpingectomy.

However, recent evidence suggests that not only the fimbrial end of the tube but also the soft tissues adjacent to the ovary in the mesosalpinx can give rise to neoplasms (11). Considering the similarity of the principal types of ovarian carcinoma to neoplasms arising in the endocervix, endometrium, or FT, and given the embryologic common origin of these organs from the müllerian ducts, probably other structures also originated from these tissues can be sites of origin for all cancers historically deemed as of primary ovarian coelomic origin (11). Müllerian epithelial elements as endocervicosis, endometriosis, and endosalpingiosis, indeed, are present in the soft tissues bordering the ovary and FT and are considered the non-neoplastic counterparts of mucinous, endometrioid/clear cell, and serous ovarian cancers, respectively. Recently, Dubeau suggested referring to

these structures, also including the FT, as "extrauterine müllerian epithelium" (EUME) (12).

It is reported in the literature that elements of the EUME can also give rise to tumors of low malignant potential; in 2001, for example, Alvarez et al. (13) found similar K-ras mutations in 50% serous ovarian borderline tumors. In two-thirds of these cases, the identical mutation was found in the serous ovarian borderline tumors and the müllerian inclusion cysts, but not in the corresponding normal DNA, suggesting a strong relation between these two processes (13). In 2003, moreover, Carrik et al. (14) reported a serous borderline tumor arising in inguinal endosalpingiosis and not associated with an ovarian serous tumor.

According to these observations, simple salpingectomy might not offer maximal protection. Some alternatives have been proposed to maximize the prophylactic effect of PBS. The "radical fimbriectomy" suggested by Leblanc et al. (15) consists of FT dissection from the uterus to the ovary to completely remove the terminal part of the tube and fimbriae and to remove less than one-quarter of the adjacent ovarian tissue with the fimbriae (15). Another modality to radicalize the standard PBS procedure might be to extend the surgical excision to the mesosalpinx tissue, but it has first to be proven that this wide excision does not functionally damage the ovary.

Therefore, the aim of this study was to evaluate the ovarian function and surgical outcomes of patients with uterine myomas or who requested permanent surgical contraception. Patients were randomized to laparoscopic standard bilateral salpingectomy or wide removal of the tube and the mesosalpinx.

MATERIALS AND METHODS Patient Selection

This was a randomized, controlled study conducted at the University "Magna Graecia" of Catanzaro, in the Department of Obstetrics and Gynecology, between March 2014 and January 2015.

The procedures used in this study followed the guidelines of the Helsinki Declaration on Human Experimentation and Good Clinical Practice. The study protocol was approved by the Ethics Committee of the Department of Gynecology and Obstetrics, University "Magna Graecia" of Catanzaro, and submitted on the website for clinical trials (www.clinicaltrials.gov, ID number NCT02086370).

All patients were informed about the recent acknowledgment on high-grade serous cancer and its presumed tubal origin and provided written consent for inclusion in the study and the use of their clinical data before enrollment.

The study included women undergoing laparoscopic surgery for uterine myoma or tubal surgical sterilization. The only women considered to be eligible for inclusion were aged 35–50 years, with regular menses and a mean interval of 21–35 days, who had reached their reproductive goals and signed a written consent form for prophylactic salpingectomy and ovarian preservation.

Excluded from this study were patients with a family history of ovarian cancer who had a known mutation of the Download English Version:

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