Could bilateral salpingectomy reduce the risk of ovarian cancer?

Poate salpingectomia bilaterală reduce riscul de cancer ovarian?

Abstract

Background. Epithelial ovarian cancer is the fifth leading cause of cancer mortality among women. There is no effective screening for ovarian cancer in the current practice that could decrease its mortality. There is a large volume of scientific proofs that prophylactic salpingectomy could give the clinicians the opportunity to prevent the development of ovarian cancer. The aoal of our paper is to sensitize the avnecologic community and then to study in a prospective national trial the potential use of prophylactic bilateral salpinaectomy as a primary preventive strategy of the ovarian cancer. **Objective.** Currently, we have no prospective evidence in order to analyze the effectiveness of prophylactic bilateral salpingectomy in preventing ovarian cancer. Through this article, we intend to launch an invitation to all Romanian gynecologic surgery centers, to participate in a prospective study evaluating the effectiveness of bilateral salpingectomy in the prevention of ovarian cancer. Materials and method. There is no strong evidence regarding the effectiveness of bilateral salpingectomy in the prevention of ovarian cancer and this is the first multicenter, prospective trial in order to study this hypothesis. Using this journal and other media channels of the Romanian Society of Obstetrics and Gynecology, we want to invite national centers of obstetrics and gynecology to attend to our study. All the centers need their ethical committee approval before starting patients' enrollment and a peculiar informed consent adapted to this study. The deadline for the approval is 1st of May 2018. The patients will be consecutively selected from a general population who undergo a surgical procedure during which the fallopian tubes could be removed in addition to the primary suraical procedure. All data needed reaardina the patient and the procedure will be collected in an online document and kept into the database of the department. The enrollment period will be from 1st of June 2018 till May 30th 2021. Outcomes. Before 1st of August 2021 all the data must be collected and prepared for publication. The effectiveness of bilateral salpingectomy in the prevention of ovarian cancer will be evaluated according to multiple variables. Keywords: bilateral salpingectomy, ovarian cancer, ovarian cancer prevention

Rezumat

Introducere. Cancerul ovarian epitelial reprezintă a cincea cauză de mortalitate prin cancer în rândul femeilor. Nu există nicio metodă eficientă de screening pentru cancerul de ovar care să scadă mortalitatea. Salpingectomia profilactică poate oferi oportunitatea de prevenție a apariției cancerului ovarian. Studiul nostru are scopul de a invita comunitatea de specialitate în vederea participării la un trial prospectiv national, care să studieze rolul potential al salpinaectomiei bilaterale profilactice ca strateaie de preventie primară a cancerului ovarian. **Obiective.** În momentul actual, nu deținem date prospective care să analizeze eficacitatea salpingectomiei bilaterale profilactice ca metodă de prevenție a cancerului ovarian. Prin intermediul acestui articol, intenționăm să lansăm o invitație centrelor de chirurgie ginecologică din România pentru a participa la un studiu prospectiv care să evalueze eficacitatea salpingectomiei bilaterale în prevenția cancerului ovarian. Materiale și metodă. Nu există evidențe valide cu privire la eficacitatea salpingectomiei bilaterale profilactice în preventia cancerului ovarian, acesta reprezentând primul trial prospectiv, multicentric care studiază această ipoteză. Prin intermediul revistei, precum și al altor canale media ale Societății Române de Obstetrică și Ginecologie, intenționăm să invităm centrele naționale de obstetrică și ginecologie să participe la studiul nostru. Toate centrele necesită avizul comisiei de etică, precum și aprobarea unui consimțământ informat adaptat studiului. Termenul stabilit pentru aprobare este 1 mai 2018. Selecția pacientelor se realizează din populația generală, paciente supuse unei proceduri chirurgicale, în timpul căreia se poate realiza salpingectomia bilaterală profilactică, aditional intervenției principale. Toate datele vor fi colectate prin intermediul unui formular online și centralizate într-o bază de date. Perioada de înrolare a pacientelor va fi începând cu 1 iunie 2018 și până pe 30 mai 2021. **Rezultate.** Până pe 1 august 2021 toate datele trebuie centralizate și pregătite spre a fi publicate. Eficacitatea salpingectomiei bilaterale profilactice în prevenția cancerului ovarian va fi evaluată în funcție de mai multe variabile. Cuvinte-cheie: salpingectomie bilaterală, cancer ovarian, prevenția cancerului ovarian

Nicolae Gică¹, Radu Botezatu¹, George Iancu^{1,2}, Gheorghe Peltecu^{1,2}, Anca Maria Panaitescu^{1,2}

1. Filantropia Clinical Hospital, Bucharest 2. "Carol Davila" University of Medicine and Pharmacy, Bucharest

Corresponding author: Dr. George lancu e-mail: klee_ro@ yahoo.com

Primit: 30.11.2017 **Acceptat:** 5.12.2017

Introduction

Ovarian cancer has the poorest prognosis and limited options in terms of early diagnosis and efficient treatment. There are no effective screening methods to prevent ovarian cancer in order to decrease mortality rate.

New theories in carcinogenesis suggest that ovarian high-grade serous carcinoma develops from the distal fallopian tube epithelium⁽¹⁾. Recent literature data suggest that the majority of ovarian cancer lesions and pre-invasive lesions in both general population and BRCA1/BRCA2 mutation carriers develop from the fallopian fimbria and then spread to the ovary⁽²⁾.

Opportunistic bilateral salpingectomy during hysterectomy or other gynecological surgery has a minimal additional surgical risk to the patient.

For this reasons, in our clinic we adopted this prophylactic surgical procedure in patients eligible for hysterectomy to treat benign conditions, with no complication or intraoperative incidences. All the patients were counseled about the potential benefits of the removal of the fallopian tubes in order to decrease the risk of ovarian cancer.

Morelli et al. found no significant difference in operative time, hemoglobin level, hospital stay, return to normal activity or complication rate between the two groups comparing 79 patients who underwent total laparoscopic hysterectomy with bilateral salpingectomy with 79 women with the same operation but without bilateral salpingectomy⁽³⁾.

A larger long-term study is needed to assess the prophylactic role of opportunistic bilateral salpingectomy and its implications in ovarian cancer development.

Materials and method

We propose a national, multicenter, prospective, descriptive non-randomized interventional trial in order to evaluate the prophylactic role of opportunistic bilateral salpingectomy in reducing the risk of developing ovarian carcinoma. The aim of our multicenter trial is to analyze the potential use of bilateral salpingectomy as a primary preventive strategy of the ovarian cancer.

The study will be in accordance with the Committee on Publication Ethics guidelines and will be approved by the institutional review board of each hospital that will join the project. Each patient who will participate in this study will be well informed regarding the procedures and will sign a consent form for data collection for research purposes. An independent data safety and monitoring committee will evaluate the results of the study.

All women candidates for different surgical gynecological interventions for benign reasons (hysterectomy, ovarian cystectomy, tubal ligation) or caesarean section, with requested voluntary tubal ligation, will be enrolled after a previous counseling with the potential benefits and fertility consequence of the method. After bilateral salpingectomy, all women will perform clinical and transvaginal ultrasound examination annually for 3 consecutive years.

All data regarding the patient and the procedure will be collected in a document in the D-Base designed for this purpose.

We will exclude from the enrollment women with malignant and borderline diseases, even in cases when the diagnosis was established intraoperatively or later (histopathological specimen). Also, will be excluded patients that do not agree to sign the informed consent. The enrollment period will start on the 1st of June 2018 till 30th of May 2021.

Outcomes

Before the end of July 2021 all the data must be collected and prepared for publication. The effectiveness of bilateral salpingectomy in the prevention of ovarian cancer will be evaluated according to multiple variables taken into consideration.

Discussion and conclusions

Ovarian cancer is an aggressive gynecologic cancer, representing the fifth leading cause of cancer deaths among women, and has no valid screening methods⁽⁴⁾. Epithelial ovarian cancers represent approximately 90% of all ovarian malignancies. This large category comprises different histological subtypes as serous (68%), clear cell (13%), endometrioid (9%) and mucinous (3%)^(5,6).

High-grade serous ovarian carcinoma is the most common and aggressive subtype, with poor prognosis and low survival rate⁽⁷⁾.

In 2015, Venturella et al. concluded that prophylactic bilateral salpingectomy did not impair the ovarian reserve, with no postoperative effect in ovarian volume, nor on the AMH (anti-müllerian hormone) and FSH (follicle stimulating hormone) levels⁽⁸⁾. The study of Morelli et al. compared the complication rates for bilateral salpingectomy versus no salpingectomy in women who underwent total laparoscopic hysterectomy, and ended up indicating that there were no differences between the two groups⁽³⁾.

Morelli et al. found no significant difference in operative time, hemoglobin level, hospital stay, return to normal activity or complication rate between the two groups comparing 79 patients who underwent total laparoscopic hysterectomy with bilateral salpingectomy with 79 women with the same operation but without bilateral salpingectomy⁽³⁾.

To our knowledge, there are poor clinical and epidemiological data about ovarian cancer prevention and screening, and the prophylactic bilateral salpingectomy remains an accessible method with minimal risks that could be sustained by gynecologists.

However, opportunistic bilateral salpingectomy in the prevention of ovarian cancer is a patient's decision, based on her own pReferences. In order to maximize the patient's benefits and minimize risks, it is absolutely necessary to support the patient in taking decisions. Another option in the prevention of ovarian cancer would be bilateral salping ectomy in high-risk population in order to maximize their benefit $^{\rm (9)}.$

Traditionally, the ovarian tissue was regarded as the most common primary site of carcinogenesis, but the new studies suggest that this process starts in the distal fimbria and then spread to the ovary. According to the new theories, we can consider the epithelial carcinoma of the ovary, the fallopian tubes and peritoneum as a single entity⁽²⁾.

For accurate data, we need long-term studies to determine the efficacy of opportunistic bilateral salpingectomy for ovarian cancer prevention.

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