

Opportunistic Risk Reduction Salpingectomy and Ovarian Cancer

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Ovarian cancer has the highest mortality rate of all types of gynecologic cancer and is the fifth leading cause of cancer deaths among women.¹ Although other cancers are more common, ovarian cancer is more deadly because its early symptoms are nonspecific, and unlike other gynecologic cancers, there is no reliable screening test. Breast cancer can be screened for by mammograms, and cervical cancer by Pap smears, but ovarian cancer was not reliably detectable by measurements of CA 125 or transvaginal ultrasonography, so these are no longer routinely recommended.² If a reliable, and acceptable method for preventing ovarian cancer were available, this would be highly desirable.

In recent years, a compelling theory of the development of epithelial ovarian cancer has been endorsed by the American College of Obstetrics and Gynecologists (ACOG) and has led to the hope for a risk reducing intervention: salpingectomy or the removal of the fallopian tubes. We will look at whether this approach provides the reliable intervention needed, and whether it is desirable for all patients or only for a select sub-group of patients. Equally importantly, we will examine whether its

routine use would be compatible with the ethical standards of Catholic hospitals. Currently, it is believed that serous, endometrioid, and clear cell carcinomas are derived from the fallopian tube and the endometrium and not directly from the ovary.³ This is in contrast to the traditional view in which ovarian cancers were thought to originate in the ovary itself. A number of factors may be associated with an increase, or decrease, in the risk of ovarian cancer for an individual woman. There is an average overall risk for the general population of about 1.5%. This increases with age, particularly after menopause, and increases dramatically with certain familial and genetic risk factors. The most common inherited mutations that increase the risk of ovarian and tubal (and breast) cancers are the BRCA 1 and BRCA 2 genes. For women with a mutation in one of these genes, the lifetime risk of having ovarian, tubal, or peritoneal cancer is 39-46 percent in BRCA 1 carriers, and 12-20 percent in BRCA 2 mutation carriers.⁴ There are other identified genetic risks as well, such as Lynch syndrome genes, RAD 50 1C, and RAD 50 1D.⁵ A number of familial and individual factors in a woman's personal history can lead to a concern for higher risk with a recommendation for genetic counseling and testing. Conversely, those patients at average population risk may be less likely to be affected if they have a history of

oral contraceptive pill use or higher parity.⁶ As more information is gathered regarding specific mutations and other risk factors, greater accuracy of the potential risks for each specific patient will be available to healthcare professionals.

The diagnosis of ovarian cancer is particularly challenging as it is often in an advanced, metastatic stage when found, resulting in a high mortality rate. Although 92 percent of patients with localized disease at diagnosis may be alive at five years, only 28 percent of patients diagnosed with distant metastases are alive after the same interval, and the latter category accounts for the majority of ovarian cancer diagnoses.⁷ Clearly, an effective preventative intervention would be far preferable to the current state of diagnosis and treatment. Prophylactic salpingectomy, the removal of the fallopian tubes, may offer clinicians the opportunity to prevent ovarian cancer in their patients. That is why the Foundation for Women's Cancer published a consensus statement declaring, "Preventative surgery to remove the ovaries and fallopian tubes (after childbearing is complete) is the most effective method for preventing ovarian cancer in women with BRCA 1 or BRCA 2 mutations". For these high risk women, the reduction in the risk of ovarian cancer follows the removal of the ovaries as well as the tubes. Tubal ligation alone appears to have a protective effect against endometrioid and clear cell carcinomas of the ovary.⁸ Bilateral salpingectomy alone (without removal of the ovaries or uterus) does not eliminate the risk of subsequent ovarian cancer entirely, but it may reduce it to a similar degree as tubal ligation (25 percent) or even up to 40 percent.⁹ The paucity of data supporting salpingectomy without removal of the ovaries has not deterred physicians and patients from

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pursuing this approach, and ACOG has gone on record in support while acknowledging, "Randomized controlled trials are needed to support the validity of this approach to reduce the incidence of ovarian cancer."¹⁰

A salpingectomy can be done as an elective procedure added on to another indicated pelvic surgery. When this occurs, it is referred to as an elective, incidental or opportunistic procedure. This is defined as the removal of the tubes at the time of another surgical procedure unrelated to any appreciable pathology of the tubes at the time of their removal. We can consider different categories of patients at risk, and the moral acceptability of proposed interventions as follows:

Category 1: Postmenopausal patients at high risk for ovarian cancer, based on their genetics or other factors, such as family history. Such patients could be considered candidates, not only for salpingectomy (removal of fallopian tubes), but also oophorectomy (removal of ovaries), as a primary surgery, as well as an incidental or opportunistic surgery. (See discussion below for ethical analysis)

Category 2: Premenopausal patients (with childbearing potential) at high risk for ovarian

cancer. Such patients could also be considered candidates for salpingectomy with removal of ovaries, as a primary surgery as well as an incidental or opportunistic surgery, once childbearing was completed.

Category 3: Postmenopausal patients at average population risk for ovarian cancer, with no childbearing potential. Such patients could be considered as candidates for salpingectomy on an opportunistic or incidental basis during other indicated pelvic surgeries.

Category 4: Premenopausal patients of average population risk with continued childbearing potential. This category of patients could be subdivided into three groupings:

- a. Those patients undergoing a hysterectomy for some medically indicated reason who could be considered candidates for an “opportunistic” salpingectomy.
- b. Those patients who might be recommended for salpingectomy as a means of effective contraception with the possible prevention of ovarian cancer as an added benefit.
- c. Premenopausal patients of average population risk might be considered candidates for salpingectomy as a means of primary prevention of ovarian cancer.

We will discuss the ethics of each of these situations in turn.

Discussion

The ethical arguments supporting salpingectomy in the first category of high risk patients would rely on the principle of totality.

Removal of the fallopian tubes in a postmenopausal woman would dispose of healthy organs otherwise required for fertility, which is normally an intrinsic good. However, following menopause, fertility has been lost, and the sterilizing effect of the procedure is no longer an issue. In this case, the healthy tissue of the fallopian tubes is removed to serve the well-being of the whole body, the reduction of an otherwise increased risk of cancer. This is totally in keeping with the principle of totality.¹¹

In the second high risk (but potentially fertile) category, the same justification would apply according to the principle of totality. However, the patient would be deprived of her fertility by the procedure. In this case, the principle of double effect would supply sufficient additional justification. The principle states that an action having good and bad effects can be performed if the following conditions are met: 1) The action itself is morally neutral or morally good; 2) The bad effect is not the means by which the good effect is achieved; 3) The motive must be intending the good effect only; 4) The good effect is at least an equivalent importance to the bad effect.

In this case, the removal of a healthy fallopian tube could be considered morally neutral or morally good if otherwise justified by the principle of totality. The bad effect of sterilization is not the means by which the good effect is achieved. The intention must be the reduction in a real risk of ovarian cancer for this patient. Finally, it can be argued that the potential avoidance of cancer could justify an early loss of fertility in a high risk patient.

In the third category, a postmenopausal average risk woman would have no fertility to lose, so the procedure would not be considered

sterilizing. The only remaining ethical dilemma would be the question of whether the procedure would result in a sufficient reduction of risk for those patients without a known cause for any increase in risk above the average population. There is insufficient data to be certain of this, so it would require a low risk of surgery to justify, such as would occur in an opportunistic salpingectomy, rather than a primary surgery for this reason alone. The lack of solid data to support the validity of the approach for risk reduction in average risk women would not recommend it as a primary procedure, as the risks of the procedure would not clearly be exceeded by the benefit.

As we note, there are two classes of premenopausal women of average population risk for ovarian cancer who could be considered candidates for salpingectomy. Category 4a encompasses those who have a medical indication for a hysterectomy, such as malignancy hemorrhage, or infection. If a hysterectomy is medically indicated, removal of the tubes presents no additional moral or medical challenges, as it would already be a sterilizing procedure and could be ethically justified on the principle of totality.

Patients in category 4b would not be permitted to undergo salpingectomy under Catholic auspices as the primary intention would be sterilization, even if cancer prevention were an unintended but fortuitous outcome. Salpingectomy would be the equivalent of tubal ligation for contraceptive purposes and would constitute an impermissible direct sterilization

As indicated, the major ethical dilemma for Catholic health care is in category 4c: Women who are only of average population risk for ovarian cancer and are still of childbearing age

for whom salpingectomy would be considered for primary prevention for ovarian cancer. In such cases, justification of this procedure by appeal to either the rule of double effect or the principle of totality could be challenged. It becomes more difficult to apply the principle of totality when the good that is necessary for the general well-being of the whole body, resulting from salpingectomy, is not well documented for patients who have no increased risk of cancer. Moreover, a question of the intention arises when a request for tubal ligation or removal is made, making the application of the principle of double effect problematic as well. When a proportional reduction of the risk of cancer cannot be ascertained in these cases, then the persistent request for tubal surgery, may rightly be construed as a masked request for an intended direct sterilization. Were this to become a common and unexamined procedure offered to all women in Catholic hospitals, a real danger of scandal may result.

Others have considered the same problem under the same circumstances. The ACOG, while acknowledging the need for data to support the validity of the approach, supports the concept of prophylactic opportunistic salpingectomy during other surgeries in women of average risk with no genetic predisposition for ovarian cancer. Part of their argument for proceeding with this surgery in low risk women is that “clinicians can communicate that bilateral salpingectomy can be considered a method that provides effective contraception”¹² Despite these concerns, Gremmels, O’Brien, et al, also endorsed opportunistic salpingectomy in women of average risk. They base their opinion on the lack of screening tools for ovarian cancer, and poor treatment options, and ultimately considered the bad effect of infertility and removal of functioning tissue as

within the purview of the patient and physician to determine.¹³ The ethicists of the National Catholic Bioethics Center in their commentary on this article stated, “The ethicists of the National Catholic Bioethics Center do not believe that such a surgery would be morally justifiable if the woman has only an average risk of ovarian cancer”.¹⁴ Thus, they ruled out opportunistic bilateral salpingectomy for all patients of average risk, even those beyond their period of fertility.

In considering the situation of patients falling into the four categories above, we must disagree with the positions taken by both Gremmels et al., and the NCBC. All those commenting would agree with us that justification for opportunistic salpingectomy can be found for high risk patients, both postmenopausal and premenopausal. Surprisingly, the NCBC statement did not address, nor allow for, the possibility of opportunistic salpingectomy in a postmenopausal, non-fertile patient. As we have shown, the justification and benefit for the procedure in an average risk patient may be low, but the attendant risk would also be low. Therefore, we find no ethical issue that would prohibit this for postmenopausal patients in a Catholic hospital. Our opinion is evidently shared by the Catholic Medical Association, as evidenced by their published resolution.¹⁵

Finally, unlike Gremmels, et al., we are not comfortable with a routine practice permitting salpingectomy during other procedures, such as a cesarean section, in fertile women at a normally low or average risk of ovarian cancer. Medically, the benefits may be marginal, but the attendant risk would be minimized by making it an opportunistic addition to another surgical procedure. From an ethical perspective, the risk

is that this practice could be primarily motivated by an intent to sterilize. If such a procedure became commonplace in a Catholic hospital, it would indeed be at high risk for scandal, constituting a “Catholic contraceptive sterilization” as a new standard of care. Our position does not ignore the possibility that extenuating circumstances might be found to justify this procedure in fertile women. As we have indicated, such a justification should prove straightforward in those patients who are at high risk of ovarian cancer. It may at times be found with greater difficulty in other patients as well. In order to resolve this dilemma, we would recommend that all such sterilizing procedures in premenopausal women be scheduled only after review by a properly constituted ethics committee or subcommittee. This would allow consideration of the justification for this intervention in average risk patients, recognizing that the definition of “high risk” and therefore the risk-benefit ratio, may be a moving target as additional information is developed. This routine referral for ethical evaluation prior to surgery would allow needed and beneficial procedures to proceed while protecting Catholic health care institutions from any unneeded risk of scandal.



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Creating Dialogue

1. How would you state the real ethical question(s) involved in OPRRS?
2. Is this a situation in which new clinical data has substantially changed the way we evaluate a particular care? Can you think of other situations in which new data altered either the ethical question or our answer?
3. The “moral systems” of old used various categories of probability (e.g. probabilism, probabiorism, tutiorism) to assess moral risk. Is that what the authors are doing in this article?
4. How sure do we have to be before we can act, i.e., what constitutes “moral certitude”?

ENDNOTES

- ¹ Salpingectomy for ovarian cancer prevention. Committee Opinion No. 620. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125:279–81.
- ² Hereditary breast and ovarian cancer syndrome. Practice Bulletin No. 182. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;130:e110-26
- ³ Kurman RJ, Shih I. The origin and pathogenesis of epithelial ovarian cancer: a proposed unifying theory. *Am J Surg Pathol* 2010;34:433–43. Erickson BK, Conner MG, Landen CN Jr. The role of the fallopian tube in the origin of ovarian cancer. *Am J Obstet Gynecol* 2013;209:409–14. Crum CP. Intercepting pelvic cancer in the distal fallopian tube: theories and realities. *Mol Oncol* 2009;3:165–70. Kindelberger DW, Lee Y, Miron A, Hirsch MS, Feltmate C, Medeiros F, et al. Intraepithelial carcinoma of the fimbria and pelvic serous carcinoma: Evidence for a causal relationship. *Am J Surg Pathol* 2007;31:161–9. Kamran MW, Vaughan D, Crosby D, Wahab NA, Saadeh FA, Gleeson N. Opportunistic and interventional salpingectomy in women at risk: a strategy for preventing pelvic serous cancer (PSC). *Eur J Obstet Gynecol Reprod Biol* 2013;170:251–4.
- ⁴ <http://www.foundationforwomenscancer.org/risk-awareness/ovarian-cancer-risk-consensus-statement/>
- ⁵ Hereditary breast and ovarian cancer syndrome. Practice Bulletin No. 182. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2017;130:e110-26
- ⁶ *Cancer Epidemiol Biomarkers Prev.* 2015 Apr; 24(4): 671–676.
- ⁷ World Cancer Research Fund and American Institute for Cancer Research, Ovarian Cancer Report 2014: Food, Nutrition, Physical Activity and the Prevention of Ovarian Cancer (Washington, DC: AIRC, 2014), 6, <http://www.aicr.org/>.
- ⁸ Rosenblatt KA, Thomas DB. Reduced risk of ovarian cancer in women with a tubal ligation or hysterectomy. The World Health Organization Collaborative Study of Neoplasia and Steroid Contraceptives. *Cancer Epidemiol Biomarkers Prev* 1996;5:933–5.
- ⁹ Department of Oncology, University of Cambridge, Cambridge, UK
- ¹⁰ Salpingectomy for ovarian cancer prevention. Committee Opinion No. 620. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125:279–81.
- ¹¹ Pope Pius XII “The Moral Limits of Medical Research and Treatment.” September 14, 1952, www.papalencyclicals.net
- ¹² Salpingectomy for ovarian cancer prevention. Committee Opinion No. 620. American College of Obstetricians and Gynecologists. *Obstet Gynecol* 2015;125:279–81.
- ¹³ National Catholic Bioethics Quarterly 16.1 (Spring 2016): 99–131
- ¹⁴ <https://www.ncbcenter.org/resources/news/opportunistic-salpingectomy-reduce-risk-ovarian-cancer/>
- ¹⁵ <http://www.cathmed.org/programs-resources/health-care-policy/resolutions/obstetricsgynecology/>

*Note: See a previous article about this topic entitled, “Prophylactic Salpingectomy to Reduce the Rise of Cancer: Ethical Considerations,” *HCEUSA*, winter 2015.

<https://www.chausa.org/docs/default-source/hceusa/prophylactic-salpingectomy-to-reduce-the-risk-of-cancer.pdf?sfvrsn=6>